# The Origin and Evolution of the HARMONIC® Scalpel

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## ABSTRACT

**When Jacques and Pierre Curie first researched ultrasonic energy and piezoelectric effects in the 1880s, they likely had no idea of the profound impact it would eventually have on surgical patients. Today in operating rooms around the world, ultrasonic energy is used for tissue manipulation, dissection, cutting, and coagulation. Surgeons including but not limited to the specialties of gynecology, general surgery, colorectal, thoracic, breast, and bariatric have activated ultrasonic energy in thousands of patients. As a mainstay surgical energy device, patients have benefited from the ultrasonic versatility of its cutting and coagulating effects. The ability of ultrasonic energy to be used near vital organs with precision by adjusting for tissue tension, power settings, and activation time has accounted for its safety and clinical outcomes. This overview of the mechanics of ultrasonic energy and the evolution of the HARMONIC® (UltraCision, Providence, Rhode Island, now owned by Ethicon Endo-Surgery, Inc., Cincinnati, Ohio) surgical tools since 1988 provides readers an understanding of this energy platform and its distinct advantages. Clinical implications of key research and clinical studies are explored and discussed with a focus on patient and surgical outcomes. Research in a variety of fields and tissues is presented with a special emphasis on the gynecological patient.**

## SURGICAL NEED

Surgeons have an innate desire to continuously improve surgical outcomes through their surgical methods and instruments used.[1] Cutting tools are not immune to this improvement either. Over the years, surgeons have traded up their scalpels from copper blades to iron ones to those made of hardened alloys.[2] Trading scalpels and staplers for a cutting instrument, such as bipolar electrosurgery that could assist in preventing hemorrhaging using heat during surgery, made sense. In bipolar electrosurgery, the electrical generator transmits an electric current from the active electrode which conducts the current through patient tissue to the dispersive electrode returning to the generator.[3] With bipolar electrosurgery, as tissue water is lost, resistance to the current increases and current begins flowing laterally to the instrument, thereby increasing lateral thermal damage and subsequently more desiccation and charring.[3] Tissue transection occurs once the water in the tissue begins to boil and vaporizes.[3]

The risk of accidental and collateral thermal injury when using bipolar electrosurgery needed to be addressed. Heat can cause a variety of tissue effects as well as molecular and cellular changes. The amount of time and the temperature of the heat transference to the tissue, as well as how quickly the tissue is cooled afterwards, all impact the severity and extent of direct and collateral damage. The impact of heat on tissue and healing rates has been studied extensively by burn surgeons and researchers. As early as 1953, when Jackson's three zones of burn injury were introduced, burn surgeons knew the immediate point of injury had the most tissue destruction, was irreversible, and was called the zone of coagulation.[4] The adjacent tissue was known as the zone of stasis where tissues were viable but no circulation was present. The zone of hyperemia lay between the zone of stasis and uninjured tissue and while minimal cellular injury was present, the area was inflamed and vasodilated. In the burn community, preventing the zone of stasis and zone of hyperemia from converting to nonviable tissue is of utmost importance.[5]

Burn research has shown that as temperature and size of injury increases, the severity of protein destruction occurs.[6] At the point of high temperature burn injury, eschar, necrosis, and tissue desiccation are present.[6] Adjacent to the point of injury, high temperature protein denaturation causes coagulation and forms new bonds within the zone of coagulation.[6] Cells within the zone of stasis are viable, but the heat and inflammation must be reduced, otherwise the tissue will die leaving more necrotic tissue for the body or surgeon to remove. At the point of burn injury, toxins, dead tissue, and inflammatory mediators can all inflict additional subsequent damage to the patient and the injured tissues. Given that the etiology of cutaneous burn injury affects the metabolism, immune, and endocrine systems differently, selecting an instrument that performs well, yet leaves little residue and collateral damage, is preferable for a quick recovery.[7,8]

The use of ultrasonic energy attempted to address this problem. Ultrasonic energy does not use electricity to achieve hemostasis, but instead uses mechanical energies of coaptation and cavitation. Coaptation approximates and coagulates the tissue via heat generated from the frictional motion (from ultrasonic energy) and pressure (from applying the jaws). Blade vibration induces cavitation as cell fluid vaporizes at small confined areas at the blade tip facilitating precise dissection between tissue planes as the vapor helps expand and separate the layers. Harnessing the mechanical energy via coaptation and cavitation resulted in precise tissue cutting like a scalpel and sealing like a bipolar, but without the use of electrosurgery. The first instrument was thusly named the UltraCision HARMONIC® scalpel (UltraCision, Providence, Rhode Island, now owned by Ethicon Endo-Surgery, Inc., Cincinnati, Ohio). Unless otherwise noted, the ultrasonic products described hereafter are HARMONIC® brand (Endo-Surgery, Inc., Cincinnati, Ohio) specific.

An investigation examining the thermal damage using ultrasonic energy was undertaken using harvested human vessels; 10 arteries and 10 veins.[9] Each vessel was clamped with 10mm shears using ultrasonic energy at level power 3 until transected. Tissues were fixed in preparation for both scanning and transmission electron microscopy (SEM, TEM). Four distinct sections were noted within both arterial and venous vessel tissues. From the SEM images, the end closest to the transection, the end tip was completely enclosed and appeared homogenous with no detectable lumen. Approximately 250μm from the end tip, vessel walls were collapsed, but tissues were not homogeneous. The endothelial and media layers were fused and there were a few amorphous bridges between the walls. The wall diameter increased farther from the tip end. The next distinct section, approximately 500–800μm from the end tip, vessels showed circular vessel structure with some individual vessel layers and blood clotted lumen. The last section was approximately 1.5mm from the tip end and showed a normal to almost normal histology. The TEM confirmed the SEM findings. The TEM clearly showed remnants of endothelial cell membranes bound together in the dense amorphous substance that filled an altered vessel wall; evidence of coagulation necrosis. Throughout the areas of coagulated dense substance and the vessel walls, collagen fibers were recognizable and appeared relatively normal. Similar histological and clinical observations have been made by other investigators suggesting that the use of ultrasonic energy does indeed have distinct advantages that address minimizing lateral thermal damage while cutting and coagulating tissues.[10-13] These studies showed small zones of coagulation, stasis, and hyperemia near the transected tissue end suggesting and demonstrating tissue healing should be prompt compared to other devices.[12]

## ULTRASONIC ENERGY

The ultrasonic energy system requires energy to perform. A generator supplies electrical energy to the handpiece which contains an acoustic transducer. Within the handpiece, the electrical energy excites the piezoelectric ceramics causing them to expand and contract and in doing so, mechanical motion is introduced, thus energy is transformed into ultrasonic waves. The wave of ultrasonic motion is transferred to the blade extension and the motion is amplified and is sometimes referred to as a harmonic wave. The activated blade can vibrate longitudinally 55,500 cycles per second.[11,14] Vibration of the blade over 50–100 microns results in cavitation.[11,14] This low-frequency ultrasonic energy coupled with jaw pressure has the ability to both cut and coagulate the tissue without passing electrical energy to the patient, thereby increasing safety.

Cavitation causes cell fluid to vaporize and rupture at small confined areas at the blade tip. As the vapor expands, precise dissection between tissue planes occurs with little physical force. When jaw pressure is applied, coaptation seals the tissue via mechanical frictional heat and pressure. As cells are disrupted, proteins denature and hydrogen bonds break through the coaptation process, a sticky coagulum forms and seals the vessels.[11,14] The coagulation typically occurs in less than seven seconds and results in minimal smoke, char, and lateral tissue damage.[11,12,14] The contact time to transect the same size vessel is one to three seconds less for a harmonic energy device than a comparable electrosurgical device.[12,13] The lateral thermal damage is reduced in the harmonic energy transected vessels (1.0mm) compared to transections via electrosurgery (5.5mm).[12,13,15] The initial harmonic energy devices transected tissues at temperatures of less than 80ºC and sealing vessels was limited to 2mm or smaller.[11] Improvements in vessel size sealing has increased over time with innovations. Introduction of the clamp arm increased vessel size to 3mm. Consistent compression coupled with proper heat was optimized with the introduction of the ACE® (Ethicon Endo-Surgery, Inc., Cincinnati, Ohio) family and 5mm vessels were sealed. Further improvements in the software algorithm with modulated power delivery coupled with the hardware resulted in sealing vessels 7mm and improved vessel bursting pressure.[13] Several studies have revisited the extent of lateral thermal damage given that the temperature profile has been modified.[16-19] The results found the thermal spread remains minimal and significantly smaller compared to monopolar and bipolar electrosurgery in a variety of tissues.[16-19] The amount of tissue grasped and the amount of lateral thermal damage was also assessed.[16] The authors found that the ultrasonic device temperature was statistically highest when only the tip (1/3 of jaw) was used and the lowest when all of the device was used. Whereas, the bipolar device was hottest when 2/3 of the device was engaged and lowest when all of the device was used.[16] The amount of lateral thermal damage was consistent for each device regardless of how much tissue was grasped, and the ultrasonic device had statistically less collateral damage than the bipolar mechanism for all grasping models.[16]

The elevated temperatures of HARMONIC® devices result in less thermal damage which may seem counterintuitive at first, but the application time and contact areas are limited and thus minimize tissue damage. Tissue temperature at 1mm from the device showed, in real-time, baseline to peak temperature in five seconds. Then, it began to decline when grasping with only the tip. Whereas, using all of the jaw, the temperature peaked from baseline in eight seconds and then declined.[16] As is known in the burn community, size, time, and intensity of heat affects the severity of injury and lower temperature over time can cause more extensive damage than higher temperature over a short time.[5] The second item is the HARMONIC® device. It has a smaller jaw and clamp arm and is more narrow in width compared to a similar bipolar device which leads to a smaller, lateral thermal footprint and less heat applied to the tissue.[17] Lastly, energy is limited to the points of applied pressure between the jaw and arm which helps reduce collateral damage. Limited energy to pressure points and limited tissue temperature is why past and current harmonic energy devices have similar lateral damage even though the temperature of harmonic devices has changed over time.[11,13,15-19]

Macroscopically, the ultrasonic and electrosurgical device transected tissue appearance and had stark tissue viability differences.[18,20,21] Histologically, significantly less thermal damage, inflammation, polymorphonuclear leukocytes (PMNs), and β-APP (β amyloid precursor protein) staining was seen in acute, sub-acute, and healed harmonic transected tissues.[17,18,20,21] It is interesting to note that ovine uterine healing in harmonic energy heteronomies had statistically less fibrosis than the standard of care incision and stapler group suggesting healing proceeds normally.[18]

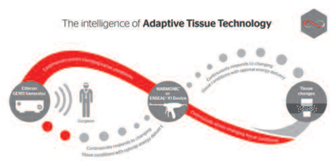
The impact of energized devices, such as ultrasonic or electrosurgical on nerves, is clinically important, not only because the nervous system innervates the body, but also because of the sensitivity of myelinated and unmyelinated nerve cells to temperature and electrical current. Three studies specifically accessed the impact of temperature, ultrasonic, monopolar, and bipolar electrosurgery on sciatic and recurrent laryngeal nerve (RLN).[16,20,21] The authors discovered that the compound action potential (CAP) and the conduction velocity for sciatic nerves with HARMONIC® and sham incisions were similar. Whereas, for electrosurgical incisions, they were significantly lower at post-0 time points through day 7.[20,21] Likewise, tissues that had electrosurgery required significantly higher von Frey hair (VFH) electrical stimulation for a neural response, and there was significantly higher hind paw numbness compared to HARMONIC® even at day 7.[20,21] Histologically, sciatic nerves treated at a distance of 2mm or 3mm with sham or harmonic energy incisions had significantly less PMN and β-APP infiltration than electrosurgical incisions, suggesting that the presence of electrosurgical treatment caused more inflammation and greater nerve damage corroborating what had been physically measured.[20,21] Similar thermal spread and nerve dysfunction has been observed by others.[16] The reduced amounts of histopathology in harmonic incised tissues corroborate with faster wound healing and quick recovery periods that have been reported in the literature.[9,10,12,18,22]

The amount of energy and how the tissue is impacted depends on time, which can be influenced by several factors: generator settings, selected instrument blade, tissue tension, tissue density, surgical technique, and compression. The HARMONIC® generator power ranges from 1–5. Adjusting the power settings are helpful depending on surgeon preference as well as the intended use of the ultrasonic energy. Selecting the power level to balance time to cut with level of required hemostasis is key. For slower cutting and more coagulation to achieve good hemostasis, lower power settings result in longer activations which allows for more time to coapt tissue and less cavitation. Higher power settings result in faster cutting speeds and less coagulation through increased cavitation. Energy transferred to the tissue through the active blade under applied force minimizes lateral thermal spread. The tissue separates when clamping force of pressure is applied to the tissue with the

**Table I**
**Generator evolution**

| Year | 1988 | 1995 | 2001 |
|---|---|---|---|
| **Photo** |  |  |  |
| **Equipment** | UltraCision<br>(Harmonic energy) | Gen 01<br>(Harmonic energy) | Gen 300 also known as<br>Gen04<br>(Harmonic energy) |
| **Improvement** | -First ultrasonic cutting and coagulator generator on market | -First EES generator after UltraCision purchase<br>-Power knobs replaced with touch arrows<br>-Digital screen<br>-Troubleshooting error codes | -Foot-pedal activated<br>-Touchscreen<br>-Larger, easy-to-read digital power numbers<br>-Easy-touch buttons for standby, test, and activation |
| **Comments** | *** Historic Image Ultracision** | *** Image courtesy of EES** | *** Image courtesy of EES** |

**Table I (continued)**
**Generator evolution**

| Year | 2011 | 2012 |
|---|---|---|
| **Photo** |  |  |
| **Equipment** | GEN11 combination Smart generator HARMONIC® and ENSEAL® (Ethicon Endo-Surgery, Inc., Cincinnati, Ohio) | Adaptive Tissue Technology (ATT) software for Smart generator |
| **Improvement** | -Optimized energy delivery dependent on tissue changes<br>-Ultrasonic and bipolar capabilities<br>-Supports all devices<br>-High-resolution and touchscreen display<br>-Sleeker for easier cleaning | -Enhances surgical precision<br>-Manages energy and temperature dependent on changes in tissue |
| **Comments** | *** Image courtesy of EES** | *** Image courtesy of EES** |

blade in motion, independent of whether the tissue is under tension. The amount of energy required to transect filmy adhesions during adhesion lysis is far less than that required for denser tissues, such as the posterior vaginal fornix during a colpotomy. The introduction of Adaptive Tissue Technology (ATT) software assists the surgeon by managing and finely adjusting the energy and temperature based on tissue feedback.

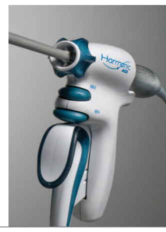
## EVOLUTION OF HARMONIC ENERGY TECHNOLOGY

Harmonic energy technology has continued to evolve over the years like its humble predecessor the scalpel. The original 1988 technology offering to plastic surgeons, the UltraCision HARMONIC® Scalpel, consisted of a generator and a wand-like grip containing the transducer handpiece with a flat blade, and it was foot-pedal activated (Tables I–III). Tissue tension was required to transect tissue, but the minimal lateral damage and minimal smoke were major clinical advantages. The hook and ball blades became popular and the use of harmonic energy in surgery surged across the US (Table III). The inner portion of the hook blade allowed tissue to be cut under tension; whereas, the outer curve was used for spot coagulation. For bigger coagulation needs, the

**Table II**
**Hand grip evolution**

| Year | 1988 | 1992 | 1992 | 1999 |
|---|---|---|---|---|
| **Photo** |  |  |  |  |
| **Equipment** | UltraCision (Harmonic energy) | CS 151/150 (10mm)<br>LCS 15/6 (10mm) | CS 151/150 (10mm)<br>LCS 15 6/5 (10mm) | CS 14C (5mm) |
| **Handpiece description** | Wand | "Pistol" grip | Scissor grip | Scissor grip |
| **Improvement** | -First ultrasonic cutting and coagulator on market | -"Pistol" grip to provide better maneuverability and lessen hand fatigue | -Scissor grip to provide better maneuverability and lessen hand fatigue | -Larger thumb and finger handles<br>-Larger dial at base of shaft<br>-Short shaft<br>-Small diameter shaft |
| **Comments** | *** Historic Image Ultracision** | *** Image courtesy of EES** | *** Image courtesy of EES** | *** Image courtesy of EES** |

**Table II (continued)**
**Hand grip evolution**

| Year | 1999 | 2005 | 2005 |
|---|---|---|---|
| **Photo** |  |  |  |
| **Equipment** | LCS with rotation blade dial (5mm) | HARMONIC® ACE-P | HARMONIC® ACE-E |
| **Handpiece description** | "Pistol" grip | Pistol grip | Shepherd hook grip |
| **Improvement** | -"Pistol" handle for clamp arm of shear<br>-Blade rotates for three different cutting and coagulation modes<br>-Longer shaft | -Pistol grip with button activation<br>-Rotation knob for easier device movement | -Fits all hand sizes<br>-Shepherd hook combined with pistol grip |
| **Comments** | *** Image courtesy of EES** | *** Image courtesy of EES** | *** Image courtesy of EES** |

ball tip could be used for sealing and coagulation. In another short two years, the first ultrasonic shears, CS (10mm), and LCS (10mm) with blade rotation, became available (Tables II and III). The ability to grasp, rotate, cut, and coagulate without an instrument change led to explosive popularity across different surgical fields, but especially in the thoracic and gynecological fields that routinely operate on highly vascular and small, deep spaces. A disposable "pistol"-like grip or scissor-like grip enabled the grasper, and the blade could be rotated using a dial, while the reusable transducer handpiece was inserted at the rear of the device. Tissue tension was no longer required for cutting since the grasper could compress the tissue during transection. Likewise, once the blade was rotated to the flat side, coagulation of a vessel was facilitated by the compression of the grasper on the tissue. The reconfigured blade allowed for sealing slightly larger vessels of up to 3mm. Because of the length of the shears, the instrument could be used in laparoscopic surgery which also contributed to an increase in its popularity.

By 1995, Ethicon Endo-Surgery purchased the UltraCision HARMONIC® scalpel technology and attachments. Within two years of the purchase, and listening to surgeon input, new blade shapes were available and greatly

**Table III**
**Application tip evolution**

| Year | 1988 | 1990 | 1990 |
|---|---|---|---|
| **Photo** |  |  |  |
| **Equipment** | UltraCision (Harmonic energy) | Hook blade (10mm)<br>(5mm available 2000) | Ball coagulator (10mm)<br>(5mm available 2000) |
| **Category** | Generator and Blade | Blade | Sealer |
| **Indication** | Hemostatic cutting and coagulation | Hemostatic cutting and coagulation | Hemostatic coagulation |
| **Vessel Size** | ≤2mm vessels | ≤2mm vessels | ≤2mm vessels |
| **Blade Configuration** | Flat blade with point | Hook. Outer radius for coagulation<br>Inner radius for cutting under tension | Spherical ball |
| **Compression Force** | Requires tension to cut | Requires tension to cut | Requires contact to coagulate |
| **Improvement** | -First ultrasonic cutting and coagulator on market | -Easier to use<br>-Blade geometry improved<br>-Better spot coagulation<br>-More effective cutting | -Easier to use<br>-Better coagulation |
| **Approach** | Open | Open | Open |
| **GYN Clinical Application** | Used to coagulate tissue instead of staples during procedures | Coagulate/excise endometriosis, spot coagulate small vessels, adhesion lysis , colpotomy | Coagulate endometriosis, coagulate small vessels |
| **Comments** | Lack of smoke and char minimized degraded protein debris and clear field of vision<br>Control of lateral thermal spread<br>- **Historic Image Ultracision** | Lack of smoke and char minimized degraded protein debris and clear field of vision<br>-**Image courtesy of EES** | Ball tip allowed precise coagulation<br>- **Image courtesy of EES** |

**Table III**
**Application tip evolution**

| Year | 1992 | 1999 | 1999 |
|---|---|---|---|
| **Photo** |  |  |  |
| **Equipment** | CS Jaw (10mm) with blade rotation<br>LCS Jaw (10mm) with blade rotation | CS14C (5mm) | LCS (5mm) |
| **Category** | Shears | Shears | Shears |
| **Indication** | Hemostatic cutting and coagulation | Hemostatic cutting and coagulation | Hemostatic cutting and coagulation |
| **Vessel Size** | ≤3mm vessels | ≤3mm vessels | ≤3mm vessels |
| **Blade Configuration** | Broad or narrow flat rectangle | Curved, broad blade with blunt tip | Rounded, long blade |
| **Compression Force** | Jaws close to provide pressure from grip | Jaws close to provide pressure from grip | Jaws close to provide pressure from grip |
| **Improvement** | -Clamping<br>-Blade rotates for three different cutting and coagulation modes<br>-Increased vessel size<br>-Wider opening | -Blunt end | -Smaller blade<br>-Smaller shaft diameter |
| **Approach** | Laparoscopic | Open | Minimally invasive laparoscopic |
| **GYN Clinical Application** | Coagulate/excise endometriosis, adhesions, uterine fibroids, myomectomy, ovarian/tubal surgery, total and subtotal hysterectomy, colpotomy, appendectomy | Rarely used.<br>Limited to:<br>excisional endometriosis and abdominal wall excisional (i.e., skin tags, caesarian scar, etc.) | Coagulate/excise endometriosis, adhesions, uterine fibroids, myomectomy, ovarian/tubal surgery, total and subtotal hysterectomy, colpotomy, appendectomy |
| **Comments** | Lack of smoke and char minimized degraded protein debris and clear field of vision. Quicker cutting and vessel coagulation<br>- **Image courtesy of EES** | Lack of smoke and char minimized degraded protein debris and clear field of vision. Quicker cutting and vessel coagulation<br>- **Image courtesy of EES** | Lack of smoke and char minimized degraded protein debris and clear field of vision. Quicker cutting and vessel coagulation<br>- **Image courtesy of EES** |

## Table III (continued)
## Application tip evolution

| Year | 2000 | 2000 | 2005 |
|---|---|---|---|
| **Photo** |  |  |  |
| **Equipment** | Curved blade | LCSC (5mm) | Harmonic ACE |
| **Category** | Blade | Shears | Shears |
| **Indication** | Hemostatic cutting and coagulation | Hemostatic cutting and coagulation | Hemostatic cutting and coagulation |
| **Vessel Size** | ≤2mm vessels | ≤3mm vessels | ≤5mm vessels |
| **Blade Configuration** | Curved blade with rounded tip | Curved blade with smooth tip for better dissection | Curved, blunt and flat blade |
| **Compression Force** | Requires tension to cut | Jaws close to provide pressure from grip | Consistent compression |
| **Improvement** | -Curved blade allows for cutting or scraping | -Curved blade for better dissection at tip<br>-Better visualization at tip | -Pistol grip and then shepherd's crook with button activation<br>-Rotation knob for easier device movement<br>-Ability to seal 5mm vessels<br>-Audible and tactile click once clamp is fully engaged |
| **Approach** | Open | Minimally invasive laparoscopic | Minimally invasive laparoscopic |
| **GYN Clinical Application** | Cut and coagulate tissues, excise endometriosis, lyse or excise pelvic adhesions | Coagulate/excise endometriosis, adhesions, uterine fibroids, myomectomy, ovarian/tubal surgery, total and subtotal hysterectomy, colpotomy, appendectomy | Coagulate/excise endometriosis, adhesions, uterine fibroids, myomectomy, ovarian/tubal surgery, total and subtotal hysterectomy, colpotomy, appendectomy |
| **Comments** | Curved blade allowed precise cutting and coagulation. Lack of smoke and char minimized degraded protein debris and clear field of vision. Quick cutting<br>*** Image courtesy of EES** | Lack of smoke and char minimized degraded protein debris and clear field of vision. Quicker cutting and vessel coagulation<br>*** Image courtesy of EES** | Lack of smoke and char minimized degraded protein debris and clear field of vision. Quicker cutting and vessel coagulation<br>*** Image courtesy of EES** |

improved the versatility of the instrument both for more efficient cutting as well as better coagulation. In 1999, the first 5mm ultrasonic shears, LCS (5mm), were introduced to meet the need created by the improvement in surgical technique from laparoscopic surgery to minimally invasive laparoscopic surgery (Tables II and III). Within two years, curved 5mm ultrasonic shears, LCSC (5mm), were available (Table III). The curved blade with smooth tip allowed for better dissection and visibility at the tip end. As the grips and application tips evolved, the generator also underwent improvements. Soon the Gen04, also known as generator 300, was powering harmonic energy in 2001 (Table I). This generator was larger, but capable of much more than its smaller predecessor. The screen no longer used knob controls, and instead, had a touch panel for power settings. Several safety alarms and troubleshooting modes were developed to be user friendly and assist in preventing issues from occurring. Activation of the energy flow and blade were via a foot pedal.

As the use of harmonic energy grew, surgeons continued giving feedback for instrumentation improvements. HARMONIC® ACE®-P shears were developed using surgeon ideas and introduced in 2005 (Tables II and III). The newly designed pistol grip helped combat hand fatigue associated with scissor grips. The foot-pedal was no longer needed because easy access activation buttons were on the grip. A rotation dial on the grip allowed for easier blade movement. An audible and tactile click once the clamp was fully engaged was also added to ensure proper compression. The new instrument was also able to seal vessels up to 5mm, making it more versatile than before. In 2008, the ACE®-E with an ergonomic handle was modified with a shepherd's hook grip so that all hand sizes fit well and reduced hand fatigue (Table II).

In 2011, a new combination generator called Gen11 was introduced (Table I). This particular generator has the ability to be used by harmonic energy instruments or by bipolar devices. The new generator was smaller than before and could take the place of two generators for harmonic and electrosurgical devices, addressing both the footprint of the generator and space issues within the operating room (OR). The generator uses sophisticated software that optimizes the energy depending on tissue changes allowing less energy to be used more effectively. The touchscreen was also upgraded to a high-resolution with easier-to-read panels, on-screen diagnostics, and fast set up. A year later, Adaptive Tissue Technology (ATT) software was introduced for the Gen11 (Table I). The software upgrade better manages the energy and temperature dependent on changes in tissue which further minimizes thermal damage. The ATT software update also

**Table III (continued)**
**Application tip evolution**

| Year | 2012 | 2014 | 2016 |
|---|---|---|---|
| **Photo** |  |  |  |
| **Equipment** | ACE+ | Advanced Hemostasis Mode with Ace +7 Shears | Harmonic HD 1000i shears |
| **Category** | Shears | Shears | Harmonic HD 1000i shears |
| **Indication** | Soft tissue cutting | Hemostatic cutting and coagulation | Soft tissue cutting, coagulating |
| **Vessel Size** | ≤5mm vessels | ≤7mm vessels | ≤7mm vessels |
| **Blade Configuration** | Rounded blunt tip with curved blade | Narrow, tapered, curved blade | Curved, tapered, thin finger of blade |
| **Compression Force** | Consistent compression | Consistent compression | Less force needed to achieve compression |
| **Improvement** | -Uses ATT for active heat management<br>-Less thermal spread<br>-Faster transection<br>-Coated blade to reduce sticking | -Improved hemostasis using ATT<br>-7mm vessel sealing<br>-Increased cutting and sealing capabilities<br>-Reduced collateral damage<br>-Reduce from 3 buttons to activate to 2 buttons | -Improved sealing capability with advanced hemostasis mode<br>-Large, curved tapered narrow jaw improves dissection<br>-Increased sealing speed<br>-7mm vessel sealing<br>-Increased strong tip grasping for better manipulation<br>-Less force for clamping |
| **Approach** | Minimally invasive laparoscopic | Minimally invasive laparoscopic | Minimally invasive laparoscopic |
| **GYN Clinical Application** | Coagulate/excise endometriosis, adhesions, uterine fibroids, myomectomy, ovarian/tubal surgery, total and subtotal hysterectomy, colpotomy, appendectomy | Coagulate/excise endometriosis, adhesions, uterine fibroids, myomectomy, ovarian/tubal surgery, total and subtotal hysterectomy , colpotomy, appendectomy | Coagulate/excise endometriosis, adhesions, uterine fibroids, myomectomy, ovarian/tubal surgery, total and subtotal hysterectomy, colpotomy, appendectomy |
| **Comments** | Lack of smoke and char minimized degraded protein debris and clear field of vision. Quicker cutting and vessel coagulation<br>*** Image courtesy of EES** | Lack of smoke and char minimized degraded protein debris and clear field of vision. Quicker cutting and vessel coagulation<br>*** Image courtesy of EES** | Lack of smoke and char minimized degraded protein debris and clear field of vision. Quicker cutting and vessel coagulation<br>*** Image courtesy of EES** |

enhances surgical precision by continuously monitoring and adjusting the energy within the instrument so that thermal collateral damage is further reduced by modifying the temperature.

The same year the ATT software was made available, the HARMONIC® ACE®+ shears were also introduced (Table III). These shears were made specifically to use the ATT software to manage heat resulting in less thermal damage. The ACE®+ shears also have a coated blade which reduces sticking of denatured protein. The combination of the heat management software and the coated blade on the Ace+ shears led to faster tissue transection. Two years later, in 2014, the Advanced Hemostasis Mode on HARMONIC® ACE®+7 shears were introduced (Table III). Utilizing the ATT software in conjunction with a special advanced hemostasis mode improved hemostasis such that 7mm vessel sealing using only ultrasonic energy was possible. The new shears increased both its cutting and sealing capabilities while reducing collateral damage. These particular shears also improved procedure time because of its enhanced ability to cut and coagulate at the same time.

Recently HARMONIC® HD 1000i was introduced (Table III). The large, curved, tapered, and narrow jaw improves dissection so much that the need for an additional dissector instrument is often eliminated. The tip strength has also increased the grasping capability resulting in better manipulation of tissue. Less force is required to clamp the jaws around tissue. These shears have improved sealing capability compared to prior versions. The instrument can seal 7mm vessels using the advanced hemostasis mode and faster speeds than before, saving surgical time.

## GYNECOLOGICAL CLINICAL APPLICATIONS

Using UltraCision to coagulate bleeding tissue in lieu of a stapler during gynecological procedures was a natural first use of harmonic energy. Once the hook and ball tips were available, the harmonic energy could be used to transect or coagulate tissue during a procedure. When the laparoscopic LCS 10mm shears became available though, multiple procedures, such as coagulating and/or excising endometriosis, adhesion lysis, removal of uterine fibroids, myomectomy, ovarian surgery, tubal surgery, total and subtotal hysterectomies, colpotomy, and appendectomy could be undertaken with harmonic energy. Once the 5mm shears were available for minimal invasive surgery, all these procedures could be

**Table IV**
**Statistically significant benefits of harmonic energy use for patients**

| Author | Symptom | Value | P value | Study | Surgery |
|---|---|---|---|---|---|
| 22 Litta22 Litta | 24-hour pain | 4.40 | p=0.0001 | RCT | Lap myomectomy |
| 23 Revelli | 24-hour pain | 1.33 | p=0.02 | MA | Thyroidectomy |
| 24 Jiang | 24-hour pain | 1.19 | p<0.00001 | MA | Cholecystectomy |
| 24 Jiang | 24-hour abdominal pain | 0.95 | p<0.00001 | MA | Cholecystectomy |
| 25 Mushaya | Pain | 0.98 | p<0.001 | MA | Hemorrhoidectomy |
| 26 Sasi | 2-hour nausea | 0.90 | p=0.01 | RCT | Cholecystectomy |
| 26 Sasi | 4-hour nausea | 0.80 | p=0.002 | RCT | Cholecystectomy |
| 26 Sasi | 24-hour nausea | 1.20 | p=0.004 | RCT | Cholecystectomy |
| 23 Revelli | Postoperative drainage | 12.90ml | p=0.01 | MA | Thyroidectomy |
| 27 Ren | Total drainage | 64.86ml | p=0.005 | MA (regular analysis) | Neck dissection |
| 28 Cheng | Total drainage | 134.36ml | p<0.00001 | MA | Open gastrectomy |
| 28 Cheng | Total drainage | 486.00ml | p=0.007 | MA | Lap gastrectomy |
| 29 Huang | Total drainage | 0.74ml | p=0.01 | MA | Mastectomy |
| 29 Huang | Wound seromas | 0.49 | p<0.0001 | MA | Mastectomy |
| 30 Cheng | Wound seromas | 0.54 | p<0.0001 | MA | Mastectomy |
| 22 Litta | Length of stay | 2.27 days | p<0.0001 | RCT | Lap myomectomy |
| 23 Revelli | Length of stay | 0.6 days | p=0.005 | MA | Thyroidectomy |
| 30 Cheng | Length of stay | 1.4 days | p=0.007 | MA | Mastectomy |
| 24 Jiang | Length of stay | 0.37 days | p=0.002 | MA | Cholecystectomy |
| 31 Lei | Length of stay | 9 days | p=0.04 | MA | Pancreatectomy |
| 26 Sasi | Return to work | 3.8 days | p=0.002 | RCT | Cholecystectomy |
| 25 Mushaya | Return to work | 8.8 days | p=0.001 | MA | Hemorrhoidectomy |

performed but with smaller incisions and subsequently, smaller scars. The introduction of instruments that could seal larger vessels of 5mm (ACE®, ACE®+) and 7mm (Advanced Hemostasis Mode ACE®+7 and ACE® HD 1000i shears) provided one instrument that could handle the tissue manipulation, dissection, cutting, and coagulation of a highly vascularized and compact space.

## GENERAL CLINICAL BENEFITS

Objective benefits of ultrasonic energy, such as minimal histological pathology and improved bursting strength of sealed vessels, has been clearly shown.[9,10,12,13] Multiple randomized clinical trials and meta-analysis studies have also shown clinical benefits to patients receiving harmonic energy devices for various etiologies and clinical procedures. Table IV provides a summary of the statistics discussed below.

### Pain and nausea

A reduction in postoperative pain and/or postoperative medications is a clear patient benefit. A gynecological randomized controlled study of 160 premenopausal subjects underwent laparoscopic myomectomy with either electrosurgery with a vasoconstrictive solution and epinephrine or ultrasonic energy in order to evaluate outcome differences.[22] Among the benefits observed, a significant reduction in postoperative pain at 24 hours was statistically lower than the electrosurgical group ($p=0.0001$) and at 48 hours, the pain was equal between the groups. Other surgical specialties have also noted statistically significant reductions in postoperative pain in HARMONIC® energy treated groups. Meta-analysis of multiple clinical trials on the use of HARMONIC® devices showed a statistical reduction in pain for subjects receiving thyroidectomy ($p=0.02$), laparoscopic cholecystectomy for less pain ($p<0.00001$) and fewer abdominal pains ($p<0.00001$), and less hemorrhoidectomy pain ($p<0.001$).[23-25] Although nausea is not common in most gynecology procedures, a significant reduction in nausea at two hours postoperative ($p=0.01$), four hours ($p=0.002$), and 24 hours ($p=0.004$) after laparoscopic cholecystectomy when performed using a HARMONIC® device was seen.[26] Another meta-analysis on laparoscopic cholecystectomy did not find a significant difference in nausea at 24 hours though.[24]

### Wound drainage, postoperative bleeding, and seroma

Wound drainage or postoperative bleeding at worst can indicate a potential problem and at best is annoying for the patient and a cause of concern. Meta-analysis on the use of HARMONIC® devices showed a significant reduction in drainage or postoperative bleeding for subjects receiving thyroidectomy ($p=0.01$), neck dissection ($p=0.005$), gastrectomy (open $p<0.00001$; lap $p=0.007$), and mastectomy ($p=0.01$).[23,27-29] A significant reduction in wound seromas ($p<0.0001$) were also noted in HARMONIC® device use in the mastectomy meta-analysis.[29] Another mastectomy

**Table V**
**Statistically significant benefits of harmonic energy use for doctors and facilities**

| Author | Symptom | Value | P value | Study | Surgery |
|---|---|---|---|---|---|
| 22 Litta | Blood Loss | 135.2ml | p=0.004 | RCT | Lap Myomectomy |
| 32 Lamblin | Blood Loss (Salpingectomy) | 1.75ml | p<0.005 | RCT | Bilateral Salpingectomy |
| 33 Fitz-Gerald | Blood Loss | 9.08ml | p=0.006 | RCT | during Lap Hysterectomy |
| | | | | | Vag Hysterectomy |
| 23 Revelli | Blood Loss | 30.49ml | p=0.008 | MA | Thyroidectomy |
| 28 Cheng | Blood Loss | 93.15ml | p<0.00001 | MA | Open Gastrectomy |
| 29 Huang | Blood Loss | 1.14ml | p<0.0009 | MA | Mastectomy |
| 24 Jiang | Blood Loss | 47.24ml | p=0.004 | MA | Cholecystectomy |
| 23 Revelli | Transient Hypocalcemia | 0.76 | p=0.002 | MA | Thyroidectomy |
| 24 Jiang | Perforations | 0.48 | p<0.00001 | MA | Cholecystectomy |
| 30 Cheng | Complications | 0.48 | p=0.002 | MA | Mastectomy |
| 30 Cheng | Tissue Necrosis | 0.51 | p=0.04 | MA | Mastectomy |
| 31 Lei | Fistula | 0.46 | p=0.003 | MA | Distal Pancreatectomy |
| 31 Lei | Abdominal Abscesses | 0.78 | p=0.01 | MA | Distal Pancreatectomy |
| 28 Cheng | Complications | 0.58 | p=0.03 | MA (Sensitivity Analysis) | Gastrectomy |
| 25 Mushaya | Complications | 0.45 | p=0.001 | MA | Hemorrhoidectomy |
| 34 Mahabaleshwar | Patient need Clean Lens | 19Pts | p=0.015 | RCT | Lap Cholecystectomy |
| 34 Mahabaleshwar | Number Lens Cleaning | 1 | p=0.004 | RCT | Lap Cholecystectomy |
| 34 Mahabaleshwar | OR Time | 27.20min | p=0.001 | RCT | Lap Cholecystectomy |
| 22 Litta | OR Time | 71.8min | p=0.0001 | RCT | Lap Myomectomy |
| 32 Lamblin | OR Time | 48.16sec | p<0.0001 | RCT | Right Salpingectomy |
| | (Right salpingectomy) | | | | during Lap Hysterectomy |
| 32 Lamblin | OR Time | 56.55sec | p<0.0001 | RCT | Left Salpingectomy |
| | (Left salpingectomy) | | | | during Lap Hysterectomy |
| 23 Revelli | OR Time | 25.99min | p<0.00001 | MA | Thyroidectomy |
| 27 Ren | OR Time | 40.04min | p<0.00001 | MA (both analyses) | Neck Dissection |
| 24 Jiang | OR Time | 14.86min | p=0.0001 | MA | Cholecystectomy |
| 31 Lei | OR Time | 63.00min | p=0.02 | MA | Distal Pancreatectomy |
| 35 Cheng | Total Costs | $229.27USD | p=0.02 | MA | Thyroidectomy |
| 35 Cheng | OR Only Costs | $236.27USD | p=0.04 | MA | Thyroidectomy |
| 35 Cheng | Total Fixed Effect Costs | $298.05USD | p<0.00001 | MA | Thyroidectomy |

meta-analysis saw a significant 46% decrease in seromas ($p<0.00001$) and a non-significant 43% reduction in hematomas ($p=0.09$).[30]

### Length of stay and return to work

Length of hospital stay is always a concern for patients as well as the surgeon and hospital. For gynecological subjects receiving myomectomies using a HARMONIC® device, their length of stay was significantly reduced ($p<0.0001$).[22] A reduction in length of stay for ultrasonic energy compared to conventional technique was seen in several meta-analysis articles in thyroidectomy ($p=0.005$), mastectomy ($p=0.007$), laparoscopic cholecystectomy ($p=0.002$), and pancreatectomy ($p=0.04$).[23,24,30,31] A significantly quicker return to work was seen for laparoscopic cholecystectomy ($p=0.002$) and hemorrhoidectomy ($p=0.001$) subjects when performed using a HARMONIC® device.[25,26]

When these benefits are taken together, the use of ultrasonic energy provides a variety of benefits to the patient for less pain and discomfort and a quicker recovery and return to normal activities when compared to conventional techniques.[22-31]

## GENERAL SURGICAL BENEFITS

Like patient benefits, surgeons and hospitals can also benefit from the use of ultrasonic energy during surgery. Multiple meta-analysis and randomized clinical trials have shown several clinical benefits to surgeons and hospitals. Not all clinical trials attempt to ask and answer the same questions but can give new insights. Because meta-analysis papers often analyze the same clinical trials, not all meta-analysis articles on HARMONIC® devices are included below, but the most current ones have been cited. It should be noted that not all meta-analysis papers analyze the same outcome. Table V provides a summary of the statistics discussed below.

**Blood loss**

Less blood loss has been consistently observed in conjunction with HARMONIC® devices compared to conventional techniques. The pelvic cavity is a vascular rich area and preventing blood loss is important. Three clinical trials using ultrasonic energy found that blood loss was significantly less for laparoscopic myomectomy ($p=0.004$), bilateral salpingectomy during laparoscopic hysterectomy ($p<0.005$), and for vaginal hysterectomy ($p=0.006$).[22,32,33] It should be noted that total blood loss of the laparoscopic hysterectomies, apart from the bilateral salpingectomy, was not statistically different.[32] A significant reduction in intraoperative blood loss was seen in subjects undergoing thyroidectomy ($p=0.008$), gastrectomy (open $p<0.00001$), mastectomy ($p<0.0009$), and laparoscopic cholecystectomy ($p=0.004$) when performed with HARMONIC® devices.[23,24,28,29]

**Complications**

Surgery requires a lot of dissection. Compared to conventional methods, many surgeons feel that HARMONIC® devices are safer for tissue dissection since it is precise and has little lateral thermal damage, especially near vital structures such as nerves or organs. A meta-analysis with a trial sequential analysis (TSA) in laparoscopic cholecystectomy compared conventional electrosurgical and ultrasonic energy for surgical dissecting.[24] The TSA indicated that the meta-analysis evidence for postoperative pain at 24 hours and gall bladder perforation (and even operation time) firmly concluded the HARMONIC® device was indeed a safe tissue dissection device.

Fewer complications are associated with ultrasonic energy technology than conventional methods as seen in the following meta-analysis papers. For thyroidectomy, a significantly reduced risk of transient hypocalcemia ($p=0.002$)[23] with the use of HARMONIC® focus shears for laparoscopic cholecystectomy resulted in fewer perforations ($p<0.00001$). There was also a 52% reduction in mastectomy complications ($p=0.002$) and a 49% reduction in tissue necrosis ($p=0.04$). With regard to distal pancreatectomy, fewer pancreatic fistulas ($p=0.003$) and abdominal abscesses ($p=0.01$) were seen. There were fewer complications for gastrectomy noted ($p=0.03$) and for hemorrhoidectomy, there was a reduction in complications ($p=0.001$).[23-25,28,30,31] Use of HARMONIC® devices appear to improve clinical outcomes through both a reduction in complications and minimizing tissue damage during surgery.

**OR time**

Many surgeons have noticed that using HARMONIC® devices during surgery saves time because the tissue is cut, coagulated, and sealed quickly, it is often the only instrument needed, and it leads to fewer complications and even less laparoscopic lens cleaning.[34] Significantly less time was needed for laparoscopic myomectomy ($p=0.0001$) and bilateral salpingectomy (left and right were each $p<0.0001$).[22,32] It should be noted that there was no difference in total OR time when laparoscopic hysterectomy was assessed.[32] Other specialties have also found ultrasonic energy saves OR time in thyroidectomy ($p<0.00001$), neck dissection ($p<0.00001$), laparoscopic cholecystectomy ($p=0.0001$), and distal pancreatectomy ($p=0.02$).[23,24,27,31]

**Costs**

Cost reduction is always an important financial piece that must be assessed as well. A cost comparison of a HARMONIC® device and conventional monopolar electrosurgery with clamp, cut, and tie technique showed a significant 10% reduction in total reported costs ($p=0.02$), a 10% reduction in operation-only costs ($p=0.04$), and a 13% reduction in total reported costs with a fixed effect model ($p<0.00001$) from mean baseline costs.[35]

**Versatility**

One of the biggest surgeon-oriented benefits is the HARMONIC® device's versatility. By being able to grasp, lyse, excise, tie, cut, dissect, and seal with one instrument and little smoke makes surgery go smoothly since there is clear field of vision and no delay or risk in receiving a new instrument. Not needing to use multiple instruments also saves time and money for the hospital, leading to a cost reduction. Since multiple fields now use the same harmonic instrument but for different surgical procedures, the number of instruments to have ready and available is reduced.

## DISCUSSION

As a surgeon, I am always looking for techniques and tools to make my patients' surgical experience a positive one. The UltraCision HARMONIC® device was first used in my practice in 1988 as a replacement for laser energy. As the technology improved and broadened, so did my use of it because of the surgical and clinical outcomes I witnessed with my patients. When the LCS 10mm shears became available in 1992, I found I could do more with the instrument and it became a replacement for linear staples. A retrospective review of charts for laparoscopic-assisted vaginal hysterectomies or laparoscopic hysterectomies was performed and compared the use of the LCS shears and confirmed the cost savings and the success of the HARMONIC® device as an alternative tool (McCarus unpublished data). Over the years, and in a variety of gynecological procedures, patients that have had surgery with HARMONIC® devices in place of conventional techniques (i.e., suture, staples, bipolar, etc.), seem to have less pain and a faster recovery. Patients are voiding and ambulating quicker and are released from the hospital sooner. Having less pain and a faster recovery improves their outlook and how they feel which improves their quality of life and minimizes the disruption of their familial life. From the literature cited, it is clear that patients from various surgical fields are also having less pain and faster recovery.

When looking for techniques and tools, the impact on myself as a surgeon, my staff, and the facility must also be taken into account. From a surgical perspective, having an instrument with the surgical versatility that can lyse and excise the appendix, lyse or excise endometriosis, as well as adhesions during a hysterectomy procedure is a major breakthrough. The ability for precise cutting and dissecting with minimal collateral damage near vital structures under a clear field of vision, especially in complex procedures, leads to better clinical outcomes. The literature shows using HARMONIC® devices for surgical procedures results in fewer complications, less blood loss, and a shortened hospitalization. In my own experience of having performed over 5,000 McCarus HARMONIC® ACE® hysterectomies, I have never had a single postoperative bleed, leak, or delayed HARMONIC® device-related complication.[36] When use of robotic surgery is warranted, I utilize ultrasonic energy in conjunction with the robotic surgery because of both the literature and my experience. This versatility saves time and money intraoperatively. Being able to utilize this reduces costs and improves clinical outcomes at the same time, ultimately benefiting the patient, facility, and the surgeon.

The heat intensity and contact time to transect the same size vessel is different for a HARMONIC® device and an electrosurgical device.[11-13] Since the tissue is transected using mechanical energy instead of electrical current, there is a reduction in lateral thermal damage and little to no burn char.[9,11-13] The presence of burn eschar delays granulation tissue formation and healing, and it is known to be proinflammatory and prolongs tissue inflammation until removed.[37] Subsequently, tissues that had delayed burn eschar excision and/or those that were highly inflamed for long periods of time are associated with more contraction and scarring compared to early excised wounds.[37,38] Inflammation increases swelling, temperature, vasodilatation, and pain, so a reduction in inflammation, less lateral damage, and minimal char should not only reduce pain, but also speed tissue healing.

The reduction in inflammation in the tissues may also explain why this author has observed fewer adhesions when performing subsequent surgeries. Inflammation is known to increase the risk of developing gynecological adhesions as in prior gynecological surgery.[39] Since adhesions account for 20–40% of infertility, adhesiolysis is a common treatment. Unfortunately, adhesion reformation occurs in approximately 85% of patients following adhesiolysis, which can lead to more severe symptoms.[39] This anecdotal observation of fewer adhesions following surgery with HARMONIC® shears needs to be studied further to explore possible therapeutic breakthroughs.

Another possible contributing factor for the quicker recovery seen might be attributed to the lack of collagen destruction with the use of ultrasonic energy. As Foschi et al. showed, collagen fibers remain throughout the areas of coagulated amorphous substances within the vessel walls.[9] Collagen is an essential component of the extracellular matrix and is required for tissue repair. As seen previously, unlike cellular components, coagulation necrosis does not destroy collagen fibers. Elegant studies have shown that acellular tissue that has a collagen matrix present (i.e., frozen tissue) will not contract once repopulated as tissue ingrowth occurs unlike acellular tissue without functional collagen (i.e., burned tissue).[40,41] More recent studies have found the presence of a collagen matrix enhances tissue repair via cell signaling, while controlling contraction, and is the basis for many matrices available.[42,43] It seems plausible that the presence of collagen fibers in and near the zones of coagulation, stasis and hyperemia should facilitate healing. This should be studied to determine if collagen and the amorphous substance could beneficially impact tissue repair following ultrasonic energy.

The ability to precisely cut and dissect tissue with minimal lateral damage has been a big surgical benefit. In the oncological area though, preserving enough healthy tissue for future surgeries becomes an even bigger issue. Conserving tissue in primary breast cancer is a good example of this need.[44] Minimizing the surgical effects both systemically and locally are important for the overall health of the patient. In one breast-conserving clinical study, significant improvements in the amount of resected breast tissue was seen as well as an improved serum hemoglobin from the reduction in blood loss ultrasonic energy treated subjects compared to conventional techniques.[44] Other improvements in operative and postoperative factors contributed to improved clinical outcomes for the more fragile oncology patient. An interesting follow-up study would assess how more friable tissues, such as those often found in oncology and elderly patients, recover following surgery with HARMONIC® shears compared to conventional techniques.

## CONCLUSION

While there is still much to learn and research about ultrasonic energy and its use in surgery, our patients are currently benefiting from it. As the HARMONIC® technology and ultrasonic energy platforms continue to advance, less tissue trauma and faster recovery should remain the focal point. STI

## AUTHORS' DISCLOSURES

Ms. Parnell is the current president of the Wound Healing Foundation. All views in this manuscript are the author's and not the official position of the Wound Healing Foundation.

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