The next generation in ultrasonic vessel sealing provides faster transection with less thermal damage

HARMONIC ACE®+ Shears creates durable seals with improved performance

BACKGROUND

Since its inception, vessel sealing with ultrasonic devices has been recognized as having many advantages over conventional electrosurgery.[1] The purely mechanical action of the ultrasonic end effector eliminates the passage of any current to or through the patient. Hemostasis is achieved with minimal lateral thermal damage,[2] and minimal smoke (mist or vapor) is produced.[3]

Figure 1 End effector of the HARMONIC ACE®+ Shears.

Critical to the formation of a strong and durable vessel seal is the energy profile delivered by an ultrasonic device. Building upon the foundation of basic HARMONIC® functionality, Adaptive Tissue Technology has been developed to provide greater precision through improved energy delivery.[4] Exclusive to HARMONIC® devices, Adaptive Tissue Technology actively monitors the instrument during use and enables the system to respond intelligently to varying tissue conditions. With the HARMONIC ACE®+ Shears (Figure 1), Adaptive Tissue Technology delivers greater precision by regulating energy delivery when needed. During a transection, as tissue divides, the blade makes contact with the tissue pad of the device and the blade temperature typically begins to increase more rapidly. Adaptive Tissue Technology responds by reducing the power level and providing enhanced feedback with a change to a second activation tone. Hemostasis is achieved and unnecessary power output that could potentially lead to thermal injury is reduced. Additionally, the HARMONIC ACE®+ Shears features a tapered, coated blade that brings precision to multiple surgical jobs, including dissection, sealing, transection, grasping and otomy creation.

This study was undertaken to compare the HARMONIC ACE®+ Shears with Adaptive Tissue Technology to the previous version of the HARMONIC ACE® Shears. It was hypothesized that the technological advances incorporated into the new device would maintain rates of initial hemostasis and seal durability, while decreasing transection time, thermal damage and the risk of adhesion formation during wound healing.

Methods

All procedures used in this study were approved by the Ethicon Endo-Surgery Institutional Animal Care and Use Committee. A porcine model was chosen based on the similarity of blood vessel composition and sealing to that of humans.

The primary comparison was between HARMONIC ACE® Shears of lengths 23cm and 36cm and the new HARMONIC ACE®+ Shears with Adaptive Tissue Technology of the same lengths. For the acute procedures both the 23cm and 36cm lengths of the new and predicate devices were compared; for the survival study, only the 36cm lengths of each were utilized.

Vessel sealing was tested for ACE vs. ACE+ in porcine carotid, gastroepiploic, splenic and short gastric arteries, veins and bundles, at generator power level settings of 3 or 5. Intra-operative measurements included vessel size, transection time, initial hemostasis and tissue sticking. Postoperatively, thermal damage was assessed via hematoxylin and eosin (H&E) staining. A subset of the animals survived up to 30 days, at which time hemostasis was checked at each vessel seal after raising the blood pressure greater than 200 mmHg to induce a simulated hypertensive crisis. A visual examination for adhesions was also performed.

Continuous variables, such as transection time or thermal damage, were compared using a t-test or ANOVA, as appropriate, and binomial variables, such as hemostasis and adhesions, were compared using Fisher's exact test.

Results

There were no complications during the acute procedures, and all but one animal in the 30-day study survived until the appointed time. A single animal was found deceased after 18 days due to unrelated causes; upon necropsy, it was noted that all vessel seals were healing normally with no evidence of bleeding.

The distribution of vessel types used was not significantly different between ACE and ACE+. The diameters of vessels used ranged from 1mm to 5mm, and the mean vessel diameter was 3.4mm for both devices. There was no difference in the distribution of generator power settings used between the two devices.

A tabulation of key results is given in Table 1. Initial hemostasis was high for both devices (97.7% for ACE and 99.0% for ACE+) and not significantly different. The new HARMONIC ACE®+ Shears was 21% faster ($P<0.001$) in transection time than the HARMONIC ACE® Shears.

Table 1 *ACE vs ACE+ Results Summary*

Measure	ACE	ACE+	*P* value
Transection Time*	5.7 s	4.5 s	<0.001
Initial Hemostasis	127/130	95/96	0.639
Thermal Damage**	2.19mm	1.69mm	<0.001
Survival Hemostasis	33/33	32/32	1.000
Adhesions	13/33	0/32	<0.001

*Adjusted for vessel size and device length via ANOVA.
**Adjusted for device length and vessel type via ANOVA.

Neither device exhibited any tissue sticking. As measured by H&E staining, the mean zone of adventitial collagen denaturation (thermal damage) for ACE+ =was less than 2mm and 23% less than ACE (P<0.001, Figure 2).

At the end of the survival period, both devices showed 100% hemostasis of all seals after a simulated hypertensive crisis greater than 222 mmHg. The predicate device, ACE, had adhesion formation at 39.4% of vessel seals, while the new ACE+ had no adhesion formation at any site.[6]

Discussion

In this preclinical study, we examined the effects of incorporation of Adaptive Tissue Technology into the HARMONIC® platform. This technology provides the system with the ability to monitor the thermal condition of the blade and to identify conditions correlative to unnecessary thermal energy, namely, rapid increases in heat flux into the blade from action directly against the tissue pad rather than against tissue. When minimal tissue remains in the jaw, the generator decreases its power output and audible change in tone provides enhanced feedback to the user. This more intelligent technology reduces unnecessary power application that could potentially lead to excess thermal injury.

Historically, HARMONIC ACE® Shears have been shown to provide excellent hemostasis[7] and strong, durable seals.[8] In the current study, we observed that the HARMONIC ACE®+ Shears maintains these properties, with 99% success in initial hemostasis in vessels up to 5mm in diameter, and 100% durability of vessel seals up to 30 days postoperatively.

In contrast with electrosurgical methods, ultrasonic devices are recognized as producing less tissue sticking during use.[9] The improvements in ACE+ were shown in this study to maintain this useful characteristic, critical to operational speed and efficiency, with no observed tissue sticking.

The HARMONIC ACE®+ Shears transected tissue significantly faster than the previous model.[10] This is in part due to thermal monitoring and feedback that informs the user when vessel sealing is complete. Based on the lower temperatures produced by ultrasonic devices, it has been shown that they produce less thermal damage than electrosurgical devices.[11] With ACE+ the improved energy management has further reduced the thermal damage, leading to a 23% decrease and a mean zone of collagen denaturation less than 2mm.[4]

The inflammatory reaction to collagen denaturation has been implicated in postoperative adhesion formation.[12] Not unexpectedly, the decreased thermal damage of ACE+ has reduced the rate of adhesion formation compared to the previous version of the device, and no adhesions were observed with ACE+ in this preclinical model.

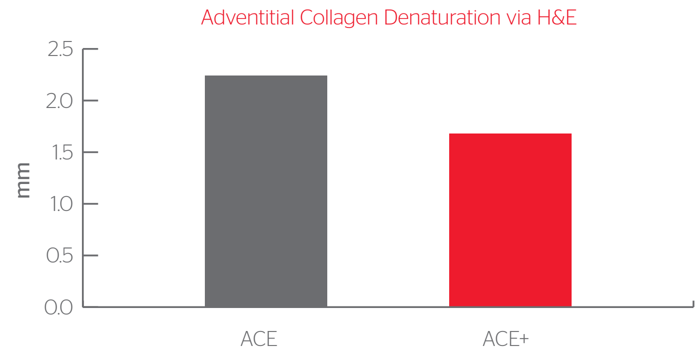

Figure 2 Mean thermal damage via H&E for ACE and ACE+. Error bars represent the 95% confidence interval. ACE+ had a significantly narrower band of thermal damage than ACE.

Conclusion

The new HARMONIC ACE®+ Shears continue to provide excellent vessel sealing hemostasis and durability with no tissue sticking. Incorporation of Adaptive Tissue Technology has optimized the management of energy transfer, resulting in faster transection, reduced tissue damage and lowered risk of postoperative adhesion formation.

References

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