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Stryker's reprocessed HARMONIC ACE®+7 Shears: a preclinical comparison to Ethicon HARMONIC ACE+7 Shears

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Introduction: Until recently, ultrasonic energy devices had only been indicated for sealing vessels up to 5mm in diameter. With the introduction of the HARMONIC ACE+7 Shears (HARH) by Ethicon, there now is an ultrasonic device capable of sealing vessels up to 7mm in diameter. This new indication has enabled ultrasonic scalpels to compete with bipolar energy devices, such as LigaSure (Medtronic), which had previously been the only devices indicated to seal up to 7mm vessels.

Stryker's Sustainability Solutions (Stryker) is a company that provides (FDA-regulated) reprocessed single-use devices. They specialize in making premium technologies (including products like the HARH) more affordable for healthcare providers. In order to market a reprocessed version of the HARH, Stryker must demonstrate to the FDA that the device is as at least as safe and effective as the legally marketed device from the original equipment manufacturer (OEM). The purpose of this study was to evaluate the performance of the Stryker reprocessed device as compared to the original Ethicon device.

Methods: In an acute porcine study, Stryker devices were compared to Ethicon devices on seal integrity, tissue sticking, shear cut quality and back cut quality. A separate lymphatic study in a porcine model evaluated the capability of the Stryker device to seal lymphatic vessels, using a methylene blue dye for visualization. A chronic, thirty (30) day animal survival study was completed to evaluate long-term seal quality, the presence of any hemostatic complications and whether thermal injury to adjacent tissues was present where Stryker devices were utilized for transection. Ex vivo benchtop studies were also performed to compare vessel burst pressure, maximum jaw and shaft temperature, Adaptive Tissue Technology (ATT) functionality and reliability testing.

Results: The acute studies found that the Stryker devices were statistically equivalent to Ethicon devices for all power levels and vessel sizes in regards to seal integrity, tissue sticking, shear cut quality and back cut quality. For vessels up to and including 7mm diameter (all generator power settings; all vessel sizes), the mean for thermal spread maximum length of the reprocessed device was statistically equivalent to the OEM device with 95% confidence (1.56mm $\bar{x}$, Stryker; 1.69mm $\bar{x}$, Ethicon). For vessels up to and including 7mm diameter (all generator power settings; all vessel sizes), mean thermal spread maximum width of the reprocessed device was statistically better than the OEM device with 95% confidence (2.69mm $\bar{x}$, Stryker; 3.34mm $\bar{x}$, Ethicon). The lymphatic acute study demonstrated that the Stryker device sealed all lymph vessels during two time points. The chronic study demonstrated effective long-term seal quality, no indication of acute post-operative or active bleeding and an absence of hemostatic complications at 30±2 days. Additionally, there was no evidence of thermal injury to the adjacent tissues attributed to the use of Stryker devices. Ex vivo benchtop studies revealed statistically equivalent performance in comparing vessel burst pressure, maximum jaw and shaft temperature, ATT functionality and reliability testing after 180 cycles.

Conclusion: Rigorous preclinical studies and ex vivo bench testing demonstrate that Stryker reprocessed HARH devices are at least as safe and effective as Ethicon original HARH devices.

Keywords: Ultrasonic, Harmonic, vessel sealing, burst pressure, 7mm, reprocessing, Stryker

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Reprocessing background:

Reprocessing of single use devices (SUDs) is the practice of cleaning, function testing, disinfecting (the process of killing pathogenic organisms or rendering them inert) and sterilizing products, per FDA regulation, so they can safely be used again. Reprocessing of SUDs may include disassembling devices down to their component parts, repairing, refurbishing and reconstructing the device using only those components that have passed all inspections, and have demonstrated substantial equivalence through Premarket Notification, or 510(k) clearance, in accordance with the Food and Drug Administration (FDA) Code of Federal Regulations (21CFR Part 807).[1] The FDA has an established regulatory framework for the premarket review and post market control of reprocessed SUDs, and 510(k) pre-market notification requirements for reprocessed devices are at least as stringent as those enforced for original equipment manufacturer (OEM) devices. In addition to the customary requirements of a 510(k) submission, FDA-registered reprocessing companies must also submit validation data regarding the cleaning, sterilization and performance of their devices. The practice has twice been evaluated by the United States Government Accountability Office (GAO), which stated in their most recent release that, "FDA oversight has increased, and available information does not indicate that use [of reprocessed devices] presents an elevated health risk."[2]

Stryker is the market-leading provider of single-use device reprocessing services. They have over a decade of experience reprocessing ultrasonic energy devices. For effective cleaning and the ability to conduct multi-point inspections on each component, the Stryker reprocessed HARMONIC ACE+7 Shears (HARH) are disassembled to its base components. To ensure premium quality standards, Stryker will sometimes elect to replace certain parts. In the case of the HARH, Stryker supplies a newly designed tissue pad and recoats the cutting blade with a non-stick coating. Once devices are reassembled, Stryker conducts simulated-use electrical testing on Ethicon generators (GEN 11). To reject devices not fit for another use, Stryker performs multiple function tests on each device. Also of significance is that Stryker has implemented the same quality system employed within other divisions of Stryker. Stryker believes that their dedicated focus on quality is what ultimately drove the outcomes of a recent, independent study conducted at Banner Health where it was reported that "Original equipment manufacturer devices are nearly five times more likely to be defective than reprocessed single-use devices."[3]

Methods:

Preclinical

The devices tested were Stryker reprocessed HARH and Ethicon original HARH. The null hypothesis was defined as no difference in performance between reprocessed and OEM devices for acute, lymphatic and chronic studies. The preclinical studies consisted of Institutional Animal Care and Use Committee (IACUC) approved protocols using a porcine model.[5] The anatomy and physiology of the porcine cardiovascular model provides a vessel sealing and healing response similar to that of humans. To eliminate bias, the surgeon, pathologist and clinical staff were blinded as to the device identification (Stryker vs. Ethicon) until after all scoring, measurements and gross evaluation were completed.

Acute animal study

The acute animal study utilized six (6) animals—composed of three (3) subject animals (evaluated with Stryker reprocessed HARH) and three (3) control animals (evaluated with Ethicon HARH). Each animal had one (1) HARH device utilized. The individual HARH devices each sealed between 20-24 vessels and completed 20 tissue dissections per animal. During this study, each animal underwent a ventral laparotomy. Vessels of different sizes and with various physiological functions were targeted (Table 1). Device performance was assessed through thermal damage measurement, seal integrity (hemostasis) at one (1) minute post-seal completion, tissue sticking to the device distal jaws and tissue dissection quality using the upper and lower (back-cutting) surfaces of the shears.

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Vessel type	Vessel identification
A/V bundle	Splenic mesentery, gastrosplenic, short gastric, right and left ovarian pedicle, bowel mesentery, uterine bundle
Artery	Splenic, right and left renal, large intestinal, right and left carotid
Vein	Splenic, right and left renal, large intestinal

Table 1. Targeted vessel type and identification.

Thermal spread maximum length and width were evaluated postoperatively by the study pathologist. Hematoxylin and eosin (H&E) were used for histological staining. Thermal spread maximum length and width were identified by the pathologist per predetermined criteria. Morphometric analysis was performed by the test facility's morphometrist. A photomicrograph of each vessel suitable for analysis was captured by a digital microscope camera attached to a microscope. Two types of measurements were made on each sealed vessel—the maximum length of thermal spread (depth, longitudinally along vessel) and the maximum width of thermal spread (lateral spread). Seal integrity (at one minute), tissue sticking and cut quality were rated on a four-tiered scale by the surgeon after performing each incision[†]. For each evaluation, the median and mode of the ratings for the Stryker HARH were compared to those of the Ethicon HARH. The raw data and analysis are contained in the report on file.[5]

Lymphatic animal study

The lymphatic animal study utilized one (1) porcine animal that underwent multiple lymphatic vessel seals with a Stryker reprocessed HARH device. Five (5) mesenteric lymph vessels and bundles and the thoracic duct were sealed using the subject device. The mesenteric lymph nodes were injected with methylene blue to stain the lymph fluid. The study surgeon evaluated each seal at one (1) minute and ten (10) minutes post-seal for seal integrity.

Chronic animal study

The chronic, 30-day survival study was designed to assess long-term seal quality and potential for injury to adjacent structures. Multiple vessel types and diameters were sealed using Stryker reprocessed HARH devices on each power level (MIN, MAX and AH). All three generator power levels were represented in each animal. The power level was assigned based on vessel diameter (1-7mm). Devices were used in accordance with instructions for use (IFU) (Table 2). One Stryker reprocessed HARH device was used on each of the six (6) subject animals. There was also one (1) control porcine animal where the Ethicon HARH was used. Each animal underwent a splenectomy, unilateral nephrectomy and bilateral oophorectomy. A gross evaluation was performed at 30±2 days to assess hemostasis of the sealed vessels and any collateral tissue changes.

Generator power level setting	MAX, Level 5 (Maximum power level)	MIN, Level 3 (Minimum power level)	Advanced Hemostasis (For large vessel sealing)
Instructions for use	Typically used for smaller vessels where cutting speed is fastest	Typically used in slightly larger vessels up to 5mm in size; has reduced cutting speed (in comparison to MAX)	Designed for larger vessels up to 7mm in size; cutting speed is further reduced (in comparison to MIN) and hemostasis is maximized.
Approximate vessel diameter	>0-2mm	2-5mm	5-7mm
Adaptive Tissue Technology (ATT) is utilized across all settings, which provides the generator with the ability to identify and monitor the instrument during use by modulating and adjusting power output during use (in addition to providing audible feedback to the user).			

Table 2. Generator power level assignment per vessel diameter.

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Benchtop studies

Ex vivo benchtop studies were also performed to compare vessel burst pressure, maximum jaw and shaft temperature, ATT functionality and reliability testing.

Burst pressure

Benchtop burst pressure testing evaluated the strength of transected 2-7mm diameter porcine carotid and iliac arteries using Stryker and Ethicon devices. During this testing, previously sealed vessels were infused with saline until they ruptured. Before the vessel burst, the maximum internal vessel pressure was determined using a customized fixture and pressure gauge. Thirty (30) vessels were tested for each of the three (3) power settings (MIN, MAX and AH).

Maximum jaw and shaft temperature

Maximum temperature of the jaw and shaft was measured utilizing a calibrated forward looking infrared (FLIR) camera to capture a video of the surgical device during activation and tissue transection. Videos were analyzed using a custom MATLAB software, which read temperature data and reported maximum temperatures attained in Regions of Interest (ROI) specified by the user. Thirty (30) porcine carotid arteries (2-7mm diameter) were tested for each of the three (3) power settings (MIN, MAX and AH) for Stryker and Ethicon devices.

ATT functionality

ATT)functionality test demonstrated the time difference between vessel transection and audible tone change (ATT tone). Thirty (30) porcine carotid arteries (2-7mm diameter) were tested for each of the three (3) power settings (MIN, MAX and AH) for Stryker and Ethicon devices.

Reliability testing

Reliability testing evaluated the preservation of Stryker reprocessed device functionality after 180 activation cycles. Thirty (30) porcine carotid arteries (2-7mm diameter) were tested for each of the three (3) power settings (MIN, MAX and AH) for Stryker and Ethicon devices as the first cycle baseline measurement. Twenty-two (22) porcine carotid arteries (2-7mm diameter) were tested for each of the three (3) power settings (MIN, MAX and AH) for Stryker devices after 180 activation cycles.

†The 4-tiered scale used for each evaluation is as follows:

Seal integrity: 1 = "Seal at tissue site, no leakage of blood (complete hemostasis)"; 2 = "Seal at tissue site, slight oozing of blood that stops within (≤) 1 min."; 3 = "Partial sealing of vessel, brisk bleeding present that requires intervention"; 4 = "Incomplete sealing with uncontrolled bleeding requiring intervention".

Tissue sticking: 1 = "No sticking, tissue falls off instrument when opened"; 2 = "Tissue sticking, minor adherence to one or both jaws"; 3 = "Tissue sticking requiring counter tension and extensive force to remove tissue"; 4 = "Tissue sticking such that tissue is damaged or torn during the removal process".

Shear and back cut quality: 1 = "Exceeds expectations in establishing dissection plane"; 2 = "Adequately establishes dissection plane"; 3 = "Requires excessive force/repeated attempts to establish dissection plane"; 4 = "Failure to establish dissection plane".

Results:

Acute animal study

Thermal spread: For vessels up to and including 7mm diameter (all generator power settings; all vessel sizes), mean thermal spread maximum length of the Stryker reprocessed device was statistically equivalent to the Ethicon device with 95% confidence (1.56mm $\bar{x}$, Stryker; 1.69mm $\bar{x}$, Ethicon). For vessels up to and including 7mm diameter (all generator power settings; all vessel sizes), mean thermal spread maximum width of Stryker reprocessed device was statistically better than the Ethicon device with 95% confidence (2.69mm $\bar{x}$, Stryker; 3.34mm $\bar{x}$, Ethicon). A P-value of 0.045 indicates a detectable statistical difference between the thermal spread maximum width in the two populations, with the thermal spread maximum width of the Stryker reprocessed device being statistically less than the Ethicon device. See Tables 3 and 4 for detailed results per vessel size range and generator power levels.

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Vessel size range	Generator power	Stryker HARH36			Ethicon HARH36			P-value
		Mean (mm)	SD (mm)	N	Mean (mm)	SD (mm)	N	
0-2mm	MAX	0.86	0.35	19	1.28	0.75	16	0.098
2-5mm	MIN	1.87	0.92	18	1.70	0.75	15	0.572
5-7mm	AH	1.97	0.66	19	2.01	0.79	19	0.942
0-7mm	All levels	1.56	0.84	56	1.69	0.81	50	0.382

Table 3. thermal spread maximum length results summary.

Vessel size range	Generator power	Stryker HARH36			Ethicon HARH36			P-value
		Mean (mm)	SD (mm)	N	Mean (mm)	SD (mm)	N	
0-2mm	MAX	1.59	0.78	19	1.95	1.28	16	0.341
2-5mm	MIN	2.69	1.06	18	3.11	1.80	15	0.435
5-7mm	AH	3.78	0.94	19	4.70	1.55	19	0.035
0-7mm	All levels	2.69	1.29	56	3.34	1.92	50	0.045

Table 4. Thermal spread maximum width results summary.

Figure 2 shows representative morphometric evaluation for the Stryker and Ethicon device seals.

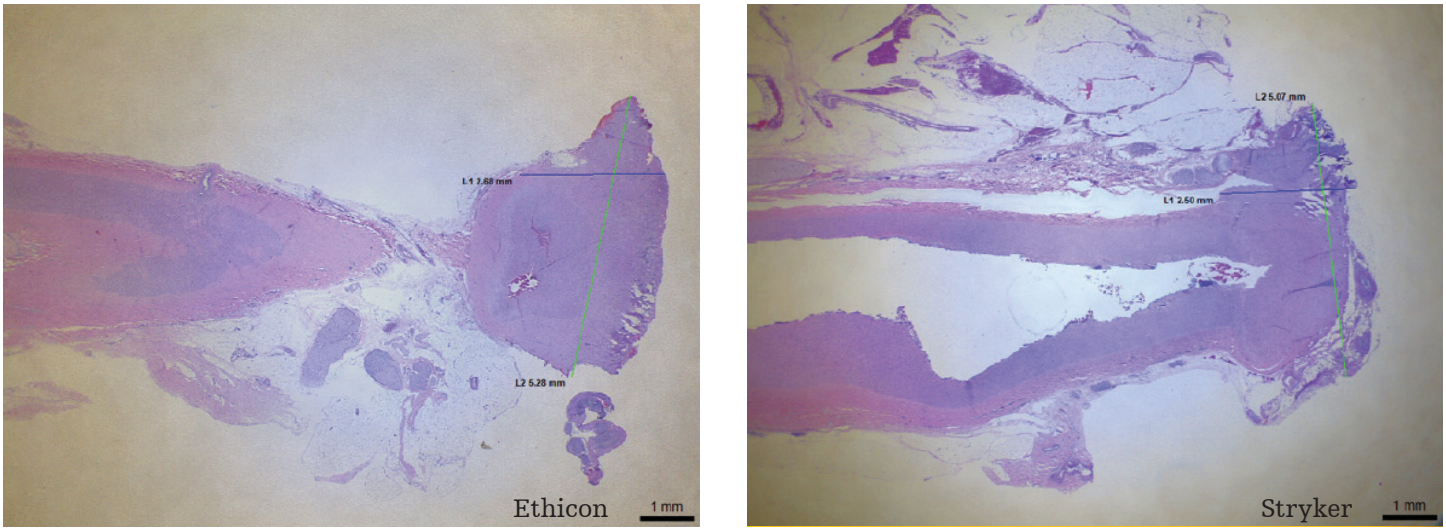

Figure 2. Representative histological images of 5mm renal arteries sealed with AH power level utilizing an Ethicon device (left) and a Stryker device (right).

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Seal integrity: Sixty-eight (68) samples from each group were evaluated by the surgeon for seal integrity. Seal integrity was recorded at one (1) minute. Overall median and mode seal integrity ratings for both Stryker reprocessed HARH and Ethicon HARH were one (1), indicating adequate seal at tissue site, with no leakage of blood (complete hemostasis). There was no detectable statistical difference between the groups for the time interval (Table 5). During microscopic examination (post-operatively by the pathologist), all acutely collected blood vessels (arteries, veins and AV bundles) from the test and control sites demonstrated similar histopathologic changes at the edge of the seal in the coagulation zone and appeared to have good microscopic seal integrity. In addition, there was no evidence of hemorrhage on the ends of the seals for either subject or control seal sites (Stryker or Ethicon).

Tissue sticking: Sixty-eight (68) Stryker reprocessed HARH and sixty-eight (68) Ethicon HARH were evaluated for tissue sticking. Overall median and mode tissue sticking ratings by the surgeon, for both groups, were one (1), indicating "no sticking, tissue falls off instrument when opened," according to the pre-established ranking scale.[†]

Dissection/Cut quality: Sixty (60) samples from each group were evaluated for dissection/cut quality. Thirty (30) samples were evaluated for shear dissection/cut quality and thirty (30) for back cut dissection/cut quality. Overall median and mode cut quality ratings for both Stryker reprocessed HARH and Ethicon HARH were two (2) for each dissection/cut method. This indicated that each shear cut and back cut "adequately established dissection plane," as evaluated by the surgeon according to the pre-established ranking scale.[†]

Criteria	Device type	Number of data points	Median rating	Mode rating
Seal integrity	Stryker	N=68	1	1
	Ethicon	N=68	1	1
Tissue sticking	Stryker	N=68	1	1
	Ethicon	N=68	1	1
Shear cut quality	Stryker	N=30	2	2
	Ethicon	N=30	2	2
Back cut quality	Stryker	N=30	2	2
	Ethicon	N=30	2	2

Table 5. Surgeon-rated results for seal integrity, tissue sticking, shear cut quality and back cut quality according to the pre-established ranking scale.[†]

Lymphatic animal study

For the thoracic duct and all mesenteric lymph vessels, the surgeon visually confirmed no leakage at 1 minute and 10 minutes post-transection for the Stryker reprocessed HARH device. Figure 3 shows an intricate mesenteric lymph vessel bundle (injected with methylene blue dye) that was effectively sealed with the Stryker reprocessed HARH device.

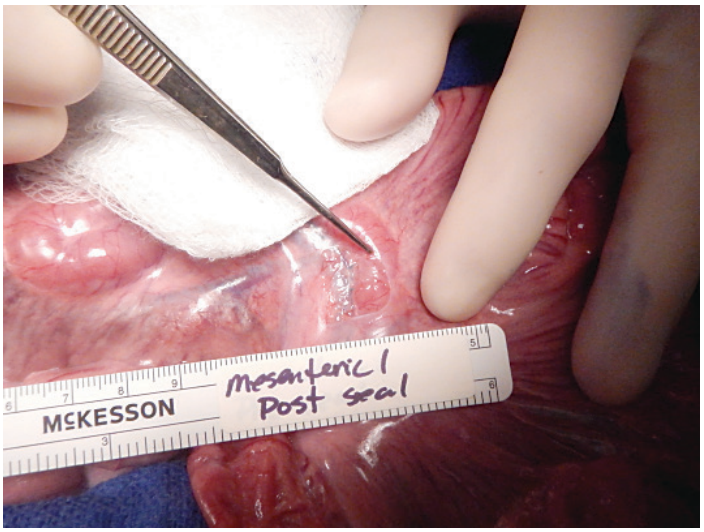

Figure 3. Mesenteric lymph vessel bundle sealed by a reprocessed Stryker HARH device.

Chronic animal study

For the six (6) subject animals totaling seventy-one (71) seal sites, there were no hemostatic complications attributed to the reprocessed device as noted by the pathologist at 30±2 day necropsy. A control animal with 14 seal sites was also evaluated. The pathological gross assessment of the subject animals demonstrated healed vascular seal sites with acceptable long-term seal quality and no indication of recent or active bleeding.

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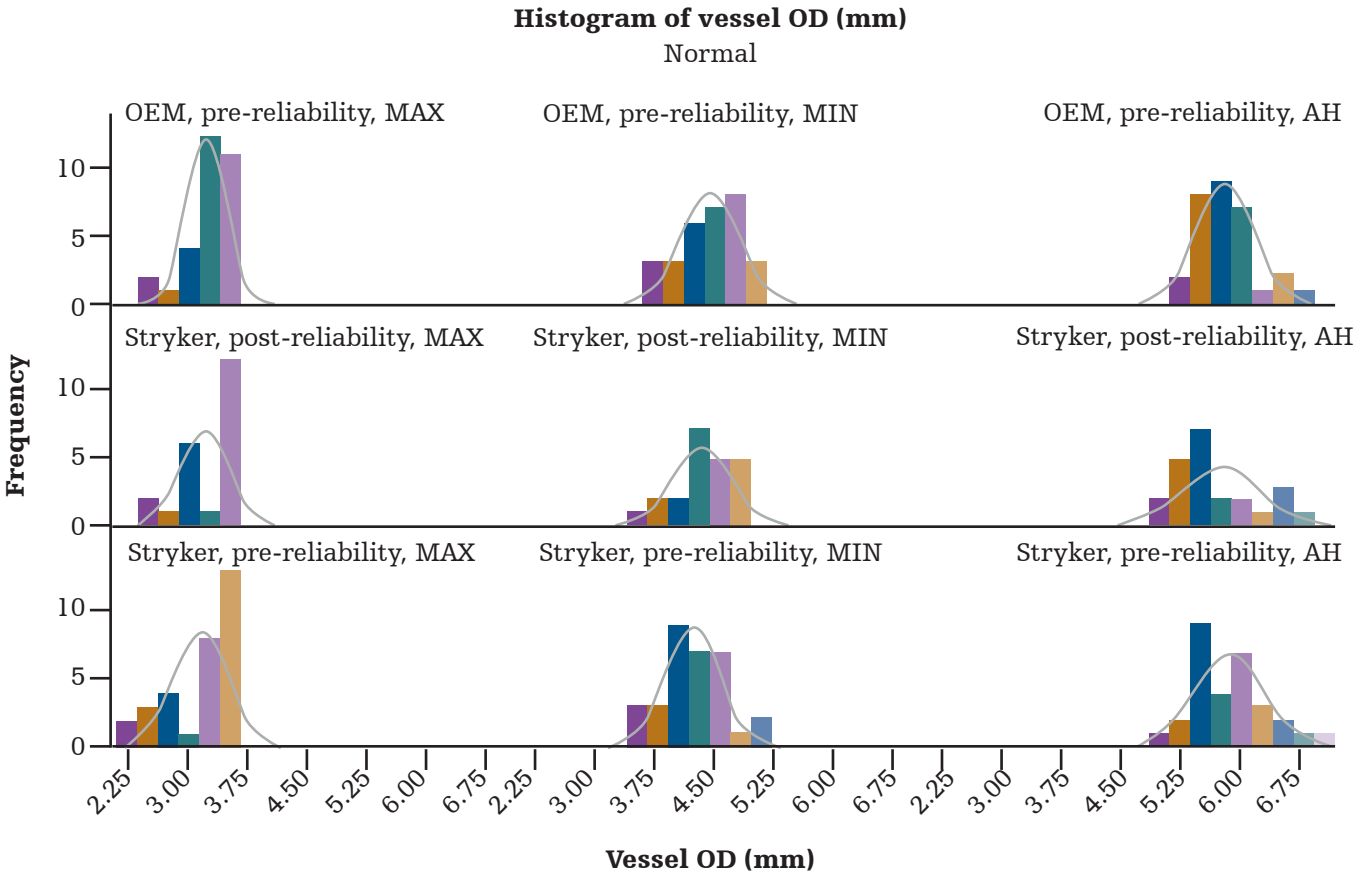

Figure 4. The porcine arteries utilized for burst pressure testing spanned the entire range of indicated vessel size and energy setting combinations.

In addition, there were no hemostatic complications or evidence of thermal injury to adjacent tissue attributed to use of the Stryker reprocessed HARH device. The chronic study provides further assurance that the Stryker reprocessed HARH device will provide acceptable long-term seal quality.

Benchtop studies

Burst pressure

The burst pressure strength of sealed porcine carotid and iliac arteries using Stryker reprocessed devices was statistically equivalent to the burst pressure strength of the Ethicon devices for all three (3) power settings (MIN, MAX and AH). The burst pressure for all subject seals exceeded the clinically important burst pressure threshold for hemostasis of 240 mmHg (4.64psi). Figure 4 (Pre-reliability charts) shows the carotid and iliac artery diameter distribution utilized for testing at each power level.

Maximum jaw and shaft temperature

The maximum jaw and shaft temperature of Stryker reprocessed HARH devices was statistically equivalent to the temperature of the Ethicon HARH jaw and shaft for all three (3) power settings (MIN, MAX and AH). Figure 5 shows a representative image of how the thermal profile was captured by the FLIR camera during porcine carotid artery transection.

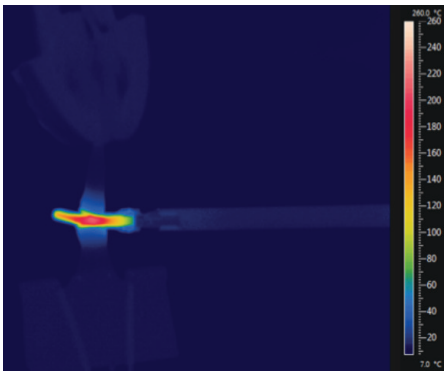

Figure 5. FLIR image of HARH jaw and shaft during porcine carotid artery transection.

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ATT functionality

The difference between the transection time and audible tone change (ATT tone) for vessel seals performed by Stryker reprocessed HARH devices was statistically equivalent to the time difference of the Ethicon devices for all three (3) power settings (MIN, MAX and AH).

Reliability testing

Reliability testing for burst pressure strength of sealed porcine carotid arteries after the 180th activation cycle was statistically equivalent to the first cycle for Stryker reprocessed HARH devices for all three (3) power settings (MIN, MAX and AH). The burst pressure for all subject seals exceeded the clinically important burst pressure threshold for hemostasis of 240 mmHg (4.64psi) after 180 cycles. Figure 4 (Post-Reliability charts) shows the carotid and artery diameter distribution utilized for burst pressure testing after the 180th cycle.

In addition, maximum jaw and shaft temperatures at the 180th activation cycle for Stryker reprocessed HARH devices were statistically equivalent to the first cycle for Ethicon devices for all three (3) power settings (MIN, MAX and AH).

Discussion:

Stryker's predecessor companies first began reprocessing ultrasonic sealing devices in 2005.[6] More recently, this technology has seen rapid advances from original manufacturers. In 2012, Ethicon introduced ATT.[6] ATT uses a proprietary set of algorithms to sense and respond to changes in tissue conditions.[7] This innovation has been credited with delivering increased seal strengths and faster cutting times at lower device peak temperatures.[7] This is important because ultrasonic device temperatures can rapidly increase when the blade of the device is activated on the tissue pad.[7] With ATT, the power level is reduced when transection is near completion, which aids in the "thermal management" of the blade.[7] Also worth mentioning is that, with ultrasonic devices, the temperature of the device is generally not the same as the temperature of the tissue. Essentially, even when device temperatures are significantly higher than normal due to, amongst other factors, tissue conditions, tissue sticking to the blade and excessive activation times, the flow of heat follows a thermal gradient as it moves from the device to the tissue.[7]

In 2013, Ethicon incorporated AH within their ATT.[6] AH leverages "predictive analytics within the ATT algorithms to modulate the delivery of energy to tissue."[7] AH receives multiple inputs from the generator that enables this feature to monitor tissue during 3 stages: preheating, vessel sealing and transection.[7] While commonly known that heat, compression and time are the primary factors in how thermal seals are formed, AH has enabled a more specific understanding of the interplay between those factors.[7] Studies by Ethicon have concluded that, "in general, longer sealing times correspond to higher burst pressures and more reliable sealing."[7] That being the case, heat over time and compression over time would now seem to be the two main components of thermal seal formation. These developments have contributed to Ethicon now being able to market the first 7mm vessel sealing indication on an ultrasonic device. While the 7mm indication is a potential breakthrough for ultrasonic technology, it is important to offer additional context. As pointed out by Ethicon, "surgeons rarely, if ever, seal 6-7mm vessels with any energy device."[7] The main benefit of AH, then, might be its ability to increase the confidence and safety margin of having a secure seal when it matters most.[7]

Stryker-sponsored acute, lymphatic and chronic GLP animal studies, as well as rigorous benchtop testing demonstrate that Stryker reprocessed HARH devices perform at least as effectively as Ethicon's HARH devices. The parameters measured included seal integrity, tissue sticking, tissue cut quality, thermal spread, burst pressure, maximum jaw and shaft temperature, ATT functionality, long-term seal quality and reliability testing. As mentioned above, certain factors drive parallel device performance between Stryker and Ethicon devices. One factor being the (GEN 11) generator, as opposed to the actual device, modulating the ATT and AH functionality. Another factor is the same reusable handpiece used on both Ethicon and Stryker devices. Electrical energy is converted to mechanical energy in the handpiece via piezoelectric crystal. Mechanical power from the handpiece is therefore restricted by the electrical

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current flowing from the generator. Relatedly, the power output to the activation buttons (MIN, MAX and AH) is also controlled by the generator. Other factors in device performance are the steps Stryker takes in reprocessing their harmonic scalpels. To reduce tissue sticking, Stryker re-coats the cutting blade with a non-stick coating. This update was first introduced in the previous generation (HAR) harmonic scalpel. To help minimize thermal spread, Stryker redesigned their own tissue pad, which they replace on each device.

Arguably the most important measure of performance is real world application. In a previously published study, it was reported that OEM vessel sealing devices "were found to be defective 4.9 times more frequently than" reprocessed devices.[3] This study was actually a retrospective review of defects as reported by a surgical team, during live procedures, over a seven month period.[3] Over 1,700 ultrasonic devices, both OEM and reprocessed, comprised the sample size.[3] Unlike many industry-funded studies, this analysis was conducted absent vendor participation or knowledge.[3] The author, a surgeon, puts forth several reasons for the results. For one, the "FDA allows for medical device testing to be performed by sampling as long as the manufacturer uses valid statistical techniques."[3] He also points out that the sampling can be derived from in vitro as opposed to in vivo testing. Reprocessing companies, by contrast, are required to function test each device, meaning more potentially defective devices are removed prior to commercial distribution. Stryker disassembles harmonic scalpels to their base components, which allows them to conduct a multi-point inspection on each of their components. Any substandard parts are rejected. Once reassembled, Stryker reprocessed devices are then subjected to simulated-use testing, which includes device activation on OEM generators. Stryker reprocessed devices, which all bear the Stryker label, then would have had each component pass every inspection step. Fully assembled devices have also been individually verified to perform as intended. Beyond in-line performance testing, another FDA 510(k) requirement unique to reprocessing companies is to submit validation studies on cleaning, sterilization, and functional performance. For medical device manufacturers like Stryker, this means testing the tolerances of OEM devices and demonstrating a reprocessed device will be just as safe and effective.

These additional requirements might help explain the favorable performance reported within the real world, "defect rate" analysis.

Conclusion:

As indicated by the 510(k) clearance, FDA has determined that Stryker's reprocessed HARH are substantially equivalent to devices manufactured by Ethicon.[4] Stryker's reprocessed HARH had statistically lower thermal spread width and statistically equivalent performance on all other measures. Preclinical animal studies and rigorous ex vivo benchtop testing provide convincing data to support the FDA's conclusion.

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