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

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Abstract: A necessary component of single-use device (SUD) reprocessing adoption, and program results, is clinical buy-in. In order to deliver the same level of clinical care to patients, reprocessed devices need to consistently perform as good or better than Original Equipment Manufacturer (OEM) devices. The purpose of this study is to compare the performance of Ethicon (EES) Harmonic Focus+ Shears with Adaptive Tissue Technology (HAR9F) to the HAR9F reprocessed by Stryker's Sustainability Solutions (SSS). In **1) bench top** (vessel burst pressure, maximum jaw and shaft temperature, transection time, and reliability), **2) acute animal** (seal integrity, tissue sticking, shear cut quality, back cut quality, lateral thermal spread, thermal spread width) and **3) chronic (30 day) animal studies** (long term seal quality, presence of hemostatic complications, thermal injury to adjacent tissues), no statistically significant differences were observed between new and reprocessed devices.

Introduction: Ethicon Endo Surgery's (EES, Cincinnati, OH) Harmonic Focus+ Shears with Adaptive Tissue Technology (HAR9F, K133314) are being touted as the "new standard for head and neck surgery" due to the device's precision, fine dissection capabilities and improved efficiency.[1-5] The HAR9F utilizes ultrasonic energy to cut and coagulate soft tissue and seal vessels up to 5mm in diameter. The key features of this device are a curved, tapered tip designed for precise grasping, cutting and sealing, and the addition of Ethicon's proprietary Adaptive Tissue Technology (ATT) platform previously introduced in other Harmonic Scalpel models. ATT uses a proprietary set of algorithms to sense and respond to changes in tissue conditions, and has been credited with delivering increased seal strengths and faster cutting times at lower device peak temperatures.[4]

Stryker's Sustainability Solutions (SSS, Tempe, AZ), a Division of Stryker Corporation, is the global leader in single-use device (SUD) reprocessing. SUD reprocessing is the practice of disassembling, cleaning, functional testing and sterilizing previously used medical devices for another use. In the U.S., SUD reprocessing is regulated by the FDA. Third party SUD reprocessing companies like SSS must objectively prove to the FDA that their devices are, consistently, at least as safe and effective as predicate devices prior to being legally marketed. For class II SUDs—such as HAR9F—this means obtaining a 510(k) clearance from the FDA.[6] The main benefit to healthcare providers is a significant cost savings by reusing devices that would have otherwise been discarded as medical waste.

In April 2017, SSS received FDA 510(k) clearance to reprocessed HAR9F (K170456) with Adaptive Tissue Technology (ATT).[7] This paper will assess the relative performance of the reprocessed SSS HAR9F to the new Ethicon HAR9F in ex vivo bench top, acute and chronic animal studies.

Results: Ex vivo benchtop studies revealed statistically equivalent performance in comparing vessel burst pressure, maximum jaw and shaft temperature, transection time and reliability testing after 225 activation cycles. An acute animal study found Stryker devices to be statistically equivalent to Ethicon devices, regardless of power level (MIN/MAX) and vessel size, across multiple metrics including seal integrity, tissue sticking, shear cut quality and back cut quality. Additionally, both mean maximum thermal spread length (1.409mm - SSS; 1.452mm - EES) as well as mean maximum thermal spread width (2.657mm – SSS; 2.794mm – EES) of the SSS devices were statistically equivalent to EES devices. 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 29 days. Additionally, there was no evidence of thermal injury to the adjacent tissues attributed to the use of either SSS or EES devices.

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Ex vivo benchtop testing

Vessel burst pressure

Vessel burst pressure test assessed seal strength under fluid pressure. To simulate in vivo application, vessels were heated to 37˚C prior to sealing. A total of one hundred (100) vessels were sealed and perfused with saline at a constant rate of 2.5ml/min until leakage occurred. The maximum pressure prior to breach was recorded for each vessel sealed. Median burst pressures for EES (690 mmHg MAX / 643 mmHg MIN) and SSS (1090 mmHg MAX / 694 mmHg MIN) were statistically equivalent. Of importance to note is that burst pressure for all seals for both SSS and EES devices exceeded the industry accepted supraphysiological burst pressure threshold of 240 mmHg.[8, 9]

Maximum jaw and shaft temperature

Maximum temperatures were recorded utilizing a FLIR A655sc IR camera (FLIR Systems, Boston, MA). Image sequences of the surgical device during activation and tissue transection were then analyzed using a custom MATLAB script. Amongst the one hundred one (101) porcine vessel samples, mean shaft temperatures were measured at 32˚C and 33˚C respectively for SSS and EES devices, mean jaw temperatures were recorded at 254ºC and 281ºC.

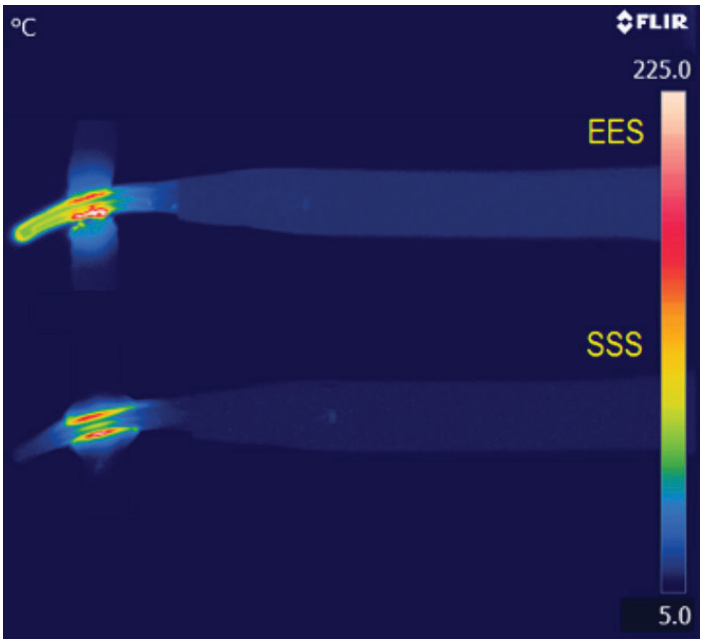

Image from time matched cut/seal sequences on <5mm vessel during benchtop testing utilizing FLIR A655sc IR camera and MARLAB script.

Transection time

Transection of a <5mm vessel clamped into a fixture with a 10g weight was recorded using video (Logitech C920 Webcam, Logitech USA, Newark, CA). Testing was performed using both MIN and MAX settings on a total of sixty (60) porcine vessel samples. Transection time was statistically equivalent between EES and SSS devices regardless of MIN or MAX setting. Median transection time with MAX power setting was 7 sec for both the EES and the SSS device. For the MIN setting, median transection time was 31 sec for the EES device and 34 sec for the SSS device.

Reliability testing

A total of twenty nine (29) SSS HAR9F devices were tested for 225 activation cycles on porcine vessels to determine whether device functionality declines as activation cycles increase. Vessel burst pressure as well as tissue pad and scalpel integrity were assessed after 225th activation cycle. Seal strength of carotid arteries measured after the 225th activation cycle (Median value of 833 mmHg) were statistically equivalent to burst pressures recorded after one (1) activation cycle demonstrating the device can reliably seal after 225 activation cycles. Additionally, a build integrity assessment of each device after the 225 activation cycles showed that both the scalpel rod and tissue pad remained intact.

Acute animal study

Study design

To assess clinical performance of the SSS HAR9F, seal integrity, hemostasis, tissue sticking, shear cut quality and back cut quality were evaluated in an acute animal study. The studies were performed using Institutional Animal Care and Use Committee (IACUC) approved protocol on porcine models. A surgeon performed ventral laparotomy and sealing on vein, artery and

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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. Vessels targeted for preclinical testing

	Mean thermal spread (width)	Mean thermal spread (length)	Seal integrity (1-4)†	Tissue sticking (1-4)†	Cut quality – Shears (1-4)†	Cut quality – Back-cut (1-4)†
SSS	(2.657mm, N = 82)	(1.409mm, N = 82)	1, N = 108	1, N = 108	2, N = 38	2, N = 34
EES	(2.794mm, N = 56)	(1.452mm, N = 56)	1, N = 60	1, N = 60	2, N = 34	2, N = 30

Table 2: acute animal study results and ratings

†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".

artery-vein bundles in four (4) test animals and two (2) control animals. One (1) EES and one (1) SSS device was used per animal. Each device sealed between 25-30 vessels and completed 20-22 dissections. Vessels of different sizes and with various physiological features were specifically targeted for the study (Table 1). Seal integrity (at one minute), tissue sticking and cut quality were rated on a four-point scale by the surgeon after performing each incision†. To eliminate bias, the surgeon, pathologist and clinical staff were blinded to manufacturer's device until after all scoring, measurements, and gross evaluations were completed.

Vessels sealed during the procedure were excised. The study pathologists analyzed samples to assess thermal damage and histomorphometry was performed to measure thermal spread. Two (2) types of measurements were made on each sealed vessel—maximum length of thermal spread (depth, measured longitudinally along vessel) and the maximum width of thermal spread (lateral spread).

Study results

Histopathology: both the EES and SSS devices performed safely without imparting damage to adjacent tissue structures. There was no gross or microscopic evidence of active hemorrhage at the sealed sites, demonstrating consistent vascular sealing with both samples of devices. Importantly, there was also no notable collateral thermal damage during necropsy. Results of additional animal study parameters appear below in Table 2. There was no statistical difference between the EES and SSS devices on any of the attributes in Table 2.

Chronic animal study

A 30 day survival study assessed long-term seal quality and potential for injury to adjacent tissue structures. In this porcine study, a laparotomy was performed prior to undergoing splenectomy, unilateral nephrectomy and ovariohysterectomy. The study group was comprised of six (6) SSS devices used on six (6) animals. One (1) EES HAR9F was used on one (1) animal in the control

Generator power level setting	MAX, Level 5 (Maximum power level)	MIN, Level 3 (Minimum power level)
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)
Approximate vessel diameter	0-2mm	2-5mm
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 3: Instructions for Use for HAR9F

group. All devices were used in accordance with the instructions for use (IFU, table 3), and all animals survived the duration of the study.

A gross necropsy was performed at 29 days to assess hemostasis of sealed vessels and any collateral tissue changes. In the SSS study group, a total of seventy-six (76) vessels were sealed. No complications related to the surgical procedure were noted. An absence of anemia in addition to the normal clinical findings suggest that seal integrity remained sufficient throughout the in-life phase of the study. A gross necropsy of both study groups revealed no evidence of hemostatic complications or thermal injury to adjacent tissue structures from either reprocessed Stryker or Ethicon devices.

Discussion

Acute and chronic animal studies, as well as rigorous benchtop testing demonstrate that Stryker reprocessed HAR9F devices perform at least as effectively as Ethicon's HAR9F devices. Certain factors drive parallel device performance between Stryker and Ethicon devices. One factor is that the generator (GEN 11), as opposed to the actual device, modulates the power output and energy delivered to the device during use. A key component in delivering consistent performance is the actual reprocessing and testing sequence for the Stryker devices. For effective cleaning and to facilitate multi-point inspections on each component, the Stryker devices are disassembled to their base components. Each component must pass a rigorous set of dimensional, strength and aesthetic criteria if it is to be used in a final product. Some components, like the tissue pad and torque wrench, are replaced on every device. Reassembled devices then undergo rigorous, simulated-use testing, including mechanical performance evaluations and device activation on an Ethicon generator (GEN 11). Only devices that pass all criteria are commercially released for reuse, which serves to control for performance variability amongst the Stryker devices.

Conclusion

As indicated by the 510(k) clearance, FDA has determined that Stryker's reprocessed HARMONIC Focus Shears+ Adaptive Tissue Technology are substantially equivalent to devices manufactured by Ethicon.[7] The ex vivo benchtop, acute and chronic animal studies presented in this paper validate that the functional and pre-clinical performance of reprocessed Stryker HAR9F devices is statistically equivalent to Ethicon manufactured HAR9F devices.

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