Stryker Sustainability Solutions' Reprocessed Harmonic ACE® Shears without Adaptive Tissue Technology versus Brand New Harmonic ACE® Curved Shears and Harmonic ACE® Shears + Adaptive Tissue Technology, a Performance Comparison

STUDY SUMMARY

Stryker Sustainability Solutions' (SSS) Reprocessed HARMONIC ACE® Shears without Adaptive Tissue Technology (ATT) (SSS HAR36) were compared to original manufacturer (OM) HARMONIC ACE® Shears + Adaptive Tissue Technology (OM HAR36) and OM HARMONIC ACE® Curved Shears (OM ACE36E) and found to perform as well as brand new devices for hemostasis and tissue sticking. Thermal spread and transection time were also found to be similar between OM and reprocessed devices.

Two independent testing groups were used in this study. For Group 1 (SSS HAR36 vs. OM ACE36E), the average transection times were 5.05 seconds for reprocessed and 4.89 seconds for OM. The average thermal spread for Group 1 was 0.66mm for reprocessed and 0.78mm for OM. For Group 2 (SSS HAR36 vs. OM HAR36), the average transection times were 5.79 seconds for reprocessed and 6.21 seconds for OM. The average thermal spread for Group 2 was 0.68mm for reprocessed and 0.67mm for OM.

BACKGROUND

In 2006, before the US House of Representatives Committee on Government Reform, the US Food and Drug Administration (FDA) concluded that reprocessed single-use devices (SUDs) that meet FDA's regulatory requirements are as safe and effective as a new device. This "substantial equivalence" is demonstrated through Premarket Notification, or 510(k) clearance, in accordance with the Code of Federal Regulations (21CFR Part 807).[1] In addition, the United States Government Accountability Office (GAO) stated in its 2008 report, that the available information regarding safety, while not providing a rigorous safety comparison between reprocessed SUDs and other devices, does not indicate that reprocessed SUDs currently in use pose an increased threat to patient safety. Stryker has a long-standing history of providing quality reprocessed surgical devices. Stryker's reprocessing programs help reduce costs while reducing environmental impact in order to support advancements in responsible healthcare. Over two decades of reprocessing experience allows Stryker to deliver clean, safe, functional, and sterile surgical devices. Stryker incorporates both internal and third-party validation of all cleaning systems and employs a rigorous validation paradigm for reprocessing even the most contaminated of devices.

STERILIZATION/FUNCTIONALITY

In addition to exhaustive pre-sterilization cleaning methods, Stryker Sustainability Solutions sterilizes devices with Ethylene Oxide (EO) which is validated to a sterility assurance level (SAL) of 10^{-6} microorganisms. In this process, the EO gas causes alkylation of nucleic acids in the microorganisms, killing the organisms and rendering the devices sterile.

All validations of sterilization processes are performed using spores of Bacillus atrophaeus, the most EO-resistant organism currently known to the scientific and medical community. This process is governed by the AAMI/ANSI/ISO 11135 standard[2], which is largely recognized as the "gold standard" of sterilization for its use of redundant overkill approaches to sterilization. In this validation scheme, Process Challenge Devices (PCDs) containing at least $1x10^6$ spores of Bacillus atrophaeus undergo varying durations of EO exposure to determine at what point the PCDs are sterile, which is termed the "half cycle." The 11135 standard[2] then requires a second half cycle of EO sterilization which provides a double margin of safety.

In addition to cleaning and sterilization, surgical devices also undergo two types of performance testing: structural and mechanical. Structural tests assess the overall soundness of devices, ensuring that devices will be delivered in working condition. Mechanical tests assess the functional capabilities of devices related to clinical use, ensuring that devices perform as well as an original manufactured device.

To further demonstrate the effectiveness of the Reprocessed Harmonic ACE® Shears without ATT (SSS HAR36), which has received FDA 510(k) clearance of substantial equivalency[3], a preclinical study was undertaken to directly compare reprocessed to brand new Harmonic Shears. The null hypothesis was defined as no difference in performance between reprocessed and OM devices.

METHODS

This preclinical study consisted of Institutional Animal Care and Use Committee (IACUC) approved procedures using a porcine model.[4] The anatomy and physiology of the porcine model provided a tissue response to electrosurgical instrumentation similar to that of human tissues. A total of twelve porcine test systems were used in this study.

The study design consisted of two groups, each comparing six reprocessed and six OM devices:

> **Group 1:** Reprocessed Harmonic ACE® Shears without ATT (SSS HAR36) to Harmonic ACE® Curved Shears with Ergonomic Handle (OM ACE36E)
>
> **Group 2:** Reprocessed Harmonic ACE® Shears without ATT (SSS HAR36) to Harmonic ACE® Shears + ATT (OM HAR36)

These two groups were used to compare the performance of reprocessed devices to OM devices with and without ATT. Both a reprocessed and an OM device were tested on each animal, thus allowing each porcine test subject to serve as its own control.

This study tested device performance on bowel tissue, liver tissue, mesenteric vessels (1-2mm diameter), and femoral vessels (3-5mm diameter). Incisions were made in each tissue type at minimum and maximum generator power levels of 3 and 5, respectively. Femoral arteries were incised once at the minimum generator power level. Device performance was assessed through tissue transection time, thermal spread measurement, tissue sticking to the end effector, and hemostasis at normal and hypertensive blood pressures (systolic pressure ≥ 200mmHg).

Transection time was measured during the procedure with a calibrated stopwatch from the initial triggering of the device to complete tissue transection. Thermal spread was measured postoperatively as the greatest distance between morphologically damaged and normal tissue, and Masson's Trichrome was used for histological staining. Tissue sticking was rated by the surgeon after performing each incision and was also evaluated after the procedure by an engineering review of the amount and location of tissue stuck to the end effector. Both normotensive and hypertensive hemostasis evaluations consisted of observations of each incision over a ten-minute period.

Tissue transection time and thermal spread data were analyzed using two sample t-tests assuming unequal variances. Both tissue sticking and hemostasis were rated on a three-tiered scale.† For statistical purposes, ratings of 2 or 3 were treated as positive, and a rating of 1 was treated as negative. The resulting binomial data were analyzed using Fisher's Exact Test. A p-value of ≤ 0.05 was considered statistically significant, which would indicate a difference in performance between the test groups. The raw data and detailed statistical analysis are contained in the report on file.[5]

†The 3-tiered scale used for both tissue sticking and hemostasis respectively is as follows:

1 = "No tissue sticking"/"No bleeding"; 2 = "Slight tissue sticking"/"Slight bleeding"; 3 = "Large amount of tissue sticking"/"Active bleeding".

RESULTS

All procedures were completed without complications. The tissue characteristics were controlled by testing the two devices on the same animal for each procedure. Vessel diameters showed no significant variation between test groups and ranged 1-2mm in diameter for mesenteric arteries and 3-5mm in diameter for femoral arteries.

Histology: The images in Figure 1 represent the manner in which the histological slides were measured for the length of thermal tissue spread.[6,7] These images were taken from liver tissue specimens (Figure 1).

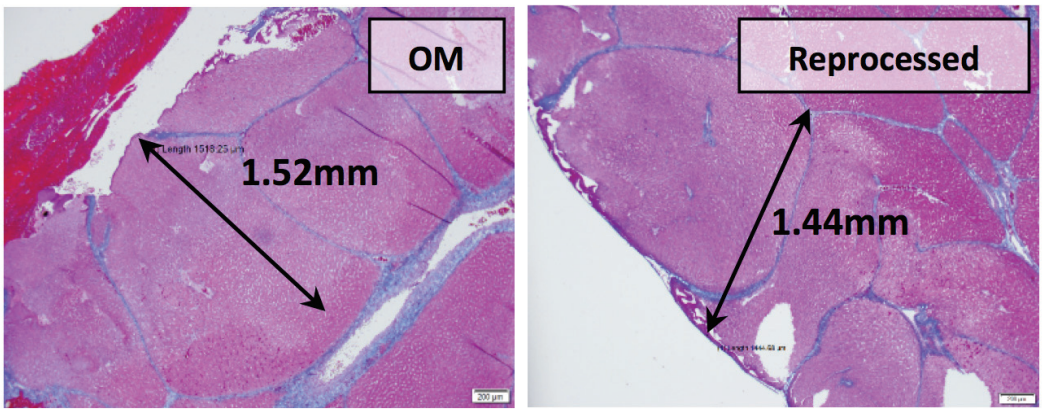

Figure 1: Representative Histological Images

Transection Time: For all groups, transection times ranged from 1.08 to 17.89 with a mean of 5.39 and a standard deviation of 2.69 seconds. In two comparisons, statistical differences were seen between transection time at minimum energy: Group 1 femoral vessels and Group 2 mesenteric vessels. In the first case, the OM ACE36E averaged 4.8 seconds as compared to 6.6 seconds for the SSS HAR36. In the second case, the SSS HAR36 averaged 4.8 seconds, and the OM HAR36 with ATT averaged 6.8 seconds (Table 1). Transection times for the other twelve comparison groups did not show a statistical difference.

Thermal Spread: The overall average thermal spreads were 0.53mm for bowel tissue, 1.59mm for liver tissue, 0.09mm for mesenteric, and 0.24mm for femoral vessels (Table 2, Figure 3). At minimum energy for Group 1, a significant difference was seen between mesenteric vessel incisions with thermal spread of 0.03mm and 0.07mm for SSS HAR36 and OM ACE36E, respectively (Table 2). For the remaining thirteen groups, comparisons of average thermal spread were not statistically different.

Tissue Sticking: There was no tissue sticking observed for bowel, liver, or femoral tissues. Tissue sticking was only noted with the OM HAR36 devices during mesenteric vessel transection, which was not shown to be significantly different from the reprocessed devices. Additional engineering evaluation which reviewed tissue sticking for all Harmonic Scalpel end effectors showed that most devices had little to no residual stuck tissue post procedure.[5]

Hemostasis: There were fewer instances of bleeding noted during physiologic blood pressure testing than elevated blood pressure testing. Reprocessed devices maintained hemostasis equivalently or better than OM devices during this study. In the Group 1 maximum energy bowel incisions comparison, OM ACE36E had a 16.67% bleeding rate while SSS HAR36 had a 0% bleeding rate with a p-value of 0.03. All other hemostasis comparisons demonstrated no significant difference between reprocessed and OM devices.[5]

Transection Time (sec)										
	Group 1					Group 2				
Tissue Type	Reprocessed (SSS HAR36)		OM (ACE36E)		*p-value*	Reprocessed (SSS HAR36)		OM (HAR36)		*p-value*
	Mean	SD	Mean	SD		Mean	SD	Mean	SD	
Bowel (min)	7.02	1.62	7.77	2.07	*0.54*	8.94	3.61	8.83	0.62	*0.95*
Bowel (max)	5.10	2.17	5.06	1.10	*0.97*	4.64	1.60	5.02	0.76	*0.64*
Liver (min)	7.27	2.34	6.25	2.13	*0.48*	6.91	2.68	7.26	1.35	*0.80*
Liver (max)	3.87	1.05	4.34	1.13	*0.51*	5.01	1.67	4.28	1.07	*0.43*
Mesenteric vessel (min)	3.45	0.52	3.52	1.04	*0.90*	4.80	1.13	6.84	0.76	*0.01*
Mesenteric vessel (max)	2.06	0.38	2.48	0.81	*0.33*	2.84	0.64	3.49	0.84	*0.20*
Femoral vessel (min)	6.60	1.02	4.79	0.89	*0.01*	7.38	0.94	7.74	3.32	*0.82*

min = minimum energy setting max = maximum energy setting

Table 1: Transection Time Results Summary

Thermal Spread (mm)										
	Group 1					Group 2				
Tissue Type	Reprocessed (SSS HAR36)		OM (ACE36E)		*p-value*	Reprocessed (SSS HAR36)		OM (HAR36)		*p-value*
	Mean	SD	Mean	SD		Mean	SD	Mean	SD	
Bowel (min)	0.42	0.20	0.47	0.20	*0.71*	0.65	0.14	0.56	0.14	*0.33*
Bowel (max)	0.46	0.18	0.54	0.14	*0.48*	0.56	0.12	0.55	0.09	*0.89*
Liver (min)	1.66	0.19	1.72	0.20	*0.63*	1.61	0.14	1.53	0.14	*0.38*
Liver (max)	1.55	0.15	1.75	0.15	*0.06*	1.46	0.12	1.45	0.10	*0.82*
Mesenteric vessel (min)	0.03	0.03	0.07	0.02	*0.04*	0.17	0.14	0.11	0.10	*0.48*
Mesenteric vessel (max)	0.05	0.03	0.05	0.04	*0.91*	0.10	0.10	0.10	0.05	*0.97*
Femoral vessel (min)	0.16	0.16	0.21	0.06	*0.49*	0.19	0.13	0.41	0.27	*0.13*

min = minimum energy setting max = maximum energy setting

Table 2: Thermal Spread Results Summary

DISCUSSION

Reprocessed Harmonic ACE® Shears without ATT (SSS HAR36) were compared to brand new models with and without ATT (OM HAR36/OM ACE36E). The reprocessed devices tested underwent an extensive device cleaning, sterilization, and functionality testing process managed by Stryker Sustainability Solutions. In this preclinical study, devices that underwent the cleaning and sterilization process[8] with performance testing performed similarly to OM Harmonic shears either with or without ATT.

In contrast to a previous paper, DSL 12-14209, which compared OM ACE® and ACE+® Harmonic Shears (OM ACE36E vs. OM HAR36), Reprocessed Harmonic ACE® Shears without ATT (SSS HAR36) transected tissue and blood vessels at similar rates as Harmonic ACE® Shears + ATT (OM HAR36) during this study. Additionally, all thermal spread comparisons between Reprocessed Harmonic ACE® Shears without ATT (SSS HAR36) and Harmonic ACE® Shears + ATT (OM HAR36) were not statistically different (Table 2, Group 2).

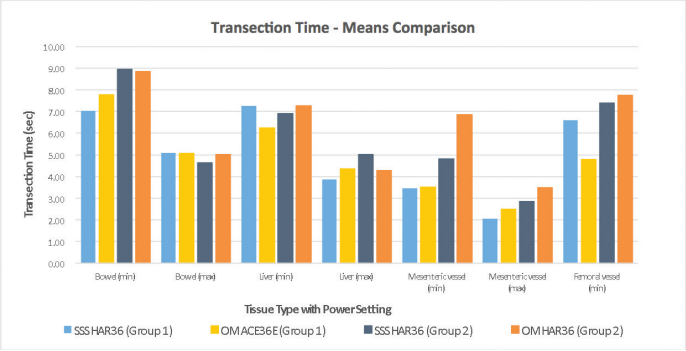

Figure 2: Transection Times—Comparison of Mean Values

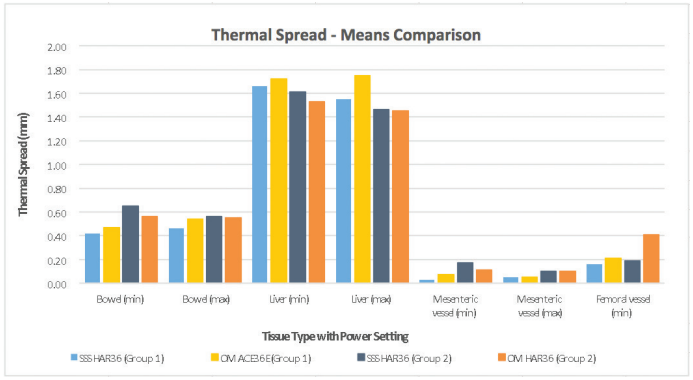

Figure 3: Thermal Spread—Comparison of Mean Values

CONCLUSION

Data from this study support similar performance of reprocessed and OM Harmonic Scalpels (Tables 1 & 2, Figures 2 & 3). After undergoing Stryker's reprocessing system, the reprocessed ACE® Harmonic Shears without ATT (SSS HAR36) were found to have few significant performance differences when compared to both OM Harmonic Shears with and without Adaptive Tissue Technology (HAR36/ACE36E). Of the four statistically significant findings, three demonstrated favorable differences in averages of the SSS reprocessed to the OM.

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