Research Article ISSN 2639-944X

Journal of Medical - Clinical Research & Reviews

Efficacy and Usability of an Ultrasonic Sealing Device in the Pediatric and Adult Population: A Prospective Evaluation

Liberman M[1], Markel T[2], Morgenthal C[3], Leung S[4], Nakeeb A[5], Shakir F[6], Yasafuku K[7], Curtis N[8], Sundaram CP[9], Canavan K[10], Veldhuis P[10]* and Atiyani O[10]

[1]*Centre Hospitalier de l'Universite de Montreal, Montreal, Canada.*

[2]*Riley Hospital for Children at Indiana University Health, Indianapolis, IN, USA.*

[3]*Baptist Health Research Institute, Jacksonville, FL USA.*

[4]*Western General Hospital, Edinburgh, UK.*

[5]*IU Health University Hospital, Indianapolis, IN, USA.*

[6]*Royal Free Hospital, London, UK.*

[7]*Toronto General Hospital, Toronto, Canada.*

[8]*Dorset County Hospital, Dorchester, UK.*

[9]*Indiana University Hospital, Indianapolis, IN, USA.*

[10]*Ethicon, Inc., Cincinnati, OH, USA.*

***Correspondence:**
Paula Veldhuis, Ethicon, Inc., 4545 Creek Rd., Cincinnati, OH, USA.

Received: 17 Oct 2024; **Accepted:** 28 Nov 2024; **Published:** 07 Dec 2024

Citation: Liberman M, Markel T, Morgenthal C, et al. Efficacy and Usability of an Ultrasonic Sealing Device in the Pediatric and Adult Population: A Prospective Evaluation. J Med - Clin Res & Rev. 2024; 8(12): 1-9.

ABSTRACT

Background: *As surgical procedures become more complex, ultrasonic energy devices, and specifically Harmonic technology, have become indispensable tools in providing precise sealing and transection of vessels demonstrating clinical utility and positive outcomes including reducing lateral thermal spread, intra-operative blood loss, and length of hospital stays. We present results from a real-world study evaluating the safety and usability of the Harmonic1100 Shears (H1100) and the accompanying Generator 11 (Gen11) across specialties in both adult and pediatric patients.*

Methods: *A prospective, multi-center observational trial was undertaken. Both pediatric (general) and adult subjects (general, gynecologic, urologic, thoracic) who presented for surgery where the device was slated to be used were included and clinical outcomes documented. The primary endpoint was the attainment of hemostasis for each vessel transected. Secondary endpoints to assess usability was measured by querying surgeons regarding specific tasks performed. Device-related adverse events (AEs) were recorded to evaluated safety.*

Results: *A total of 265 subjects comprised the final data set (40 pediatric general, 93 adult general, 32 adult gynecologic, 30 urologic, 61 thoracic). A total of 489 vessel transections occurred during the course of the study of which 99.0% of the vessel transections achieved hemostasis. Four subjects required an intra-operative transfusion (2 adult general, 2 gynecologic). Ninety-six (96) subjects had at least one vessel transected with a diameter greater than 5 mm (>5-7 mm) with 174 vessels transected. Hemostasis was achieved for 98.9% of >5 to 7 mm vessels transected (172/174). Five Grade 4 vessels transections occurred and all required additional measures to achieve hemostasis. Of the 104 cases in which the H1100 was used for sealing and transection of lymphatic vessels, surgeon satisfaction with the device, was high (97.1%). All surgeons indicated that the H1100 performed as well or better than their previous ultrasonic device of choice. Similarly, related queries were made regarding the Gen11's use with surgeons reporting that the GEN11 touchscreen was easy-to-use (98.5%) and that it performed as intended (96.6%). Of the 183 AEs reported, 7 were deemed "possibly related" to the study device and included one subject with atrial fibrillation and pericardial effusion, and the others pleural effusion, anastomotic complications, and a gastrointestinal anastomotic leak.*

Conclusion: *The data from this real-world post-market study affirms the safety and efficacy of the H1100 across specialties, supporting its continued use in clinical practice.*

Keywords
Harmonic technology, Ultrasonic energy devices, Tissue sealing and transection, Post-Market data, Surgical specialties.

Introduction and Background
With the advent of more complex surgical interventions, ultrasonic energy devices have become indispensable tools in providing precise sealing and transection of vessels. These devices function by converting electrical energy into mechanical vibrations causing frictional heat allowing for cellular disintegration and coagulation [1-3]. This mechanism allows for precise sealing and cutting with minimal lateral thermal spread there by reducing risk of collateral damage to adjacent structures [4]. Studies have demonstrated favorable clinical outcomes when utilizing ultrasonic devices. For example, a systematic review performed by Sarda et al. reported that the use of ultrasonic devices in thyroid surgery significantly reduced intraoperative blood loss, operative time and post-operative length of hospital stay when compared to conventional techniques [5]. In laparoscopic adrenalectomy, ultrasonic devices are associated with reduced operative time and intraoperative blood loss when compared to other energy devices [6]. Similarly, a randomized trial found that patients undergoing thyroidectomy with ultrasonic shears experienced less blood loss and had shorter hospital stays [7].

Since its introduction in 1988 by UltraCision (Providence, Rhode Island; now part of Ethicon Endo-Surgery, Inc., Cincinnati, Ohio), Harmonic technology has undergone continuous refinement to address various surgical challenges [8]. Contemporary devices like the Harmonic Shears (Ethicon, Inc.), which simultaneously seals and transects vessels of up to a diameter of 7 mm have facilitated dissection and apposition in both open and laparoscopic surgery in complicated procedures which require precise dissection and hemostasis [9]. Precise energy delivery is facilitated by the utilization of adaptive tissue technology with real-time feedback mechanisms which automatically adjusts for tissue thickness and tension. This ensures a lower maximum blade temperature and minimizes tissue impact resulting in the reduction of unintended thermal injury of critical structures [8,10,11]. The effectiveness of Harmonic devices have been demonstrated in a wide range of procedures including nephrectomy, laparoscopic hysterectomy, pancreatectomy, esophagectomy, thoracoscopic lobectomy and segmentectomy [12-15]. More recently the Harmonic 1100 Shears (H1100), were introduced in clinical practice. The newer device utilizes an updated adaptive tissue technology algorithm which actively monitors the device during use and enables its Generator 11 (Gen11) to modulate and adjust its power output while giving audible feedback to the user which enables active control of blade temperature. This updated device includes a longer jaw length and aperture with a tapered curved tip to allow for more precise tissue dissection. Our study was designed to evaluate the safety and usability of the H1100 in real-world, post-market use across a wide range of surgical specialties in both pediatric and adult populations.

Methods
Study Design
This prospective, single-arm, multi-center, observational trial was performed of the Harmonic H1100 Shears (H1100) at nine sites in the United States, Canada and the United Kingdom in this post-market setting clinical follow-up study (PMCF) (ClinicalTrials.gov identification #NCT05039021). Individual sites obtained approval of both protocol and consent by local Institutional Review Boards or Ethics Committees. The study was conducted in accordance with the Declaration of Helsinki and in compliance with Good Clinical Practice and any other applicable local regulatory requirements. Each procedure was performed utilizing the standard operating procedure of each institution and using the device as per Instructions for Use. Screening occurred up to 8 weeks prior to surgery and subjects were followed through surgery until clinic follow-up (approximately 28 days post-operatively).

Subject Selection
Subjects recruited included both pediatric (general) and adult subjects (general, gynecologic, urologic, thoracic) who presented for surgery where the instrument was to be used to transect at least one vessel. All study subjects provided signed informed consent prior to enrollment. Pediatric inclusion was: <18 years of age, candidate for non-emergent general surgical procedure where at least one vessel was to be transected with the H1100, and parent/legal guardian's written consent, and/or subject assent, where applicable. Adult inclusion was: ≥18 years of age, candidate for elective surgical procedures where at least one vessel was to be transected by the H1100, and willing and able to provide written consent. Preoperative exclusion included pregnant subjects, enrollment in any concurrent trial which could impact study endpoints, and physical/psychological condition which may impair study participation. Intraoperative exclusion occurred when the H1100 was not utilized.

Endpoints
The primary performance endpoint was attaining Grade 3 or lower hemostasis for each vessel transected based upon the following published scale [16]: Grade 1: no bleeding at transection location; Grade 2: minor bleeding at transection site, no intervention required; Grade 3: minor bleeding at transection site, mild intervention needed, or Grade 4: significant bleeding (e.g., pulsatile blood flow, venous pooling) requiring intervention. Secondary performance endpoints to assess device performance were measured by querying surgeons regarding specific tasks for sealing and transecting vessels. Each participating surgeon completed a usability questionnaire at the conclusion of their second procedure. A GEN11 survey was also completed by each surgeon after each case was completed.

Device-related adverse events (AEs) across the study period were recorded to assess device safety. Basic demographics were collected for each subject. Other data variables collected included procedure performed, estimated volume of intra-operative blood loss and potential transfusions, procedure duration, hospital length of stay, procedure-related AEs, and additional interventions required to achieve hemostasis for Grade 3 transections.

Device

The Harmonic 1100 Shears (Product Codes HAR1120 or HAR1136) and Generator G11 (Ethicon, Inc., Cincinnati, OH).

Statistics

To achieve a random representative cohort in this single-arm study, a projected minimum of 165 surgical subjects were to be recruited. A secondary enrollment goal was to enroll a sufficient number of subjects to achieve a minimum of 165 vessels transected with a diameter size of > 5 to 7 mm. Thus, each discreet vessel transected measuring > 5 to 7 mm in diameter counted toward both the secondary and the primary enrollment goal. No formal sample size estimation was performed given the single-arm nature of this study. Summary statistics were performed for patient demographics and surgical characteristics. Categorical variables were summarized descriptively by frequencies and associated percentages. Continuous variables were summarized descriptively by number of patients, mean, standard deviation, and median. Confidence intervals were provided for procedure-related variables. The following hypothesis was used to evaluate the primary performance endpoint: H0: $p \leq 87.5\%$; H1: $p > 87.5\%$, where p was the percentage of transections achieving a Grade 3 or lower hemostasis rating and 87.5% was set as a performance goal for the lower bound of acceptable hemostasis. A two-sided 95% confidence interval was calculated for p based on the sample proportion of transections where Grade 3 or lower hemostasis was achieved using exact Binomial methods proposed by Clopper-Pearson and the lower limit of this confidence interval was compared to 87.5% to evaluate the above hypotheses. A p-value was determined based on an exact binomial test. The null hypothesis was rejected if the lower limit of the confidence interval was greater than 87.5%. Likewise, the hypothesis for the secondary performance objective for the proportion of vessels transected of diameter size > 5 to 7 mm with hemostasis grade 3 or lower was similar to the primary performance endpoint as described above. Safety analyses summaries are provided for device-related and procedure-related AEs.

Results

From September 28, 2021 until March 13, 2024, 298 subjects provided informed consent, of whom 266 met inclusion/exclusion criteria and were enrolled in the study. The final analysis set included 265 subjects (40 pediatric general, 93 adult general, 32 adult gynecologic, 39 urologic, 61 thoracic) as shown in Figure 1.

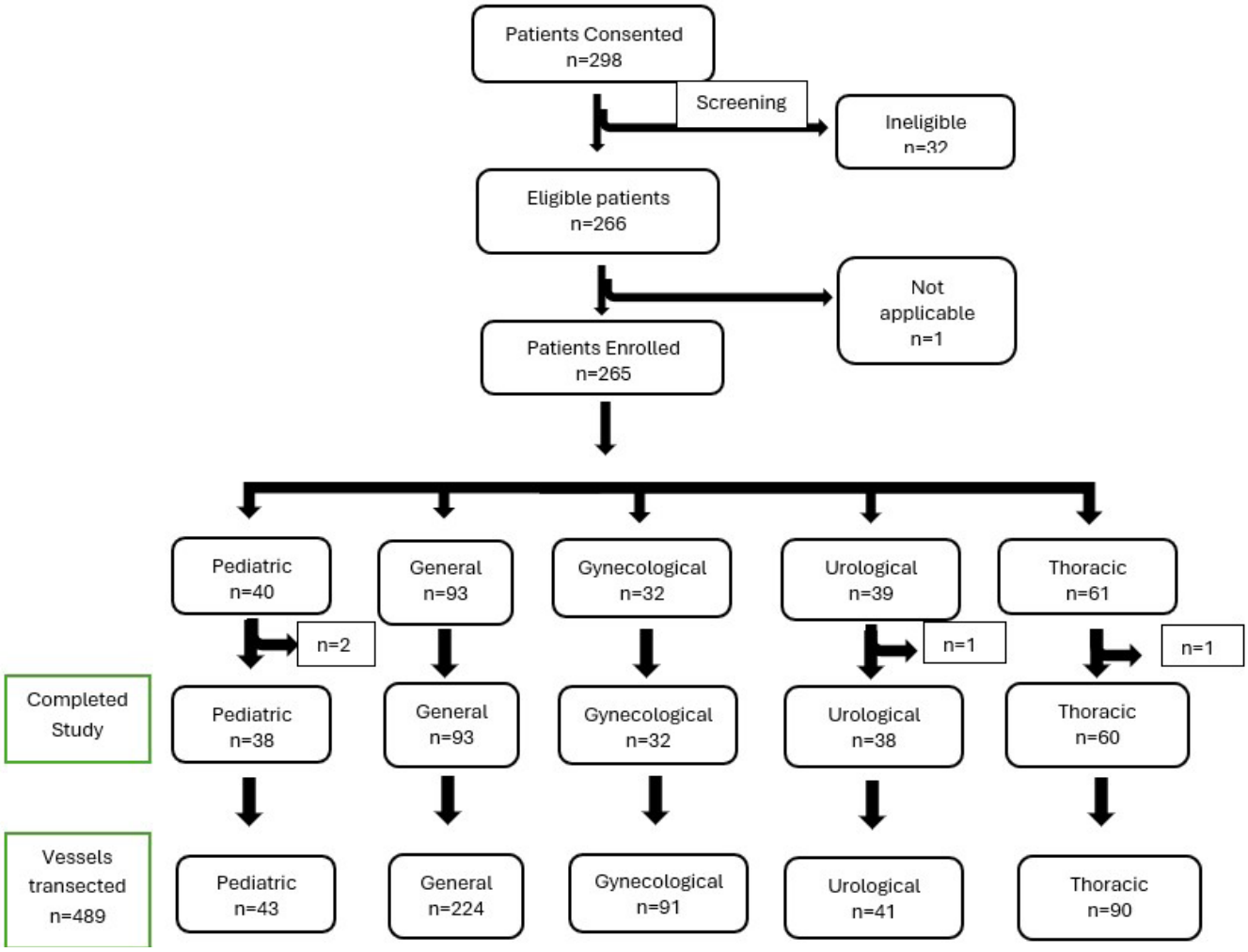

Figure 1: Subject Disposition and Vessel Transection per Group.

Table 1: Baseline Demographics.

	Pediatric	Adult				Total
	General n=40	General n=93	Gynecologic n=32	Urologic n=39	Thoracic n=61	n=265
Age at Consent (yrs)						
Mean (SD)	10.1 (4.8)	58.8 (15.8)	51.8 (16.8)	67.1 (10.7)	67.2 (7.6)	53.7 (22.8)
Median (Min, Max)	10.0 (2.1;17.0)	60.0 (19.0;86.0)	49.5 (26.0;91.0)	66.0 (44.0;85.0)	68.0 (37.0;84.0)	62.0 (2.0;91.0)
Gender, n (%)						
Male	21 (52.5%)	45 (48.4%)	0	19 (48.7%)	22 (36.1%)	107 (40.4%)
Female	19 (47.5%)	48 (51.6%)	32 (100.0%)	20 (51.3%)	39 (63.9%)	158 (59.6%)
Race, n (%)						
Asian	3 (7.5%)	0	2 (6.3%)	0	3 (5.1%)	8 (3.1%)
Black or African American	4 (10.0%)	19 (20.7%)	3 (9.4%)	3 (7.7%)	0	29 (11.1%)
White	31 (77.5%)	72 (78.3%)	26 (81.3%)	28 (71.8%)	56 (94.9%)	213 (81.3%)
Race not reported	2 (5.0%)	1 (1.1%)	1 (3.1%)	8 (20.5%)	0	12 (4.6%)
Childbearing Potential [1], if female, n (%)						
N	19	48	32	20	39	158
Of childbearing potential	10 (52.6%)	15 (31.3%)	14 (43.8%)	1 (5.0%)	0	40 (25.3%)
Permanently sterilized	0	11 (22.9%)	4 (12.5%)	2 (10.0%)	9 (23.1%)	26 (16.5%)
Postmenopausal	0	21 (43.8%)	14 (43.8%)	17 (85.0%)	30 (76.9%)	82 (51.9%)
Premenses or not childbearing age	9 (47.4%)	1 (2.1%)	0	0	0	10 (6.3%)
Body Mass Index (kg/m^2)						
Mean (SD)	22.8 (9.0)	34.5 (10.3)	27.1 (6.1)	30.0 (5.6)	27.2 (6.2)	29.6 (9.2)
Median	20.2 (13.6;55.3)	31.9 (18.8;62.0)	24.8 (18.9;39.1)	29.1 (18.9;45.4)	25.2 (17.9;52.0)	28.0 (13.6;62.0)
ASA Score, n (%)						
N	40	93	32	39	61	265
I	4 (10.0%)	0	9 (28.1%)	4 (10.3%)	0	17 (6.4%)
II	23 (57.5%)	24 (25.8%)	21 (65.6%)	19 (48.7%)	13 (21.3%)	100 (37.7%)
III	13 (32.5%)	64 (68.8%)	2 (6.3%)	15 (38.5%)	45 (73.8%)	139 (52.5%)
IV	0	5 (5.4%)	0	1 (2.6%)	3 (4.9%)	9 (3.4%)
V	0	0	0	0	0	0

Denominator and percentages are based on subjects with non-missing data.
[1] For childbearing potential, denominator is number of females in each group.

Table 2: Primary Procedure Performed.

Group	Procedure	n (%)
Pediatric General (n=40)	Appendectomy	11 (27.5%)
	Cholecystectomy	11 (27.5%)
	Other	18 (45.0%)
Adult General (n=93)	HPB:	
	Liver Resection	4 (28.6%)
	Other	10 (71.4%)
	Lower GI:	
	Lower anterior resection	6 (40.0%)
	Left colectomy	1 (6.7%)
	Right colectomy (or ileocolectomy)	4 (26.7%)
	Other	4 (26.7%)
	Gastric:	35 (54.7%)
	Sleeve Gastrectomy	24 (37.5%)
	Esophagectomy	1 (1.6%)
	Gastrectomy (subtotal)	3 (4.7%)
	Gastrectomy (total)	1 (1.6%)
	Other	
Adult Gynecologic (n=32)	Bilateral salpingo-oophorectomy	12 (37.5%)
	TAH	2 (6.3%)
	TAH/subtotal with unilateral salpingo-oophorectomy	8 (25.0%)
	TAH/subtotal with unilateral salpingo-oophorectomy	1 (3.1%)
	TAH/subtotal with bilateral salpingectomy	3 (9.4%)
	LAVH with bilateral salpingo-oophorectomy	3 (9.4%)
	Unilateral salpingo-oophorectomy	3 (9.4%)
Adult Urologic (n=39)	Nephrectomy	39 (100%)
Adult Thoracic (n=61)	Lung Resection (branches, no PA/PV)	61 (100%)

There were 32 screen failures and 5 who discontinued participation prior to study closure. Full demographic details are provided in Table 1. The pediatric cohort consisted of 47.5% female subjects with a mean age of 10.1 years and mean Body Mass Index (BMI) of 22.8 kg/m^2. The adult cohort included general 51.6%, gynecologic 100.0%, oncologic 51.3%, thoracic 63.9% female with a mean age of 58.6, 51.8, 67.1, and 67.2 years respectively. Specific procedures performed within each group is depicted in Table 2. The pediatric general procedures included appendectomy (27.5%) indicated for appendicitis (72.7%) and cholecystectomy (27.5%) for cholelithiasis with stones (63.6%). The adult general group was comprised of Gastric (68.8%), hepatopancreatobiliary (15.1%), and lower gastrointestinal (16.1%) subsets where 40.6%, 78.6%, and 80.0% surgery was indicated for cancer. All subjects in the urologic group underwent a nephrectomy (100.0%) primarily for renal cancer (66.7%). Lung resections were performed in all subjects in the thoracic group with an indication for lung carcinoma in 93.4%. The majority of cases were performed laparoscopically (96.6%) with 4 cases converted to open (1.6%).

Table 3 depicts the full vessel transection summary across groups. A total of 489 vessel transactions occurred during the course of the study. Of the 489, 99.0% of the vessel transections achieved a grade 3 or lower hemostasis with a 95% confidence interval (97.6%, 99.7%), Figure 2. Forty-three transections were performed in the pediatric general procedure group with hemostasis achieved in 100.0% of vessels transection. In the adult general, gynecologic, urologic, and thoracic procedure groups 224, 91, 41, and 90 vessels were transected, respectively where hemostasis was achieved in 98.2%, 91.2%, 100.0%, and 97.8% respectively. The majority of vessels achieved Grade 1 hemostasis: pediatric 100%, adult general 98.2%, gynecologic 91.2%, urologic 100%. Seven vessels were transected as Grade 3 (all in the gynecologic group) and all required touch-ups (n=4 bipolar device; n=4 H1100). Cumulative estimated intra-operative median blood loss was approximately 76 mL (0-800 mL range) with 1.5% of subjects requiring an intra-operative transfusion (2 adult general, 2 gynecologic), none of which was deemed device-related. A total of 174 vessels in 96 subjects had at least one vessel transected with a diameter greater than 5 mm (>5-7 mm). Hemostasis was achieved for 98.9% of >5 to 7 mm vessels transected (172/174) with a 95% confidence interval of 95.91% to 99.86%, p-value<.0001. Of these, the majority were Grade 1 on the hemostasis scale: adult general 99.2%, gynecological 85.7%, urologic 100%, thoracic 100%. Table 4 provides intra-operative variables delineated by group. There were five Grade 4 vessel transections over the course of the study (2 adult general, 1 gynecologic, 2 thoracic) all of which required additional measures (including hemoclips, staples, topical hemostats, and other advanced energy products) to obtain hemostasis.

Of the 104 cases in which the H1100 was used for sealing and transection of lymphatic vessels, surgeon satisfaction with the device, was high (97.1%). A separate usability survey was completed by surgeons after the 2nd completed case. A total of 18 questionnaires were completed in the following groups: 4 pediatric, 6 adult general, 3 gynecologic, 3 urologic, and 2 thoracic, Table 5. The majority of surgeons had previously used a Harmonic device (n=18). Most surgeons reported that they found the H1100 easier to use than their previous ultrasonic device (88.9%). Overall, all surgeons indicated that the H1100 performed as well or better than their previous ultrasonic device of choice. Similarly, related queries were made regarding the Gen11's use. A total of 263 generator questionnaires were completed with surgeons reporting that the GEN11 touchscreen was easy-to-use (98.5%) and that it performed as intended (96.6%). Seven generator alarms were reported (2.7%) including 1 "reactivate", 1 "restart generator" and 5 designated "other".

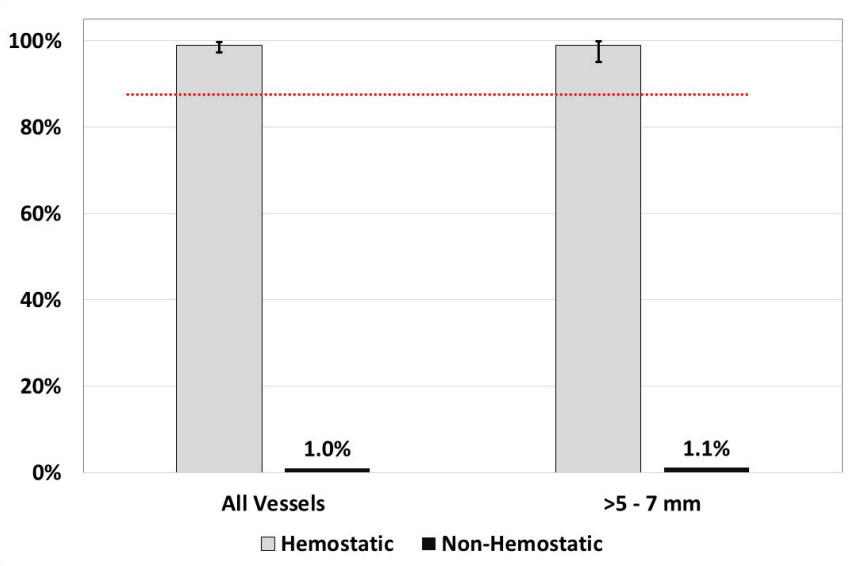

Figure 2: Hemostatic and non-hemostatic seals for all vessel diameters and for vessels >5-7 mm. Error bars are 95% confidence intervals. Dotted red line represents the lower limit of the success criterion of 87.5% hemostasis.

Table 3: Vessel Transection Summary*.

	Pediatric	Adult				Total
	General	General	Gynecologic	Urologic	Thoracic	
Total # Vessels Transected	43	224	91	41	90	489
Vessel Diameter Size						
< 3 mm	30 (69.8%)	15 (6.7%)	18 (19.8%)	14 (34.1%)	5 (5.6%)	82 (16.8%)
3 to 5 mm	13 (30.2%)	99 (44.2%)	71 (78.0%)	21 (51.2%)	29 (32.2%)	233 (47.6%)
> 5 to 7 mm	0	110 (49.1%)	2 (2.2%)	6 (14.6%)	56 (62.2%)	174 (35.6%)
Hemostasis Grading Scale						
Grade 1	43 (100.0%)	220 (98.2%)	83 (91.2%)	41 (100.0%)	88 (97.8%)	475 (97.1%)
Grade 2	0	2 (0.9%)	0	0	0	2 (0.4%)
Grade 3	0	0	7 (7.7%)	0	0	7 (1.4%)
Grade 4	0	2 (0.9%)	1 (1.1%)	0	2 (2.2%)	5 (1.0%)
Hemostasis Achieved (All Vessels)						
Yes	43 (100.0%)	222 (99.1%)	90 (98.9%)	41 (100.0%)	88 (97.8%)	484 (99.0%)
Inference for Hemostasis (All Vessels)						
Yes	43 (100.0%)	222 (99.1%)	90 (98.9%)	41 (100.0%)	88 (97.8%)	484 (99.0%)
95% CI (Exact Method)	(91.8%, 100.0%)	(96.8%, 99.9%)	(94.0%, 100.0%)	(91.4%, 100.0%)	(92.2%, 99.7%)	(97.3%, 99.7%)
P-value						<.0001
95% CI						(97.55%,99.58%)
Hemostasis Achieved >5 to 7 mm Vessels						
Yes	-	109 (99.1%)	1 (50.0%)	6 (100.0%)	56 (100.0%)	172 (98.9%)
Inference for Hemostasis >5 to 7 mm Vessels						
Yes	-	109 (99.1%)	1 (50.0%)	6 (100.0%)	56 (100.0%)	172 (98.9%)
95% CI (Exact Method)		(95.0%, 100.0%)	(1.3%, 98.7%)	(54.1%, 100.0%)	(93.6%, 100.0%)	(95.9%, 99.9%)
P-value						<.0001
95% CI						(99.91%,100.00%)
# Additional Hemostatic Measures Required	0	2	1	0	2	5
Mean (SD)	-	2.5 (2.1)	1.0 (-)	-	1.0 (2.0)	1.6 (1.3)
Type of Hemostatic measure, n Hemoclips	-	2	1	-	2	4
Staples	-	1	0	-	0	1
Adjunctive topical hemostats (except fibrin sealants)	-	1	0	-	0	1
Other Advanced Energy Products	-	1	0	-	0	1
Other	-	1	0	-	0	1
*Denominator and percentages are based on number of vessels transected in each group.						

Of the 183 total AEs reported during the course of the study, 7 were deemed "possibly related" to the study device, 4 in the adult general, 2 in gynecologic, and 1 in the thoracic adult procedure group. All device-related AEs were in the >5-7 mm vessel group. Five subjects experienced 7 adverse events. The AEs were: two cardiac (atrial fibrillation and pericardial effusion), pleural effusion, anastomotic complications, and a gastrointestinal anastomotic leak. One subject in the thoracic group died during the course of the study which the surgeon reported as "possibly" device-related. The subject was a 64-year-old male who had severe systemic disease. The H1100 was used to transect a >5 mm bronchial artery with Grade 1 hemostasis at which time there was no intraoperative bleeding at the transection site. Post-surgery, he experienced post-pneumonectomy respiratory failure, post-operative pneumonia, and pericardial effusion. The subject died from post-pneumonectomy respiratory failure 30 days post-operatively. Based on available information, particularly the delayed onset of pericardial effusion, it was then concluded that the death was not device-related.

Discussion

This post-market study evaluated the performance and safety of the Harmonic 1100 Shears across specialties. Ninety-six subjects (174 vessels) had at least one vessel transected with diameter greater than 5mm and hemostasis was achieved for 98.9% of the subjects. In the pediatric group, all vessels were ≤5 mm in diameter (Grade 1) and first-pass hemostasis was achieved for all vessels. Consistent with our study's findings, despite scant literature with regard to the use of Harmonic devices in pediatrics, comparative studies have demonstrated that it offers performance parity with conventional methods and superior recovery outcomes with fewer postoperative complications [8,17].

In surgical procedures, patient safety and clinical outcomes remain the highest priority and thus instrument selection is critical [20].

Table 4: Intra-Operative Information.

	Pediatric	Adult				Total
	General (n=40)	General (n=93)	Gynecologic (n=32)	Urologic (n=39)	Thoracic (n=61)	(n=265)
Occurrence of Vessel Skeletonization?						
Yes	23 (59.0%)	46 (49.5%)	22 (68.8%)	37 (94.9%)	50 (82.0%)	178 (67.4%)
Prophylactic use of clips or sutures as standard of surgical care before vessel transection?						
Yes	1 (2.5%)	13 (14.0%)	0	9 (23.1%)	0	23 (8.7%)
Presence of Inflamed Tissue/Vessels						
Yes	10 (25.0%)	4 (4.3%)	6 (18.8%)	15 (38.5%)	2 (3.3%)	37 (14.0%)
Presence of Calcified Tissues/Vessels						
Yes	0	1 (1.1%)	0	1 (2.6%)	1 (1.6%)	3 (1.1%)
Presence of Fibrotic Tissue						
Yes	3 (7.5%)	6 (6.5%)	3 (9.4%)	4 (10.3%)	1 (1.6%)	17 (6.4%)
Presence of Adhesions						
Yes	8 (20.0%)	2 (2.2%)	5 (15.6%)	7 (17.9%)	3 (4.9%)	25 (9.4%)
Surgical Approach						
Open	0	3 (3.2%)	4 (12.5%)	0	2 (3.3%)	9 (3.4%)
Laparoscopic	40 (100.0%)	90 (96.8%)	28 (87.5%)	(100.0%)	59 (96.7%)	256 (96.6%)
Conversion to Open	0	3 (3.3%)	0	0	1 (1.7%)	4 (1.6%)
Procedure Duration (hours)						
Mean (SD)	1.8 (1.7)	2.2 (1.4)	2.2 (1.1)	3.4 (1.2)	2.1 (0.88)	2.3 (1.4)
Median	1.1	2.0	2.3	3.0	2.1	2.2
(Min, Max)	(0.5; 8.2)	(0.7; 6.4)	(0.5; 5.6)	(1.7; 6.2)	(0.8; 4.1)	(0.5; 8.2)
Intra-operative Blood Loss (mL)						
Mean (SD)	9.6 (39.5)	88.8 (141.5)	73.1 (97.8)	99.6 (93.2)	90.3 (138.6)	76.9 (121.6)
Median	0.00	20.00	50.00	50.00	30.00	20.00
(Min, Max)	(0.0; 250.0)	(0.0; 800.0)	(0.0; 500.0)	(0.0; 300.0)	(0.0; 800.0)	(0.0; 800.0)

The Harmonic device has become widely used in various surgical procedures, largely due to surgeon preference. Comparative studies have consistently demonstrated that the Harmonic device yields improved patient outcomes across multiple procedural areas and key performance indicators [19]. One significant advantage is its impact on intraoperative blood loss. Research indicates a statistically significant reduction in intraoperative blood loss when utilizing the Harmonic device as compared to conventional techniques across a range of surgeries including tonsillectomy, thyroidectomy, mastectomy, gastrectomy, colectomy, and cholecystectomy [21-16]. The safety and performance of harmonic devices, particularly in achieving hemostasis in vessels up to 7 mm, have been well-documented and supports our findings especially in the adult population where about half of the vessels were >5mm and hemostasis being achieved in 99.1% of those. Studies have demonstrated that harmonic devices can achieve effective hemostasis with reduced thermal injury compared to traditional methods, making them particularly advantageous for vascular control [4,18]. The precision of these instruments allows surgeons to navigate around delicate structures while ensuring robust closure of vessels, thus enhancing patient safety and improving surgical outcomes [19]. Overall, the efficacy of harmonic devices in managing hemostasis has positioned them as a preferred choice in laparoscopic and open surgical settings, especially for larger vascular structures (vessels up to 7 mm). Moreover, the benefits of the Harmonic devices extend beyond intraoperative blood loss, encompassing reductions in length of hospital stay, operative time, drainage volume, and postoperative pain [19]. Collectively, these improvements contribute to fewer complications and a reduction in overall healthcare costs associated with the use of the Harmonic device [27]. Surgeons in this study reported high satisfaction regarding the performance of the H1100 with 97.1% expressing satisfaction with sealing and transection of lymphatic vessels. Of note, 101 of 104 cases involving lymphatic vessel transections received high satisfaction ratings. Feedback from surgeons using GEN11 demonstrated a high level of satisfaction: 96.6% of surgeons agreed or strongly agreed that the generator performed as intended, and 98.5% agreed or strongly agreed that the touch screen interface was user-friendly. Strengths of this study include its multi-site, prospective nature which spanned multiple surgical specialties. This design allowed for a disparate study population and a diverse variety of vessels transected. One limitation of this study is that it is a single-arm study examining with no comparator device. Further studies may be warranted to address this shortcoming.

Conclusion

The results of this study are consistent with the long history of use of Harmonic devices with positive patient outcomes in multiple specialties. In conclusion, the data from this real-world post-market study affirms the safety and efficacy of the H1100 across specialties, supporting its continued use in clinical practice.

Table 5: Surgeon Questionnaire.

	Pediatric	Adult				Total
	General	General	Gynecologic	Urologic	Thoracic	
Number of Questionnaires Completed	4	6	3	3	2	18
Ultrasonic device(s) you previously used*						
n	3	6	3	3	2	17
None	1 (33.3%)	0	0	0	0	1 (5.9%)
HARMONIC ACE+	0	4 (66.7%)	1 (33.3%)	0	0	5 (29.4%)
HARMONIC ACE+7	0	3 (50.0%)	1 (33.3%)	0	1 (50.0%)	5 (29.4%)
HARMONIC HD 1000i	1 (33.3%)	4 (66.7%)	1 (33.3%)	1 (33.3%)	1 (50.0%)	8 (47.1%)
Thunderbeat	0	1 (16.7%)	2 (66.7%)	2 (66.7%)	0	5 (29.4%)
Other	2 (66.7%)	0	0	0	0	2 (11.8%)
I experienced less tissue pad degradation using the H1100 compared to my previous ultrasonic device						
Strongly Disagree	0	1 (16.7%)	0	0	0	1 (5.6%)
Disagree	0	0	0	0	0	0
Satisfactory	3 (75.0%)	3 (50.0%)	1 (33.3%)	1 (33.3%)	0	8 (44.4%)
Agree	1 (25.0%)	2 (33.3%)	1 (33.3%)	1 (33.3%)	2 (100.0%)	7 (38.9%)
Strongly Agree	0	0	1 (33.3%)	1 (33.3%)	0	2 (11.1%)
H1100 were easier to use compared to my previous ultrasonic device						
Strongly Disagree	0	0	0	0	0	0
Disagree	0	0	1 (33.3%)	0	1 (50.0%)	2 (11.1%)
Satisfactory	3 (75.0%)	3 (50.0%)	1 (33.3%)	2 (66.7%)	0	9 (50.0%)
Agree	1 (25.0%)	2 (33.3%)	0	1 (33.3%)	1 (50.0%)	5 (27.8%)
Strongly Agree	0	1 (16.7%)	1 (33.3%)	0	0	2 (11.1%)
With H1100, transection was faster than with my previous ultrasonic device						
Strongly Disagree	0	0	0	0	0	0
Disagree	0	0	1 (50.0%)	1 (33.3%)	0	2 (11.8%)
Satisfactory	2 (50.0%)	2 (33.3%)	0	1 (33.3%)	0	5 (29.4%)
Agree	2 (50.0%)	3 (50.0%)	0	1 (33.3%)	2 (100.0%)	8 (47.1%)
Strongly Agree	0	1 (16.7%)	1 (50.0%)	0	0	2 (11.8%)
With the HD1100, I was able to grasp and manipulate tissue better than compared to my previous ultrasonic device						
Strongly Disagree	0	0	0	0	0	0
Disagree	0	0	0	2 (66.7%)	0	2 (11.8%)
Satisfactory	1 (25.0%)	3 (50.0%)	1 (50.0%)	1 (33.3%)	1 (50.0%)	7 (41.2%)
Agree	3 (75.0%)	2 (33.3%)	0	0	1 (50.0%)	6 (35.3%)
Strongly Agree	0	1 (16.7%)	1 (50.0%)	0	0	2 (11.8%)
H1100's tapered tip allowed more precise dissection compared to my previous ultrasonic device						
Strongly Disagree	0	0	0	0	0	0
Disagree	0	0	0	0	0	0
Satisfactory	2 (50.0%)	1 (16.7%)	1 (50.0%)	2 (66.7%)	1 (50.0%)	7 (41.2%)
Agree	2 (50.0%)	4 (66.7%)	0	1 (33.3%)	1 (50.0%)	8 (47.1%)
Strongly Agree	0	1 (16.7%)	1 (50.0%)	0	0	2 (11.8%)
H1100's handle mechanism allowed more precise dissection compared to my previous ultrasonic device						
Strongly Disagree	0	0	0	0	0	0
Disagree	0	0	0	0	0	0
Satisfactory	1 (25.0%)	1 (16.7%)	0	3 (100.0%)	0	5 (29.4%)
Agree	3 (75.0%)	4 (66.7%)	1 (50.0%)	0	2 (100.0%)	10 (58.8%)
Strongly Agree	0	1 (16.7%)	1 (50.0%)	0	0	2 (11.8%)
Overall, the HARMONIC 1100 Shears performed better than my previous ultrasonic device						
n	4	6	2	3	2	17
Strongly Disagree	0	0	0	0	0	0
Disagree	0	0	0	0	0	0
Satisfactory	1 (25.0%)	2 (33.3%)	1 (50.0%)	2 (66.7%)	0	6 (35.3%)
Agree	3 (75.0%)	3 (50.0%)	0	1 (33.3%)	2 (100.0%)	9 (52.9%)
Strongly Agree	0	1 (16.7%)	1 (50.0%)	0	0	2 (11.8%)

*More than 1 option could be selected

References

1. Janssen PF, Brölmann HAM, Huirne JAF. Effectiveness of electrothermal bipolar vessel sealing devices versus other electrothermal and ultrasonic devices for abdominal surgical hemostasis a systematic review. Surg Endosc. 2012; 26: 2892-2901.
2. Homma T. Advances and safe use of energy devices in lung cancer surgery. Gen Thorac Cardiovasc Surg. 2022; 70: 207-218.
3. Bond LJ, Cimino WW. Physics of ultrasonic surgery using tissue fragmentation. Ultrasound Med Biol. 1996; 22: 89-100.
4. Družijanić N, Pogorelić Z, Perko Z, et al. Comparison of lateral thermal damage of the human peritoneum using monopolar diathermy, Harmonic scalpel and LigaSure. Can J Surg. 2012; 55: 317-321.
5. Sarda H, Arora V, Sachdeva T, et al. Systematic Review of Comparison of use of Ultrasonic Scalpel Versus Conventional Haemostatic Techniques in Performing Thyroid Surgery. Indian J Otolaryngol Head Neck Surg. 2022; 74: 6285-6291.
6. Patrone R, Gambardella C, Romano RM, et al. The impact of the ultrasonic bipolar and integrated energy devices in the adrenal gland surgery literature review and our experience. BMC Surg. 2019; 18: 123.
7. Park SY, Shin MH, Hwang YM, et al. Comparative analysis between ultrasonic shears versus advanced bipolar device in transoral endoscopic thyroidectomy a randomized controlled trial. Gland surgery. 2023; 12: 1191-1202.
8. McCarus SD, Parnell LKS. The Origin and Evolution of the HARMONIC® Scalpel. Surg Technol Int. 2019; 35: 201-213.
9. Welling AL, Scoggins PJ, Cummings JF, et al. Superior dissecting capability of a new ultrasonic device improves efficiency and reduces adhesion formation. Global Surgery. 2017; 3: 1-5.
10. Silva-Filho AL, Rodrigues AM, de Castro Monteiro MV, et al. Randomized study of bipolar vessel sealing system versus conventional suture ligature for vaginal hysterectomy. Eur J Obstet Gynecol Reprod Biol. 2009; 146: 200-203.
11. Singleton DW. Intelligent Ultrasonic Energy New Adaptive Tissue Technology in Harmonic Shears. Journal of Surgery. 2020; 8: 178-183.
12. McCarus SD. McCarus Minimally Invasive Hysterectomy: 20 Years' Experience-Lessons Learned. Surg Technol Int. 2018; 33: 207-214.
13. Casadei R, Ricci C, Pacilio CA, et al. Laparoscopic distal pancreatectomy which factors are related to open conversion Lessons learned from 68 consecutive procedures in a high-volume pancreatic center. Surg Endosc. 2018; 32: 3839-3845.
14. Kim KJ, Chung JH, Lee HC, et al. Comparison of Harmonic scalpel and monopolar cautery for capsulectomy at the second stage of expander implant breast reconstruction. Arch Plast Surg. 2020; 47: 140-145.
15. Park SY, Lim S, Kim DK, et al. Safety and Performance of Harmonic® HD 1000i Shears in Thoracoscopic Procedures A Retrospective Study. Open Journal of Thoracic Surgery. 2022; 12: 33-42.
16. Siegel JM, Cummings JF, Clymer JW. Reproducible repeatable and clinically-relevant hemostasis scoring. Journal of Advances in Medical and Pharmaceutical Sciences. 2014; 1: 30-39.
17. Pogorelić Z, Beara V, Jukić M, et al. A new approach to laparoscopic appendectomy in children clipless sutureless Harmonic scalpel laparoscopic appendectomy. Langenbecks Arch Surg. 2022; 407: 779-787.
18. Ghulam Sarwar, Tanveer Hameed Sheikh, Muhammad Nadeem. Comparison of Blood Loss between Harmonic Scalpel and Monopolar Electrocautry in Modified Radical Mastectomy. PJMHS. 2016; 10: 3.
19. Kloosterman R, Wright GWJ, Salvo-Halloran EM, et al. An umbrella review of the surgical performance of Harmonic ultrasonic devices and impact on patient outcomes. BMC Surgery. 2023; 23: 180.
20. Brophy T, Srodon PD, Briggs C, et al. Quality of surgical instruments. Ann R Coll Surg Engl. 2006; 88: 390-393.
21. Alexiou VG, Salazar-Salvia MS, Jervis PN, et al. Modern technology-assisted vs conventional tonsillectomy a meta-analysis of randomized controlled trials. Arch Otolaryngol Head Neck Surg. 2011; 137: 558-570.
22. Aires FT, Matos LL, Dedivitis RA, et al. Effectiveness of harmonic scalpel in patients submitted to total thyroidectomy: systematic review with meta-analysis. Rev Assoc Med Bras (1992). 2018; 64: 649-657.
23. Zhang Z, Li L, Pang Y, et al. Comparison of harmonic scalpel and conventional technique in the surgery for breast cancer: A systematic review and meta-analysis. Indian J Cancer. 2018; 55: 348-358.
24. Cheng H, Soleas I, Ferko NC, et al. A systematic review and meta-analysis of Harmonic Focus in thyroidectomy compared to conventional techniques. Thyroid Res. 2015; 8: 15.
25. Tou S, Malik AI, Wexner SD, et al. Energy source instruments for laparoscopic colectomy. Cochrane Database Syst Rev. 2011; 11: Cd007886.
26. Jiang HP, Liu YD, Li YS, et al. Ultrasonic versus electrosurgical device for laparoscopic cholecystectomy A systematic review with meta-analysis and trial sequential analysis. Int J Surg. 2017; 40: 24-32.
27. Cheng H, Clymer JW, Qadeer RA, et al. Procedure costs associated with the use of Harmonic devices compared to conventional techniques in various surgeries a systematic review and meta-analysis. Clinicoecon Outcomes Res. 2018; 10: 399-412.