

Assessing the function of the HARMONIC® HD 1000i for procedures of the liver and pancreas

Introduction

Ethicon US, LLC, introduced HARMONIC® technology more than two decades ago. Subsequent advancements have led to the continuous development of new devices, the most recent being the HARMONIC HD 1000i, introduced in September 2016. Designed to address unique challenges in complex open and laparoscopic procedures, the HARMONIC HD 1000i offers a seamless combination of precision and strength for improved dissection, faster transection and more secure sealing.

To assess the benefits of the HARMONIC HD 1000i in procedures of the liver and pancreas, Ethicon gathered three esteemed HPB surgeons at the Center for the Future of Surgery at the University of California, San Diego:

Hong Jin Kim MD, FACS, Chief, Division of Surgical Oncology and Endocrine Surgery, and Professor of Surgery at the University of North Carolina School of Medicine in Chapel Hill, NC, USA.

Hugo Pinto Marques MD, Consultant Surgeon, Hepato-Biliary-Pancreatic and Transplantation Centre at the Curry Cabral Hospital in Lisbon, Portugal; Assistant, NOVA Medical School, Lisbon, Portugal

Perry Shen MD, FACS, Director, Department of Surgery, Section on Surgical Oncology; Professor of Surgery; and Director of the Surgical Oncology Fellowship Program at Wake Forest School of Medicine in Winston-Salem, NC, USA

In a porcine wet lab, the surgeons used the HARMONIC HD 1000i to dissect the porcine liver and simulate a Whipple procedure. Their comments and observations during the lab, and during a discussion that immediately followed the lab, were captured and are the basis for this paper.

HARMONIC® HD 1000i Shears overview

The HARMONIC HD 1000i Shears was designed to provide surgeons a combination of unmatched precision, unparalleled strength and optimized efficiency. The device features Adaptive Tissue Technology, powered by GEN11, which uses an advanced algorithm for intelligent and efficient energy delivery. The technology continuously senses changes in tissue conditions, responds with the right amount of energy and delivers greater precision and efficiency. Since its introduction, the HARMONIC HD 1000i provides improved dissection, faster transection and more secure sealing.

Surgeon experience with HARMONIC HD 1000i during liver and pancreas procedures

The surgeons tested the stated benefits of the HARMONIC HD 1000i.

Strength of sealing

The unique blade design of the HARMONIC HD 1000i delivers more secure seals even in challenging conditions. Its exceptional sealing strength is evidenced by burst pressures of 150% relative to both small and large devices.¹ In addition, the device has shown to reliably seal and transect intrahepatic vessels during hepatectomy and partial hepatectomy procedures.²

During the lab, surgeons were asked to evaluate the HARMONIC HD 1000i sealing strength. They described the HARMONIC HD 1000i as the device they currently use to perform a hepatectomy, indicating the precise tip enabled the HARMONIC HD 1000i to easily drill into the liver, then transect liver parenchyma by closing while activating.

BEST PRACTICE TO OPTIMIZE HEMOSTASIS

In liver resection: "I use the tip of the HARMONIC HD 1000i blade to fragment the liver parenchyma. I use the backside of the active blade and a painting technique to help seal the liver. Overall the liver looked hemostatic."

Hugo Pinto Marques MD

Consultant Surgeon
Hepatobiliary Surgery and Liver Transplantation
Hepato-Biliary-Pancreatic and Transplantation Centre
Curry Cabral Hospital, Lisbon, Portugal
Assistant, NOVA Medical School, Lisbon, Portugal

Efficiency

The HARMONIC HD 1000i is designed for hepatectomy and partial hepatectomy procedures to enable surgical efficiency through improved dissection, hemostasis and multi-functionality.³ These efficiencies were discussed extensively throughout the lab. The surgeons commented that the longer tip and larger jaws of the device improved transection capability. "I can definitely take bigger bites," was repeatedly stated. The surgeons also noted that the tapered tip of the HARMONIC HD 1000i would make it ideal for challenging tissue. "An energy device like HARMONIC HD 1000i works well for cirrhotic livers because you need a thin tip to get into the tissue," Dr. Shen stated.

Because the unique shape of the HARMONIC HD 1000i mimics a mechanical dissector, it may reduce the need to

use a separate dedicated dissecting instrument. In pre-clinical studies it was shown to enable reduced instrument exchanges during hepatectomy and partial hepatectomy procedures to improve surgical efficiency.⁴ During the lab, Dr. Shen referenced HARMONIC HD 1000i as a “one-person device” indicating that the HARMONIC HD 1000i and an Ethicon Endocutter would be the only tools necessary for liver procedures.

BEST PRACTICE TO OPTIMIZE EFFICIENCY

In liver resection: “For my ideal liver procedure, all I would need is HARMONIC HD 1000i and an Ethicon Endocutter. I can perform most of the procedure with the HARMONIC device. I would complete the hepatectomy using a powered Endocutter.”

Perry Shen MD, FACS

Director, Department of Surgery, Section on Surgical Oncology
Wake Forest School of Medicine

Speed

When evaluating the benefit of speed that the HARMONIC HD 1000i offers the user, it was evident that the device gave surgeons the speed they were looking for. They commented that the longer blade enabled them to work faster. They also noted the ease in using the device for tissue fracturing of liver parenchyma, and they reiterated that the tapered tip would enable them to more quickly dissect challenging tissue.

During the lab, the surgeons indicated the device’s advanced speed was a benefit over other devices. Compared to LigaSure™ Maryland the HARMONIC HD 1000i has shown to deliver 33% faster transection speed.⁵

Unmatched precision

The exceptional dissection capabilities of the HARMONIC HD 1000i were evident in the lab during procedures of the pancreas. All three surgeons praised the device’s ability to dissect. These specific comments were noted:

- “A very good dissection tool for the pancreas; better than my current device.”
- “The device’s ability to handle tiny veins makes it better [for pancreas procedures] than other devices on the market.”
- “It enables multi-functionality and an easier procedure with fewer instrument changes.”

Many of HARMONIC HD 1000i benefits that were recorded during the liver dissection were noted as being similarly applicable to pancreas/Whipple procedures. The surgeons specifically mentioned smooth tissue access and hemostasis, as well as the device’s precise tip. “We could dissect very easily along the splenic vein. I think this could easily replace the instruments we’ve been using,” they stated.

BEST PRACTICE TO OPTIMIZE PRECISION

In pancreas: “You can do ligation and dissection with HARMONIC HD 1000i...it’s better than anything I’m using now and is an excellent instrument in my opinion.”

Hong Jin Kim MD, FACS

Chief, Division of Surgical Oncology and Endocrine Surgery
University of North Carolina School of Medicine

Surgeon comparison of HARMONIC HD 1000i to competitive devices

Throughout the lab, surgeons commented on how the HARMONIC HD 1000i compares to other devices they have used. All agreed that compared to LigaSure, the HARMONIC HD 1000i is more precise and clearly superior at dissection.⁶ One surgeon added, “The tip of HARMONIC HD 1000i is thinner than LigaSure which results in less tissue trauma.”

When clinicians were asked if they experienced any additional pre-clinical benefits of the HARMONIC HD 1000i they commented that the precise tip drills easily into liver parenchyma which may improve access and may prevent damage to surrounding tissue. They stated the thinner tip enabled better precision compared to other devices.

When comparing HARMONIC HD 1000i to CUSA®, it was noted that HARMONIC HD 1000i provides better hemostasis, is faster and provides more speed. The variable speed of the HARMONIC HD 1000i was preferred over the single-speed CUSA.

HD1000i: A STAND-ALONE DEVICE

“The CUSA is not a stand-alone transection device. It disrupts liver parenchyma and exposes vessels and bile ducts which still need to be tied, clipped, or otherwise transected. On the other hand, the HD1000i is more a stand-alone device which cannot only transect parenchyma but also vessels/bile ducts.”

Perry Shen MD, FACS

Director, Department of Surgery, Section on Surgical Oncology
Wake Forest School of Medicine

Conclusion

Overall the surgeons were pleased with the distinct performance features of the HARMONIC HD 1000i, indicating it is particularly well suited for complex procedures of the liver and pancreas. Based on their experiences, these esteemed surgeons noted that the precision, strength and efficiency of the HARMONIC HD 1000i make it preferable to other energy devices.

HARMONIC HD 1000i is designed to address unique challenges in complex open and laparoscopic procedures including liver resection, pancreatectomy and Whipple procedures.

To learn more about this important technological advancement, or for a demonstration, talk with your Ethicon sales representative or visit harmonic.com/HD1000i

¹Based on a benchtop study with 5-7mm porcine carotid arteries. HARMONIC HD (1878 mmHg) vs. LigaSure Maryland (1171 mmHg) and LigaSure Impact (1224 mmHg). (p<0.05) (C2090)

²Based on a pre-clinical study of liver wedge resection (C2086)

³Based on a pre-clinical study (C2093)

⁴Based on a pre-clinical study (C2094)

⁵HARMONIC HD1000i full bite transection time for porcine mesentery tissue was 33% faster than LigaSure Maryland (median 2.22 seconds vs 3.33 seconds) (p=0.001) (C2095)

⁶Based on a pre-clinical study