Single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S) for obese diabetic patients.

Sánchez-Pernaute A¹, Rubio MÁ², Cabrerizo L², Ramos-Levi A³, Pérez-Aguirre E⁴, Torres A⁴.

Author Information

1 Department of Surgery, Hospital Clínico San Carlos, Madrid, Spain. Electronic address: pernaute@yahoo.com.
2 Department of Endocrinology, Hospital Clínico San Carlos, Madrid, Spain.
3 Department of Endocrinology, Hospital "La Princesa," Madrid, Spain.
4 Department of Surgery, Hospital Clínico San Carlos, Madrid, Spain.

Abstract

BACKGROUND: Bariatric operations achieve a high remission rate of type 2 diabetes in patients with morbid obesity. Malabsorptive operations usually are followed by a higher rate of metabolic improvement, though complications and secondary effects of these operations are usually higher.

OBJECTIVES: Analyze the results of a simplified duodenal switch, the single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) on patients with obesity and type 2 diabetes mellitus (T2 DM).

SETTING: University Hospital, Madrid, Spain.

METHODS: Ninety-seven T2 DM patients with a mean body mass index (BMI) of 44.3 kg/m² were included. Mean preoperative glycated hemoglobin was 7.6%, and mean duration of the disease was 8.5 years. Forty patients were under insulin treatment. SADI-S was completed with a sleeve gastrectomy performed over a 54 French bougie and a 200 cm common limb in 28 cases and 250 cm in 69.

RESULTS: Follow up was possible for 86 patients (95.5%) in the first postoperative year, 74 (92.5%) in the second, 66 (91.6%) in the third, 46 (86.7%) in the fourth and 25 out of 32 (78%) in the fifth postoperative year. Mean glycemia and glycated hemoglobin decreased immediately. Control of the disease, with HbA1c below 6%, was obtained in 70 to 84% in the long term, depending on the initial antidiabetic therapy. Most patients abandoned antidiabetic therapy after the operation. Absolute remission rate was higher for patients under oral therapy than for those under initial insulin therapy, 92.5% versus 47% in the first postoperative year, 96.4% versus 56% in the third and 75% versus 38.4% in the fifth. A short diabetes history and no need for insulin were related to a higher remission rate. Three patients had to be reoperated for recurrent hypoproteinemia.
CONCLUSIONS:
SADI-S is an effective therapeutic option for obese patients with diabetes mellitus.

Copyright © 2015 American Society for Bariatric Surgery. Published by Elsevier Inc. All rights reserved.

KEYWORDS:
Biliopancreatic diversion; Diabetes; Duodenal switch; Malabsorptive surgery; Metabolic surgery; One loop; SADI-S

PMID: 26048517 DOI: 10.1016/j.soard.2015.01.024
Duodenal switch in revisional bariatric surgery: conclusions from an expert consensus panel.

Merz AE1, Blackstone RB2, Gagner M3, Torres AJ4, Himpens J5, Higa KD6, Rosenthal RJ7, Lloyd A8, DeMaria EJ9.

Abstract

BACKGROUND:
Duodenal switch (BPD/DS) is gaining popularity as a secondary procedure for inadequate weight loss after an initial operation.

OBJECTIVES:
We aimed to generate expert consensus points on the appropriate use of BPD/DS in the revisional bariatric surgical setting.

SETTING:
Data were gathered at an international conference with attendees from a variety of different institutions and settings.

METHODS:
Sixteen lines of questioning regarding revisional BPD/DS were presented to an expert panel of 29 bariatric surgeons. Current available literature was reviewed extensively for each topic and proposed to the panel before polling. Responses were collected and topics defined as achieving consensus (≥70% agreement) or no consensus (<70% agreement).

RESULTS:
Consensus was present in 10 of 16 lines of questioning, with several key points most prominent.
CONCLUSIONS:
As a second-stage procedure, BPD/DS is most appropriate after sleeve gastrectomy (SG) for the treatment of super morbid obesity (96.7% agree) or as a subsequent operation for a reliable patient with insufficient weight loss after SG (88.5%). In a patient with weight regain and reflux and/or enlarged fundus after SG, Roux-en-Y gastric bypass is preferable and BPD/DS should be avoided (90%). BPD/DS should not be used prophylactically in patients with a history of jejunoileal bypass who are otherwise doing well (80.8%). Applicability of BPD/DS is limited by technical difficulty; 86.2% of experts would routinely recommend or consider the procedure if it were more technically feasible after failed bypass. No consensus was found on approaches to revision of BPD/DS for protein malnutrition.

Copyright © 2019 American Society for Bariatric Surgery. Published by Elsevier Inc. All rights reserved.

KEYWORDS:
Duodenal switch; Expert consensus; Obesity; Revisional bariatric surgery

PMID: 31076367 DOI: 10.1016/j.soard.2019.03.009
UNIQUE HYBRID TECHNOLOGY

DOUBLE YOUR ENERGY
THUNDERBEAT Type S – Next Generation of Safety and Speed
Philosophy
Olympus aims to provide innovative energy solutions delivering surgical safety and instrument versatility for efficient and streamlined operations with optimal patient outcomes. This is why Olympus developed the unique hybrid technology THUNDERBEAT for open and laparoscopic surgery.

THUNDERBEAT is the world’s first and only advanced energy system that delivers two well-established forms of energy to a tissue simultaneously:

- **Ultrasonic energy** for superior dissection and fast tissue-cutting capability
- **Advanced bipolar energy** for fast and secure hemostasis for vessels up to and including 7 mm in diameter

The THUNDERBEAT Modes

**SEAL & CUT**
Advanced bipolar and ultrasonic energy for reliable vessel sealing and tissue coagulation with simultaneous cutting.

**SEAL**
Advanced bipolar energy for reliable vessel sealing and secondary hemostasis.

Reduced blood loss and optimal visibility on anatomic structures by superior primary and secondary hemostasis through advanced bipolar technology.

**Primary Hemostasis and Secure 7 mm Vessel Sealing**
Using the combined energy types of the THUNDERBEAT SEAL & CUT mode simultaneously allows for safe coagulation and fast tissue transection. Fewer vessel-ligation steps are required due to the ability of pre-coagulation as well as due to the secure cutting and sealing of 7 mm vessels.¹

**Secondary Hemostasis**
The THUNDERBEAT SEAL mode without simultaneous cutting allows for:
- Immediate sealing of secondary bleeder,
- Control of oozing bleeding by spot coagulation,
- Pre-sealing of vessels through the precise application of advanced bipolar energy.

¹ Data on file, Olympus Corporation
Superior Dissection with Optimal Temperature Control

The precision of ultrasonic technology enables accurate preparation of the correct anatomic layers with the protection of vital structures.

Ultraprecise Tissue Dissection
THUNDERBEAT allows for sharp and blunt tissue dissection even in hard-to-reach places, such as deep pelvic areas. This is achieved through the wide reach of the tip, the high tip-opening force, and the slim tip design to enter planes most accurately.

Optimal Temperature Control
THUNDERBEAT Type S with Intelligent Tissue Monitoring (ITM) offers precise dissection close to vital structures thanks to minimal thermal spread and an accurately targeted application of energy to the tissue. ITM is the world’s first and only safety assist system for ultrasonic-driven technologies that automatically stops the energy output when the tissue transection is complete. This leads to a decrease in the residual probe temperature by 26.9%, which consequently reduces the risk of accidental tissue damage. The result is a safer and more streamlined operation.

How Intelligent Tissue Monitoring Works

1. Detection of sudden pressure change on probe
2. Transmission of the information to the generator
3. Immediate stop of energy supply with audible feedback
4. Start of cooling phase

High Operating Speed

The fast tissue transection with less interrupting instrument exchanges leads to a reduced operating time and allows surgeons to concentrate more on surgery over the whole length of the procedure.

Fastest-in-Class Tissue Cutting
The unique hybrid technology causes a synergy effect that leads to unprecedented fast tissue transection.

All-in-One Versatility
In addition to these benefits of the hybrid technology, the patented tip and ergonomic handle design make THUNDERBEAT a true multifunctional instrument for laparoscopic and open surgery:
- Enhanced atraumatic tissue grasping and uniform tissue compression due to the unique wiper-jaw technology,
- High tip-opening forces facilitate blunt tissue dissection and manipulation,
- Fast and reliable hemostasis even under challenging conditions,
- Reduced mist generation for improved visibility due to proprietary tip design.

The resulting potential saving of material and time makes THUNDERBEAT one of the most efficient advanced energy instruments on the market.

ITM is the world’s first and only safety assist system for ultrasonic-driven technologies that automatically stops the energy output when the tissue transection is complete. This leads to a decrease in the residual probe temperature by 26.9%, which consequently reduces the risk of accidental tissue damage. The result is a safer and more streamlined operation.

How Intelligent Tissue Monitoring Works

1. Detection of sudden pressure change on probe
2. Transmission of the information to the generator
3. Immediate stop of energy supply with audible feedback
4. Start of cooling phase

THUNDERBEAT Type S

The fast tissue transection with less interrupting instrument exchanges leads to a reduced operating time and allows surgeons to concentrate more on surgery over the whole length of the procedure.

Fastest-in-Class Tissue Cutting
The unique hybrid technology causes a synergy effect that leads to unprecedented fast tissue transection.

All-in-One Versatility
In addition to these benefits of the hybrid technology, the patented tip and ergonomic handle design make THUNDERBEAT a true multifunctional instrument for laparoscopic and open surgery:
- Enhanced atraumatic tissue grasping and uniform tissue compression due to the unique wiper-jaw technology,
- High tip-opening forces facilitate blunt tissue dissection and manipulation,
- Fast and reliable hemostasis even under challenging conditions,
- Reduced mist generation for improved visibility due to proprietary tip design.

The resulting potential saving of material and time makes THUNDERBEAT one of the most efficient advanced energy instruments on the market.

THUNDERBEAT Type S

1. Detection of sudden pressure change on probe
2. Transmission of the information to the generator
3. Immediate stop of energy supply with audible feedback
4. Start of cooling phase

**Data on file, Olympus Corporation**

*Fagotti et al., Randomized study comparing use of THUNDERBEAT technology vs standard electrosurgery during laparoscopic radical hysterectomy and pelvic lymphadenectomy for gynecologic cancer. J Minim Invasive Gynecol. 2014 May-Jun;21(3):447-53*
Olympus Energy Solutions Work Together to Provide:

**Electrosurgery**

**ESG-400 – A Fully Equipped, Latest-Generation HF Generator**
Optimizing your state-of-the-art electrosurgery in all surgical disciplines for monopolar, bipolar, and advanced bipolar modes for open, laparoscopic, and endoscopic applications, as well as transurethral or transcervical resection (TURs/TCRs).

**Ultrasonic Surgery**

**USG-400 – Ultrasonic Energy for Advanced Tissue Management**
The USG-400 Generator provides ultrasonic energy for the SONICBEAT Ultrasonic Dissector.

**Combined Energy Surgery**

**Surgical Tissue Management System (THUNDERBEAT Platform)**
Both surgical energy generators combined provide a unique platform that delivers the most widely used energy requirements to the surgical suite, eliminating the need for multiple devices in the operating room.

**Visibility**
The Olympus Surgical Tissue Management System communicates intelligently with the Olympus insufflators (UHI-3 and UHI-4) in order to evacuate any smoke and mist whenever required during laparoscopic surgery. Coupled with the reduced mist production of the THUNDERBEAT laparoscopic instruments and Olympus imaging equipment, the surgeon enjoys the best possible visualization.

**Utility**
Olympus energy devices can be seamlessly integrated into the Olympus ENDOALPHA OR solutions. This enables clinical staff to easily select the desired function of THUNDERBEAT directly from the HomeScreen user interface of UCES-3. It also allows for intuitive navigation through the device using the touch screen or voice control.
UCES-3 offers centralized one-touch control for all sterile and/or non-sterile medical devices – for example, electrosurgical generators, surgical cameras, or surgical lights and tables, providing greater efficiency and improved ergonomics during procedures. Finally, the Scene Selection function, an intelligent combination of user- and procedure-specific actions operated using one-touch control:
- Helps to standardize procedures,
- Decreases turnaround time,
- Enhances quality and overall workflow.
THUNDERBEAT Study Summaries
Overview

Animal
Ear, Nose, Throat
General Surgery
Gynecology
**Animal**

- **Applewhite et al. (2017)** — Ultrasonic, Bipolar, and Integrated Energy Devices: Comparing Heat Spread in Collateral Tissues

- **Brecht et al. (2018)** — Implementation of a Novel Efficacy Score to Compare Sealing and Cutting Devices in a Porcine Model

- **Kwak et al. (2016)** — Thermal Injury of the Recurrent Laryngeal Nerve by THUNDERBEAT during Thyroid Surgery: Findings from Continuous Intraoperative Neuromonitoring in a Porcine Model

- **Milsom et al. (2012)** — Evaluation of the Safety, Efficacy, and Versatility of a New Surgical Energy Device (THUNDERBEAT) in Comparison with Harmonic ACE, LigaSure V, and EnSeal Devices in a Porcine Model

- **Seelhofer et al. (2012)** — Safety and Efficacy of New Integrated Bipolar and Ultrasonic Scissors Compared to Conventional Laparoscopic 5-mm Sealing and Cutting Instruments

- **Tanaka et al. (2015)** — Evaluation of Vessel Sealing Performance among Ultrasonic Devices in a Porcine Model
Study Summary

Ultrasonic, Bipolar, and Integrated Energy Devices: Comparing Heat Spread in Collateral Tissues

Megan Applewhite, Michael White, Benjamin James, Layth Abdulrasool, Edwin L. Kaplan, Peter Angelos, Raymon Grogan
Department of Surgery, University of Chicago, Chicago, Illinois

Conclusion
The study showed a similar heat transfer of THUNDERBEAT Open Fine Jaw and all other devices for different tissue types. Harmonic Focus showed higher temperatures when used in liver at short distance (1 mm). The distance-to-injury of the recurrent laryngeal nerve (RLN) was ≥ 2 mm for all devices.

Objective
To compare THUNDERBEAT (TB), LigaSure (LS), and Harmonic Focus (HF) relating to thermal spread and recurrent laryngeal nerve (RLN) functional data

Design
Comparative experimental animal study (porcine model)

Indication
Thermal spread: muscle, liver and thyroid tissue

Subjects
Porcine model

Results
- No statistically significant difference between devices in heat generated by LS, TB and HF
- There was no significant difference of the mean maximum temperature at any measured distance from the devices in liver tissue, muscle, or thyroid tissue
- There was no injury to the RLN with any device at a distance of ≥ 2 mm
- Injury occurred with all three devices when fired at a distance of ≤ 1 mm from the RLN

Key Findings
- When compared to the LS and the HF devices, the TB device showed equivalent lateral heat spread in open surgery on various types of tissue
- The distance-to-injury of the RLN was also comparable in all three devices: (≥ 2 mm)
Study Summary
Implementation of a Novel Efficacy Score to Compare Sealing and Cutting Devices in a Porcine Model

Lea Brecht, Markus Wallwiener, Sarah Schott, Christoph Domschke, Christine Dinkic, Michael Golatta, Florian Schuetz, Herbert Fluhr, Albrecht Stenzinger, Marietta Kirchner, Christof Sohn, Joachim Rom
Department for Internal Medicine, St. Josef’s Hospital, Heidelberg, Germany

Objective
To compare the safety and efficacy of nine laparoscopic sealing and cutting devices by means of a new score (SCD)

Design
Comparative study

Indication
Vessel sealing and burst pressure (BP), thermal spread (TS), maximum heat, sealing/cooling time (ST/CT), and compression strength over the full jaw

Subjects
German domestic pigs weighing 40 – 60 kg

Results
· All sealed vessels with different devices could withstand a median BP of more than 300 mmHg (range 112 – 2046 mmHg)
· Higher temperatures and faster tissue cooling was found with the use of ultrasonic devices compared to bipolar devices
· The median compression area for the ultrasonic devices was 67 mm² and that for the bipolar devices was 98 mm²

Key Findings
· The burst pressure measurements showed reliable sealing results on explanted porcine arteries
· All instruments had a similar closing pressure and a decrease of this pressure from the base to the tip
· Instruments can reach temperatures above 350°C (SC), but the temperature of the tissue did not exceed 94°C (BCf)
· HA reached 233.5°C, LS reached 94.1°C, and the median temperature of TB was 232°C
· Sealed tissue takes up to 80 s (BCf) to cool to body temperature (38°C)

Conclusion
This study compared the majority of the laparoscopic cutting and sealing devices and showed that all tested instruments (Ligasure [L], Sonicision [SC], BiCision [BC], BiClamp fenestrated [BCf], BiClamp Maryland [BCm], Enseal [ES], Harmonic [HA], MarSeal [MS], THUNDERBEAT [TB]) are safe for daily use. An indirect comparison of the devices by means of the new SCD scoring system is also possible.
Study Summary

Thermal Injury of the Recurrent Laryngeal Nerve by THUNDERBEAT during Thyroid Surgery: Findings from Continuous Intraoperative Neuromonitoring in a Porcine Model

Hee Yong Kwak, Gianlorenzo Dionigi, Dasom Kim, Hye Yoon Lee, Gil Soo Son, Jae Bok Lee, Jeoung Won Bae, Hoon Yub Kim
Department of Surgery, Korea University College of Medicine, Seoul, South Korea

Conclusion
This study assessed the safety profile of THUNDERBEAT (TB) and showed that it can be used safely 3 mm from the RLN, at least 1 mm to avoid injury, but must be used for <8 s at more proximal locations.

Objective
To examine safe application of TB proximal to the recurrent laryngeal nerve (RLN) during thyroidectomy

Design
Experimental animal study using a porcine model

Indication
Threshold for thermal injury of RLN

Subjects
Four Yorkshire-Landrace-Duroc female piglets weighing 30 – 40 kg

Results
- TB showed no adverse event/injury of the RLN when applied at a distance of at least 3 mm
- At 2 mm neuromonitoring remains unaffected as long as TB activation time is limited to less than 8 seconds
- A substantial change in RLN function can be observed when TB is operated within a 1 mm distance
- No decrease in amplitude (>50%) or increase in latency (> 10%) when the distance between the RLN and TB application was >3 mm, and the duration of application did not affect RLN signals at these distances

Key Findings
- Lateral thermal damage from TB is minimal
- TB can be safely applied >3 mm from the RLN
- Direct contact or close proximity use of TB should be discouraged
Study Summary

Evaluation of the Safety, Efficacy, and Versatility of a New Surgical Energy Device (THUNDERBEAT) in Comparison with Harmonic ACE, LigaSure V, and EnSeal Devices in a Porcine Model.

Jeffrey Milsom, Koiana Trencheva, Sebastien Monette, Raghava Pavoor, Parul Shukla, Junjun Ma, Toyooki Sonoda
Department of Surgery, Weill Cornell Medical College, New York, New York

Conclusion
THUNDERBEAT (TB) provides a faster dissection speed, similar bursting pressure, acceptable thermal spread, and a higher versatility score compared to other devices. TB is a promising, safe alternative for cutting, coagulation, and tissue dissection during surgery. Its use in human surgery seems promising due to increased versatility and reduction of time.

Objective
To evaluate the versatility, bursting pressure, thermal spread, and dissection time of TB compared with other available devices: Harmonic ACE (HA), LigaSure (LS), and EnSeal (ES)

Design
Ex vivo experimental animal study using a porcine model

Indication
Vessel (2 cm long) sealing: small (2 – 3 mm), medium (4 – 5 mm) and large (6 – 7 mm) diameter arteries; burst pressure and histological evaluation

Subjects
Ten female Yorkshire pigs weighing 30 – 35 kg

Results
· The versatility score, calculated based on scoring of hemostasis, histologic sealing, cutting, dissection, and tissue manipulation, was significantly higher for TB in comparison to the other three devices (p < 0.05)
· The burst pressure varied with vessel size but was similar for all four devices
· Thermal spread was similar between TB and each of the other three devices
· TB produced less charring than ES but a comparable amount to HA and LS
· Dissection time was lower with TB compared with the other three devices (p < 0.01)

Key Findings
· TB is a highly versatile instrument, demonstrating excellent hemostasis and sealing quality
· Tissue manipulation with TB was superior to that with the bipolar devices, likely due to the jaw design
· Seals performed with TB demonstrate comparable burst pressures and thermal spread to other devices.
· The TB device is a safe and effective alternative to the other commercially available electrosurgical instruments
Surgical Endoscopy and Other Interventional Techniques (2012)

Study Summary

Safety and Efficacy of New Integrated Bipolar and Ultrasonic Scissors Compared to Conventional Laparoscopic 5-mm Sealing and Cutting Instruments

Daniel Seehofer, Martina Mogl, Sabine Boas-Knoop, Juliane Unger, Anja Schirmeier, Sascha Chopra, Dennis Eurich
Department of General, Visceral and Transplantation Surgery, Charite-Universitätsmedizin Berlin, Campus Virchow-Klinikum, Berlin, Germany

Conclusion
THUNDERBEAT had the fastest dissection in combination with the highest burst pressure values and surpasses the dissection speed of ultrasonic devices with the sealing efficacy of bipolar clamps.

Objective
Compare the safety and efficacy of the integrated bipolar/ultrasonic THUNDERBEAT (TB) with conventional ultrasonic scissors (Harmonic Ace, HA) and a bipolar vessel clamp (LigaSure, LS)

Design
Randomized preclinical in vivo trial using a porcine model

Indication
· Vessel cutting and sealing: small, medium, and large arteries
· Small bowel mesentery dissection

Subjects
Eight German Landrace pigs weighing 45 – 60 kg

Results
· Cutting speed was significantly higher for TB than for the other two devices (HA and LS)
· The burst pressure of TB in the larger-artery category (5 – 7 mm) was superior to that of HA
· In the small diameter group (2 – 4 mm) the burst pressure was similar for all devices
· The dissection speed of TB was significantly faster than that of LS
· Heat production of TB and HA was comparable

Key Findings
· TB is able to cut and seal arteries at a faster rate than both the harmonic HA and the ultrasonic LS
· The efficacy of vessel sealing using TB has the capacity to be at least as good as that obtained using HA or LS, with a better quality of seal possible for large arteries using TB in comparison to HA
· In terms of safety, TB and HA were comparable, with similar heat production profiles and lack of histological damage to the small bowel wall after dissection of the mesentery
Study Summary

Evaluation of Vessel Sealing Performance among Ultrasonic Devices in a Porcine Model

Ryota Tanaka, Matthew Gitelis, Danny Meiselman, Bijan Abar, Matthew Zapf, JoAnn Carbray, Yalini Vigneswaran, Jin-Cheng Zhao, Michael Ujiki
Department of Surgery, Section of Minimally Invasive Surgery, NorthShore University HealthSystem, Evanston, IL, USA

Conclusion
THUNDERBEAT provides a faster cutting speed, similar burst pressure, and the most rapid and reliable and broader histological sealing. As a result, THUNDERBEAT may be safer and more reliable for tissue dissection and might reduce time during surgical procedures.

Objective
To analyze vessel sealing performance (cutting speed, burst pressure, etc.) among the three most common commercially available ultrasonic energy devices: Sonicision (SC), Harmonic ACE (HA), and THUNDERBEAT (TB)

Design
Experimental animal study (in vivo porcine model)

Indication
Cutting speed in vivo, burst pressure, and seal failure. Width of tissue seal was examined histologically

Subjects
Eight female Yorkshire pigs weighing 30 – 35 kg; a total of 47 arteries and 37 veins were harvested

Results
· Cutting speed was significantly faster with TB (3.4 ± 0.7 seconds) than with SC and HA (5.8 ± 2.4 and 6.1 ± 3.1 seconds; p < .0001) in both vessel types
· Histological sealing width with TB was significantly longer than with SC and HA (p < .0001)
· SC and HA had two seal failures, while no failure was reported in the TB group
· Burst pressure tended to be higher with TB, but not statistically significantly

Key Findings
· TB demonstrated the fastest cutting speed and broader histological sealing, resulting in slightly higher burst pressure compared to the other devices
· TB was considered as safe and more reliable in tissue dissection, and also as a time-efficient instrument during surgical procedures
Van Slycke et al. (2016) — Comparison of the Harmonic Focus and the THUNDERBEAT for Open Thyroidectomy
Study Summary

Comparison of the Harmonic Focus and the THUNDERBEAT for Open Thyroidectomy

Langenbeck’s Archives of Surgery (2016)

Sam Van Slycke, Jean-Pierre Gillardin, Klaas Van Den Heede, Joan Minguet, Hubert Vermeersch and Nele Brusselaers
Department of General and Endocrine Surgery, Onze-Lieve-Vrouw (OLV) Clinic Aalst, Moorselbaan 164, 9300 Aalst, Belgium

Evidence-Based Conclusion
THUNDERBEAT is noninferior to the Harmonic Focus in patients undergoing partial or total thyroidectomy when looking at length of hospitalization, blood loss and duration of surgery.

Objective
Compare the efficacy and safety of the THUNDERBEAT with the Harmonic Focus in a cohort of consecutive patients who underwent open thyroidectomy.

Design
Retrospective single-center clinical study with prospectively collected data (2009-2014).

Indication
Patients with partial or total open thyroidectomy (with or without neck dissection).

Patients
761 consecutive patients.

Main Results
- THUNDERBEAT is noninferior to the Harmonic Focus in terms of days spend in hospital, minutes spend on the surgery and blood loss
- Both devices showed similar results when partial thyroidectomy was performed.
- Devices have differences in procedural time and length of hospitalization when thyroidectomy was performed.
- THUNDERBEAT showed a trend towards a lower postoperative complication rate or lower incidence of transient recurrent nerve paralysis.

Key Findings
- THUNDERBEAT performance was the same as the Harmonic Focus device in patients undergoing partial or total thyroidectomy.
General Surgery

Liberman et al. (2014) — Pilot Study of Pulmonary Arterial Branch Sealing Using Energy Devices in an Ex Vivo model

Milsom et al. (2015) — A Prospective Trial Evaluating the Clinical Performance of a Novel Surgical Energy Device in Laparoscopic Colon Surgery

Steinemann et al. (2016) — Efficacy and Safety of Combined Ultrasonic and Bipolar Energy Source in Laparoscopic Surgery

Weyhe et al. (2017) — Experience and Dissection Device Are More Relevant than Patient-Related Factors for Operation Time in Laparoscopic Sigmoid Resection – A Retrospective 8-Year Observation Study
Study Summary

Pilot Study of Pulmonary Arterial Branch Sealing Using Energy Devices in an Ex Vivo model

Moishe Liberman, Mohamed Khereba, Eric Goudie, Jordan Kazakov, Vicky Thiffault, Edwin Lafontaine and Pasquale Ferraro
Division of Thoracic Surgery, Centre Hospitalier de l’Universite de Montreal, Quebec, Canada

Conclusion
Energy sealing of pulmonary arterial (PA) branches with four commercially available energy devices was effective and PA branches were shown to sustain high intraluminal bursting pressures in a simulated ex vivo environment.

Objective
To compare the efficacy of four (EnSeal [ES], Harmonic Ace [HA], LigaSure [LS], THUNDERBEAT [TB]) commercially available energy sealing devices in PA branch sealing and division using an ex vivo PA sealing model

Design
Pilot study using an ex vivo model

Indication
Pulmonary arterial branch sealing

Subjects
Anatomical lung resection of 11 patients with non-hilar tumors and 3 specimens from transplant recipients

Results
- There were no sealing failures in any PA branch sealed with TB and HS; one failure in LS and one failure in ES occurred
- Devices using ultrasound energy (HA, TB) seemed superior to advanced bipolar technology (LS and ES) in sealing PAs
- Mean bursting pressure was highest (847 mmHg) when a combination of the two technologies was used (TB), followed by HA (415 mmHg)

Key Findings
- Sealing of pulmonary arterial branches was successfully achieved ex vivo using four different energy devices in a pilot study
- Ultrasound technology appeared to be more effective than advanced bipolar
- The combination of ultrasound and bipolar energy in TB resulted in higher burst pressures in comparison to HA, LS, and ES

Specifications, design, and accessories are subject to change without any notice or obligation on the part of the manufacturer.
Surgical Endoscopy and Other Interventional Techniques (2015)

Study Summary

A Prospective Trial Evaluating the Clinical Performance of a Novel Surgical Energy Device in Laparoscopic Colon Surgery

Jeffrey Milsom, Koiana Trencheva, Toyooki Sonoda, Govind Nandakumar, Parul Shukla, Sang Lee
Department of Surgery, Weill Cornell Medical College, New York, New York

Conclusion
For right and left laparoscopic colectomy procedures THUNDERBEAT (TB) can be effectively used as a tissue dissector and vessel ligator, and operation times can be reduced due to faster dissection.

Objective
To evaluate the clinical performance of the TB device during laparoscopic right and left colectomy

Design
Prospective single-center pilot study

Indication
Laparoscopic colon resection for neoplasm (tissue dissection and vessel ligation)

Patients
30 patients: 12 with right and 18 with left laparoscopic colon resection

Results
· Mean surgical procedure time was 163 ± 86 min and mean time for dissection using the TB device was 80.6 ± 35 min
· All major vessel ligations were successfully completed and with no hemostasis failure
· A median number of three TB applications were needed to seal the inferior mesenteric artery, with the other major arterial vessels requiring a median of two
· No intraoperative complications (bleeding, thermal injury, or organ injury) related to TB were noted
  Like with other ultrasonic devices, the TB jaw gets very hot and care is needed to avoid vital structure injuries
· The median hospital stay was four (3 – 10) days, and there was no mortality at 30-day follow-up

Key Findings
· TB is a safe and efficient device for use in laparoscopic colon resection
· Hemostasis was successfully maintained both intraoperatively and postoperatively
· TB is highly effective for both tissue dissection and blood vessel ligation

Specifications, design, and accessories are subject to change without any notice or obligation on the part of the manufacturer.
Conclusion
THUNDERBEAT (TB) showed reliable and effective hemostasis. Nevertheless, the surgeon should avoid any tension on the vessel during dissection to allow safe coagulation. As for any kind of electrosurgery, the hot tip of the instruments bear the risk of a possible thermal injury.

Objective
To evaluate TB efficacy and possible adverse events

Design
Consecutive series (prospective study)

Indication
Large vessel dissection in laparoscopic surgery

Patients
683 consecutive patients underwent laparoscopic procedures: 291 patients: gynecology, 254 patients: colorectal, 111 patients: upper GI, and 27 patients: GS

Results
- The complication and bleeding rate did not change (two sealing failures with subsequent bleeding)
- TB allowed the omission of vascular clips and staplers in laparoscopic surgery at the institution

Key Findings
- TB showed a high level of efficacy
- Using TB in laparoscopic procedures allowed the omission of vascular clips and staplers; in the case of any doubt additional clips should be used 
- As the tip of TB reaches high temperatures, caution is warranted while handling
Study Summary

Experience and Dissection Device Are More Relevant than Patient-Related Factors for Operation Time in Laparoscopic Sigmoid Resection – A Retrospective 8-Year Observation Study

Dirk Weyhe, Verena Nicole Uslar, Navid Tabriz, Ina Burkowski, Ralf Heinzle, Andreas Müller, Annette Belling, Ferdinand Köckerling

Clinic for Visceral Surgery, Pius-Hospital Oldenburg, Medical Campus University of Oldenburg, Oldenburg, Germany

Conclusion
The combination of bipolar coagulation and simultaneous ultrasonic dissection reduces the operation time of laparoscopic-assisted sigmoid resection, regardless of the surgeon’s experience. Patient-specific factors did not have a significant effect on operation time.

Objective
To investigate the influence of a new dissection technology (THUNDERBEAT [TB], Harmonic [HA], LigaSure [LS]) on the operation time considering other potentially influential factors

Design
Among a consecutive cohort study, 161 eligible operations performed by seven surgeons – three experienced and four inexperienced – were considered

Indication
Laparoscopic sigmoid resections: Complicated diverticulitis IIa and IIb, adenocarcinoma < T4

Patients
161 eligible operations performed by seven surgeons – three experienced and four inexperienced

Results
· The bimodal dissection device (BDD = TB) shortened the operation time by a median of 25 min to 30 min depending on the surgeon’s experience
· No significant time difference between experienced and inexperienced surgeons was detected for the BDD. A significant difference in operation time between these two groups was detected in the conventional dissection device (CDD) group
· No device-related complications were observed. Complications such as anastomotic leakage (BDD – 6% and CDD – 1%) were equally distributed between the groups

Key Findings
· Surgeon expertise and the dissection instrument were more decisive for the operation time than patient-related factors
· TB reduced operation time for experienced and inexperienced surgeons compared to the conventional dissection devices (HA and LS)
· No heat-related or any other device-related complications were observed
Gynecology

**Fagotti et al. (2013)** — Randomized Study Comparing Use of THUNDERBEAT Technology vs Standard Electrosurgery during Laparoscopic Radical Hysterectomy and Pelvic Lymphadenectomy for Gynecologic Cancer

**Lin et al. (2013)** — Application of a New Integrated Bipolar and Ultrasonic Energy Device in Laparoscopic Hysterectomies


**Roy et al. (2017)** — Impact of Energy Devices on the Post-Operative Systemic Immune Response in Women Undergoing Total Laparoscopic Hysterectomy for Benign Disease of the Uterus

**Steinemann et al. (2016)** — Efficacy and Safety of Combined Ultrasonic and Bipolar Energy Source in Laparoscopic Surgery
Study Summary

Randomized Study Comparing Use of THUNDERBEAT Technology
vs Standard Electrosurgery during Laparoscopic Radical Hysterectomy
and Pelvic Lymphadenectomy for Gynecologic Cancer

Anna Fagotti, Giuseppe Vizzielli, Francesco Fanfani, Valerio Gallotta, Cristiano Rossitto,
Barbara Costantini, Salvatore Gueli-Allelli, Nicola Avenia, Raffaella Iodice, Giovanni Scambia
Departments of Minimally Invasive Gynecology, University of Perugia, St. Maria Hospital, Terni, Italy

Conclusion
Surgeons (in this case experienced) can use the THUNDERBEAT (TB) system and conventional bipolar electrosurgery safely in laparoscopic radical hysterectomy. TB offers key advantages in intraoperative techniques and postoperative outcomes.

Objective
To compare operative time with the use of TB vs. the conventional technique using a bipolar grasper and cold and monopolar scissors (SES)

Design
Prospective randomized clinical trial

Indication
Laparoscopic radical hysterectomy with pelvic lymphadenectomy

Patients
50 women out of 71 with early cervical cancer/locally advanced cervical cancer or early stage endometrioid endometrial cancer

Results
· The median operative time of TB was approximately 30 minutes shorter than with SES
· TB and endometrial cancer were independently associated with shorter operating times
· No differences between TB and SES in terms of perioperative outcomes and postoperative complications
· Patients experienced less postoperative pain and required less analgesics when TB was used over SES

Key Findings
TB provides shorter operative times and less postoperative pain than the standard technique (SES) in patients with uterine cancer
Application of a New Integrated Bipolar and Ultrasonic Energy Device in Laparoscopic Hysterectomies

Harvard Lin, Ying Woo Ng, Anupriya Agarwal, Yoke Fai Fong
Department of Obstetrics and Gynecology, National University Hospital, Singapore

Conclusion
This study demonstrates the safe and efficient use of THUNDERBEAT (TB), making it a genuine alternative to the standard bipolar devices in laparoscopic hysterectomy.

Objective
To evaluate the safety and effectiveness of TB

Design
Retrospective study; operations were mainly done by three main surgeons and two residents

Indication
Coagulation, cutting, hemostasis dissection and tissue manipulation of uterine arteries

Patients
12 patients underwent a total laparoscopic hysterectomy (TLH) due to fibroids, endometriosis, or both: four cases of TLH only, six TLHs with bilateral salpingo-oophorectomy, and two TLHs with cystectomy

Results
· No complications were encountered intraoperatively or postoperatively
· TB successfully sealed all major vessels without the need for additional energy sources
· Hemostasis was good, and no incidents of postoperative bleeding or hematoma were reported
· Sealing/coagulation was effective with complete seal as noted at the end of each application of the “cut” mode
· Cutting was quick with complete tissue transection at each application

Key Findings
· TB is a safe and efficient alternative to conventional bipolar devices for use in laparoscopic hysterectomy
· The large blood vessels involved in hysterectomies can be effectively sealed and cut in one step using TB
· TB is easy to use and become familiar with

Specifications, design, and accessories are subject to change without any notice or obligation on the part of the manufacturer.
Conclusions

Due to its high versatility and multifunctional usage THUNDERBEAT (TB) will further enhance the feasibility of the minilaparoscopic hysterectomy approach, which results in reduced operating time and fewer instrument exchanges.

Objective

To highlight the first case of minilaparoscopic hysterectomy reported in Asia and the use of a new integrated energy platform, TB

Design

Case report

Indication

Vessel sealing; minilaparoscopic hysterectomy, coagulation, and cutting

Patient

51-year-old woman

Results

- TB provided good vessel sealing, coagulation, and cutting, so no instrument changes were needed
- Uterus was removed vaginally, with no complications
- 3 mm telescope from Karl Storz provided sufficient vision of pelvic structures

Key Findings

- A 5 mm port helped to facilitate traction of tissue and better dissection of the planes
- TB is proposed as an alternative instrumentation which ensures good coagulation, vessel sealing, and cutting throughout the surgery, without the need for instrument exchanges
- Karl Storz 3 mm bipolar forceps was not successful in hysterectomy, due to inadequate coagulation and vessel-sealing ability
Impact of Energy Devices on the Post-Operative Systemic Immune Response in Women Undergoing Total Laparoscopic Hysterectomy for Benign Disease of the Uterus

Kallol Kumar Roy, Netra GC, Seema Singhal, Juhi Bharti I, Sunesh Kumar, Dipendra K. Mitra, Ruma Ray, Jyoti Meena, Perumal Vanamail
Department of Obstetrics and Gynecology, All India Institute of Medical Sciences, New Delhi, India

Conclusion
A greater inflammatory response was seen after the use of LigaSure indicating greater tissue damage. However, this response was not correlated with any difference in postoperative recovery.

Objective
To evaluate and compare the inflammatory response in terms of cytokines and chemokines in total laparoscopic hysterectomy (TLH) using THUNDERBEAT (TB), Harmonic (HA), and LigaSure V (LS)

Design
Prospective randomized controlled study

Indication
Laparoscopic hysterectomy due to abnormal uterine bleeding (benign uterine disease that was not responsive to medical therapy); Postoperative systemic immune response: cytokine and chemokine levels pre-op and post-op (3, 24, and 72 h)

Patients
60 patients

Results
· In the LS group the increase in serum IL-6 levels was significantly higher compared to the TB and HA groups at 24 hours (p = 0.010). This indicates greater tissue damage in the LS group
· In terms of inflammatory response in levels of TNF-α, RANTES, MIP-1 α, and MIP-1 β, there was no significant difference between the LS, TB, and HA groups
· The levels of IL-2, IL-17, and IFN-γ markers did not rise at the chosen time points post-surgery

Key Findings
· Each device led to some amount of inflammatory response (rise in cytokines and chemokines) in the immediate postoperative period, with LS producing a more sustained and greater inflammatory response at 24 hours post-surgery
· No differences in postoperative outcomes with the use of any of the devices was found
Conclusion

THUNDERBEAT (TB) showed reliable and effective hemostasis. Nevertheless, the surgeon should avoid any tension on the vessel during dissection to allow safe coagulation. As for any kind of electrosurgery, the hot tip of the instruments bear the risk of a possible thermal injury.

Objective
To evaluate TB efficacy and possible adverse events

Design
Consecutive series (prospective study)

Indication
Large vessel dissection in laparoscopic surgery

Patients
683 consecutive patients underwent laparoscopic procedures: 291 patients: gynecology, 254 patients: colorectal, 111 patients: upper GI, and 27 patients: GS

Results
- The complication and bleeding rate did not change (two sealing failures with subsequent bleeding)
- TB allowed the omission of vascular clips and staplers in laparoscopic surgery at the institution

Key Findings
- TB showed a high level of efficacy
- Using TB in laparoscopic procedures allowed the omission of vascular clips and staplers; in the case of any doubt additional clips should be used
- As the tip of TB reaches high temperatures, caution is warranted while handling
THUNDERBEAT Product Information

Unique Hybrid Technology

THUNDERBEAT is the world’s first and only advanced energy system that simultaneously delivers two well-established forms of energy to a tissue:

- **Ultrasonic energy** for superior dissection and fast tissue-cutting capability.
- **Advanced bipolar energy** for fast and secure hemostasis for vessels up to and including 7 mm in diameter.

The combination doubles your energy — and sets new standards in the application of advanced energy in the operating room.

![Ultrasonic Energy Only](image1)

Ultrasonic Energy Only

![Bipolar Energy Only](image2)

Bipolar Energy Only

![THUNDERBEAT](image3)

THUNDERBEAT

Rapid tissue cutting

Reliable vessel sealing

Rapid tissue cutting and reliable vessel sealing

---

**THUNDERBEAT Performance in General Surgery**

To learn more about the unbeatable versatility in general surgery procedures such as colorectal, hepatobiliary, bariatric and thyroid surgery, please visit the Olympus website at:

[www.olympus.eu/medical](http://www.olympus.eu/medical)
THUNDERBEAT has an equivalent level of reliably sealing vessels ≤ 7 mm Ø compared to all competitors but achieves superior sealing performance in terms of shorter sealing cycles.

### Burst Pressure (all)

<table>
<thead>
<tr>
<th>Device</th>
<th>Probability</th>
<th>Burst Pressure (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harmonic ACE+7 AH mode</td>
<td>99.2%</td>
<td>1,537.3</td>
</tr>
<tr>
<td>LigaSure Maryland Lv. 2/3</td>
<td>99.2%</td>
<td>1,259.5</td>
</tr>
<tr>
<td>THUNDERBEAT Type S S&amp;C Lv. 1</td>
<td>99.9%</td>
<td>1,521.6</td>
</tr>
</tbody>
</table>

3 times normal systolic blood pressure:

- 360 mmHg
- 500 mmHg
- 1,000 mmHg
- 1,500 mmHg
- 2,000 mmHg
- 2,500 mmHg

### Sealing Cycle

<table>
<thead>
<tr>
<th>Device</th>
<th>Sealing Cycle (sec)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harmonic ACE+7 AH mode</td>
<td>11.22</td>
</tr>
<tr>
<td>LigaSure Maryland Lv. 2/3</td>
<td>4.06</td>
</tr>
<tr>
<td>THUNDERBEAT Type S S&amp;C Lv. 1</td>
<td>2.51</td>
</tr>
</tbody>
</table>
THUNDERBEAT Performance Data

Safe Heat Management

THUNDERBEAT in SEAL & CUT mode and Harmonic ACE+7 reach the same temperature level to fully transect the tissue. The cooling time for both devices down to the level of reversible tissue damage is equivalent.

Max. Temperature*

Cooling Time to 42°C*

* Report number: 149P-1824: [Report] Max Temperature and Cooling Test Of the Grasping Section (bench)

THUNDERBEAT in SEAL mode and LigaSure Maryland reach the same temperature level to coagulate the tissue. Cooling time for both devices down to the level of reversible tissue damage is equivalent.

Max. Temperature*

Cooling Time to 42°C*

* MDD Comparison Data Report.
*** The mechanism of bipolar sealing of THUNDERBEAT Type S is the same as conventional THUNDERBEAT.
THUNDERBEAT Type S SEAL & CUT mode provides minimal lateral thermal spread/margin when compared to other leading energy devices.*

* LigaSure Maryland and Harmonic ACE+7

Report number: 149P-1911: Thermal effect test for in-house and competitor products
THUNDERBEAT Performance Data

Operational Speed

Faster cutting speed than existing ultrasonic and bipolar devices.
▶ Fastest-in-class cutting device on the market!

Cutting Cycle

<table>
<thead>
<tr>
<th>Device</th>
<th>Cutting Speed</th>
<th>Time (sec)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harmonic ACE+7 Lv. 5</td>
<td></td>
<td>42.51</td>
</tr>
<tr>
<td>LigaSure Maryland Lv. 2</td>
<td></td>
<td>50.79</td>
</tr>
<tr>
<td>THUNDERBEAT Type S S&amp;C Lv. 1</td>
<td></td>
<td>32.25</td>
</tr>
</tbody>
</table>

THUNDERBEAT is 32% faster
THUNDERBEAT is 63% faster
THUNDERBEAT Type S

Report number: 149P-1383: [Report] THUNDERBEAT Type S Ex-vivo Cutting Performance Comparative Test on Mesentery
THUNDERBEAT Performance Data

Dissection Capability

Finest tip design for precise dissection compared to Harmonic ACE+7 and LigaSure Maryland.

Tip Size (a)

<table>
<thead>
<tr>
<th></th>
<th>Harmonic ACE+7</th>
<th>LigaSure Maryland</th>
<th>THUNDERBEAT Type S</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tip Size (mm)</td>
<td>3.2</td>
<td>2.7</td>
<td>1.9</td>
</tr>
</tbody>
</table>

Tip Size (b)

<table>
<thead>
<tr>
<th></th>
<th>Harmonic ACE+7</th>
<th>LigaSure Maryland</th>
<th>THUNDERBEAT Type S</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tip Size (mm)</td>
<td>4.1</td>
<td>4.4</td>
<td>2.9</td>
</tr>
</tbody>
</table>

Report number: 149P-4313: [Report] THUNDERBEAT Type S Dissecting Test (Bench)
THUNDERBEAT Performance Data

Dissection Capability

Higher grasping force and widest jaw opening aperture compared to Harmonic ACE+7 and LigaSure Maryland.

Grasping Force

![Graph showing grasping force comparison]

Opening Aperture

![Bar chart showing opening aperture comparison]

Report number: 149P-4313: [Report] THUNDERBEAT Type S Dissecting Test (Bench)
THUNDERBEAT

Selected Evidence

Preclinical Evidence
Seehofer et al. 2012
All tested devices (HA, LS, TB) were equally able to safely divide arteries of up to 4 mm in diameter. THUNDERBEAT had the fastest dissection in combination with the highest burst-pressure values, even in vessels measuring 5-7 mm in diameter. According to the present data, THUNDERBEAT has the potential to surpass the dissection speed of ultrasonic devices with the sealing efficacy of bipolar clamps.

www.ncbi.nlm.nih.gov/pubmed/22447285

Clinical Evidence
Liberman et al. 2014
In this pilot study evaluating four commercially available energy devices (HA, LS, TB, ES), energy sealing of PA branches (ex vivo) was effective and showed to sustain high intraluminal bursting pressures in a simulated ex vivo environment. In this pilot study, ultrasound technology (HA, TB in cutting mode) seemed to be superior to advanced bipolar technology (LS, ES).

www.ncbi.nlm.nih.gov/pubmed/25125207

Milsom et al. 2015
The THUNDERBEAT device can be effectively used as a tissue dissector and vessel ligator in patients undergoing right and left laparoscopic colectomy procedures. It appears to save time through faster dissection.

www.ncbi.nlm.nih.gov/pubmed/25159634

Wehye et al. 2017
The combination of ultrasonic dissection and simultaneous bipolar coagulation reduces operation time of laparoscopic-assisted sigmoid resection, regardless of the surgeon’s expertise even taking the learning curve into account. Patient-specific factors did not show a significant effect on operation time. Device-related complications were not observed.

www.ncbi.nlm.nih.gov/pmc/articles/PMC5691094

European Medical Expert Training Centers
Olympus organizes Professional Education training courses in close cooperation with health care experts and leading teaching hospitals. These courses are aimed at supporting you in widening and improving your medical and technical skills in an empathetic and comprehensible manner for professional excellence in order to improve patient care. To learn more about the opportunities we offer for you to strengthen your procedure skills and competency in the safe and effective use of Olympus products, please visit the Olympus website at:

www.olympus-europa.com/medical/en/Professional-Education