

THUNDERBEAT

Система работы с тканью

Справочное руководство для медицинских работников



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Информация об изделии THUNDERBEAT

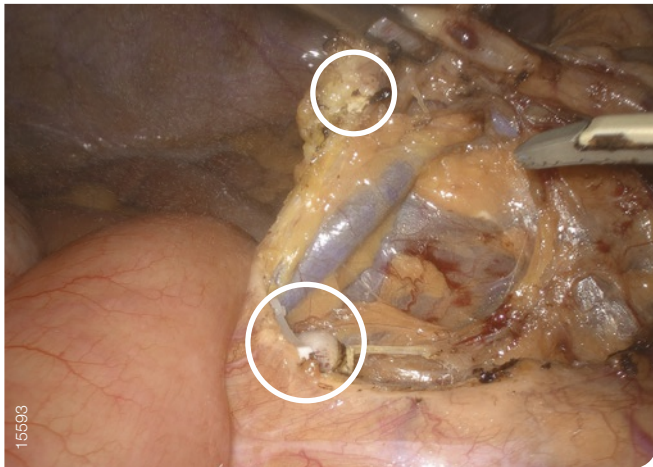
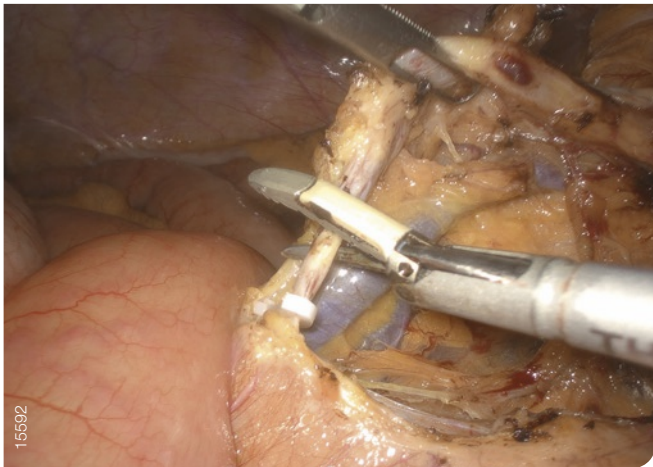
Единственный в мире инструмент с полностью интегрированными биполярной и ультразвуковой технологиями.

Улучшенный гемостаз

Меньшая кровопотеря и оптимальная видимость анатомических структур благодаря высокоточному первичному и вторичному гемостазу с использованием усовершенствованной биполярной технологии.

Первичный гемостаз и надежное сваривание сосудов диаметром 7 мм

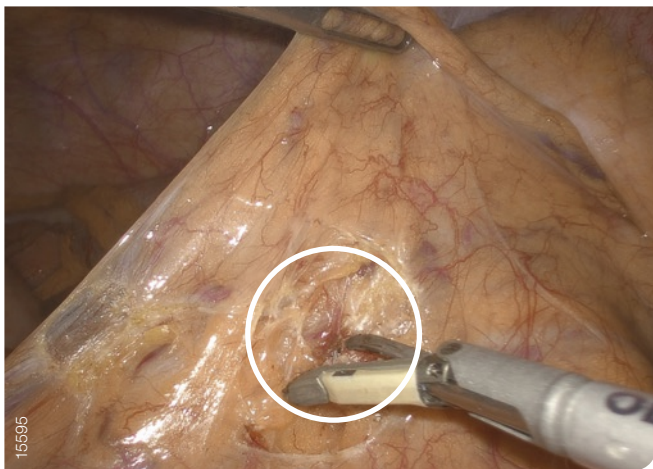
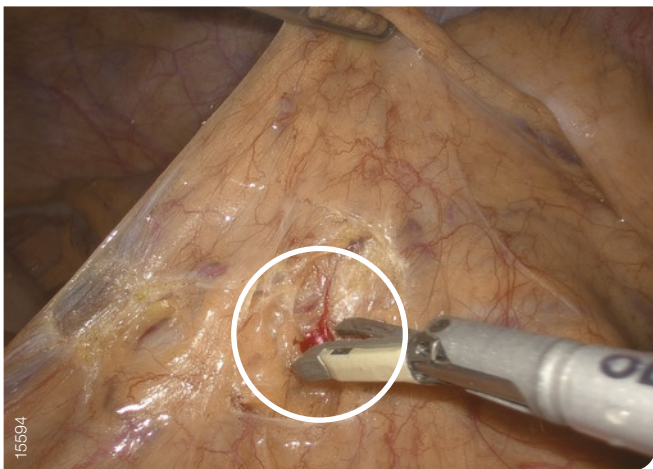
Одновременное использование двух типов энергии режима THUNDERBEAT SEAL & CUT (Сварка и резание) обеспечивает безопасность коагуляции и высокую скорость пересечения тканей. Благодаря возможности проведения предварительной коагуляции, а также надежному резанию и свариванию сосудов диаметром 7 мм требуется меньше шагов для лигирования сосудов.¹



Вторичный гемостаз

Режим THUNDERBEAT SEAL (Сварка) без одновременного резания позволяет:

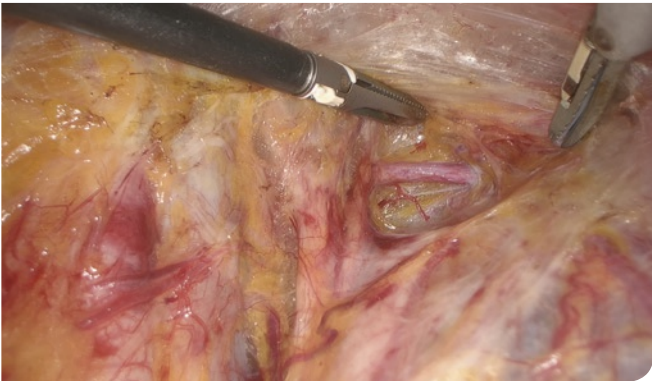
- выполнять немедленную сварку сосудов с повторно открывшимся кровотечением;
- контролировать диффузные кровотечения посредством точечной коагуляции;
- осуществлять предварительную сварку сосудов посредством точно направленной усовершенствованной биполярной энергии.



¹ Неопубликованные данные, кооперация Olympus

Превосходная точность разделения с контролем оптимальной температуры

Высокая точность ультразвуковой технологии позволяет безошибочно подготавливать требуемые анатомические слои, не повреждая жизненно важные структуры.



Сверхточное разделение тканей

Инструмент THUNDERBEAT позволяет выполнять острое и тупое разделение тканей даже в труднодоступных областях, таких как глубокие отделы таза. Это достигается за счет широкой направленности, высокой силы раскрытия и тонкого дизайна наконечника для более точного введения в требуемые области.

Контроль оптимальной температуры

Инструмент THUNDERBEAT Type S с функцией Intelligent Tissue Monitoring (ITM) предлагает высокоточное разделение тканей вблизи жизненно важных структур благодаря минимизации термического распространения и точности целевого воздействия энергии на ткань.² ITM — это первая и единственная в мире вспомогательная система безопасности для ультразвукового оборудования, которая автоматически прекращает подачу выходного сигнала по завершении пересечения тканей. В результате остаточная температура нагрева зонда снижается на 26,9 %, что, в свою очередь, уменьшает риск случайного повреждения тканей.³ Как итог — более безопасная и четко организованная процедура.

Принцип работы функции Intelligent Tissue Monitoring

- | | | | |
|--|---------------------------------|---|----------------------------|
| 1. Обнаружение внезапной смены давления на зонде | 2. Передача данных на генератор | 3. Мгновенное прекращение подачи энергии со звуковым сопровождением | 4. Запуск этапа охлаждения |
|--|---------------------------------|---|----------------------------|



^{2,3} Неопубликованные данные, кооперация Olympus

Высокая скорость работы

Быстрое пересечение тканей без необходимости затраты времени на смену инструментов снижает время операции и позволяет хирургам в большей степени сосредоточиться на самой процедуре, а не на ее длительности.

Самая высокая в своем классе скорость разрезания ткани

Уникальная гибридная технология несет в себе синергетический эффект, обеспечивая непревзойденно высокую скорость пересечения тканей.

Комплексная универсальность

Помимо перечисленных преимуществ гибридной технологии, запатентованный наконечник и эргономичный дизайн рукоятки делают THUNDERBEAT поистине многофункциональным инструментом для лапароскопических и открытых хирургических операций.

- Усовершенствованный метод атравматичного захвата тканей и равномерная компрессия тканей благодаря уникальной технологии скользящих браншей.
- Высокая сила раскрытия наконечника упрощает тупое разделение тканей и манипуляции с инструментом.
- Быстрый и надежный гемостаз, даже в сложных условиях.
- Уменьшенное образование аэрозоля для улучшения видимости благодаря запатентованному дизайну наконечника.

Итоговый потенциал экономии материалов и времени делает THUNDERBEAT одним из наиболее эффективных современных энергетических инструментов на рынке.⁴

THUNDERBEAT Type S



Рецензируемые публикации
по инструменту THUNDERBEAT

⁴ 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 май-июнь;21(3):447-53

Рецензируемые публикации по инструменту THUNDERBEAT: рефераты

1

Safety and efficacy of new integrated bipolar and ultrasonic scissors compared to conventional laparoscopic 5-mm sealing and cutting instruments

Seehofer D, Mogl M, Boas-Knoop S, Unger J, Schirmeier A, Chopra S, Eurich D.

Surg Endosc. 2012 Sep; 26(9): 2541-9

Background: Hemostasis is a central issue in laparoscopic surgery. Ultrasonic scissors and bipolar clamps are commonly used, with known advantages with each technique.

Methods: The prototype of new surgical scissors, delivering ultrasonically generated frictional heat energy and bipolar heat energy simultaneously THUNDERBEAT (TB), was compared to ultrasonic scissors Harmonic ACE (HA) and an advanced bipolar device LigaSure (LS) using a pig model. As safety parameters, temperature profiles after single activation and after a defined cut were determined. As efficacy parameters, seal failures and the maximum burst pressure (BP) were measured after in vivo sealing of vessels of various types and diameters (categories 2–4 and 5–7 mm). Moreover, the vertical width of the tissue seal was measured on serial histological slices of selected arteries. The cutting speed was measured during division of isolated arteries and during dissection of a defined length of compound tissue (10 cm of mesentery). Burst-pressure measurement and histological analysis were performed by investigators blinded to the used sealing device.

Results: Using the TB, the burst pressure in larger arteries was significantly higher (734 ± 64 mm Hg)

than that of the HA (453 ± 50 mm Hg). No differences in the rate of seal failures were observed. The cutting speed of the TB was significantly higher than that of all other devices. Safety evaluation revealed temperatures below 100 °C in the bipolar device. The maximum temperature of the HA and the TB was significantly higher. No relevant differences were observed between the HA and the TB.

Conclusions: The ultrasonic and bipolar technique of the TB has the potential to surpass the dissection speed of ultrasonic devices with the sealing efficacy of bipolar clamps. However, heat production that is comparable to conventional ultrasonic scissors should be minded for clinical use.

2

Postoperative efficacy and safety of vessel sealing: an experimental study on carotid arteries of the pig

Berdah SV, Hoff C, Poornorozy PH,

Razek P, Van Nieuwenhove Y.

Surg Endosc. 2012 Aug; 26(8): 2388-93

Background: The aim of this preclinical study was to analyze the burst pressure of large in vivo sealed vessels, not just immediately, but also in the first 7 postoperative days.

Methods: In 26 anesthetized pigs, the right carotid artery was sealed and cut using a novel device that integrates bipolar and ultrasonic energy. The animals were then awakened. They underwent a second surgical procedure after different follow-up periods

ranging from 1 to 7 days: the left common carotid artery was sealed and cut in the same way as the contralateral artery. Perioperative and postoperative clinical events, evolution of burst pressure over time, and comparison between immediate and delayed burst pressure were analyzed.

Results: All sealings were successful. There were no perioperative or postoperative complications. Median immediate (day 0) burst pressure was 949 mm Hg (IQR 781–1181). Burst pressure decreased postoperatively but was never below 500 mm Hg in any pig.

Conclusion: Postoperative variations are observed in the burst pressure of in vivo sealed arteries. Immediate burst pressure alone should not be used for validating vascular sealing devices.

3

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

Milsom J, Trencheva K, Monette S, Pavoor R, Shukla P, Ma J, Sonoda T.

J Laparoendosc Adv Surg Tech A. 2012 May; 22(4): 378-86

Background: THUNDERBEAT (TB) (Olympus, Japan) simultaneously delivers ultrasonically generated frictional heat energy and electrically generated bipolar energy. The aim of this study was to evaluate the versatility, bursting pressure, thermal spread, and dissection time of the TB compared with

commercially available devices: Harmonic ACE (HA) (Ethicon Endo-Surgery, USA), LigaSure V (LIG) (Covidien, USA), and EnSeal (Ethicon).

Methods: An acute study was done with 10 female Yorkshire pigs (weighing 30–35 kg). Samples 2 cm long of small (2–3 mm)-, medium (4–5 mm)-, and large (6–7 mm)-diameter vessels were created. One end of the sample was sent for histological evaluation, and the other was used for burst pressure testing in a blinded fashion. Versatility was defined as the performance of the surgical instrument based on the following five variables, using a score from 1 to 5 (1 = worst, 5 = best), adjusted by coefficient of variable importance with weighted distribution: hemostasis, 0.275; histologic sealing, 0.275; cutting, 0.2; dissection, 0.15; and tissue manipulation, 0.1. There were 80 trials per vessel group and 60 trials per instrument group, giving a total of 240 samples.

Results: Versatility score was higher ($P < .01$) and dissection time was shorter ($P < .01$) using TB compared with the other three devices. Bursting pressure was similar among TB and the other three instruments. Thermal spread at surgery was similar between TB and HA ($P = .4167$), TB and EnSeal ($P = .6817$), and TB and LIG ($P = .8254$). Difference in thermal spread was noted between EnSeal and HA ($P = .0087$) and HA and LIG ($P = .0167$).

Conclusion: TB has a higher versatility compared with the other instruments tested with faster dissection speed, similar bursting pressure, and acceptable thermal spread. This new energy device is an appealing, safe alternative for cutting, coagulation, and tissue dissection during surgery and should decrease time and increase versatility during surgical procedures.

A randomized study comparing the use of Thunderbeat technology vs. standard electrosurgery during laparoscopic radical hysterectomy and pelvic lymphadenectomy for gynecological cancer

A. Fagotti, G. Vizzielli, F. Fanfani, V. Gallotta, C. Rossitto, B. Costantini, S. Gueli-Alletti, N. Avenia, R. Iodice, G. Scambia

J Minim Invasive Gynecol. 2014 May-Jun;21(3):447-53

Study objective: To compare the use of Thunderbeat (TB) with standard electrosurgery (SES), during laparoscopic radical hysterectomy and pelvic lymphadenectomy for gynecological tumors, with respect to operative time

Design: Evidence obtained from a properly designed, randomized, controlled trial.

Design: classification: Canadian Task Force classification I

Setting: Gynecologic Oncology Unit of the Catholic University of the Sacred Heart in Rome

Patients: Fifty patients with early stage cervical cancer (FIGO stages IA2-IB1-IIA<2cm), locally

advanced cervical cancer (FIGO stages IB2-IIA>2cm-IIB) submitted to neo-adjuvant treatment (chemotherapy or radio-chemotherapy) showing a complete/partial clinical response and early stage endometrioid endometrial (FIGO stages IB-II) were randomly assigned to undergo TB (arm A) and SES (arm B)

Intervention: Laparoscopic radical hysterectomies with bilateral pelvic lymphadenectomy, with an easily reproducible technique were performed.

Measurements and main results: Fifty patients were available for the analysis, with 25 women randomly assigned to TB (arm A) and 25 to SES (arm B). The median operative time was 85 min vs. 115 min for TB and SES, respectively ($p=0.001$). At multivariate analysis, endometrial cancer ($p=0.0001$) and TB ($p=0.001$) were independently associated with less operating time. No differences in terms of peri-operative outcomes and post-operative complications were observed in both arms. Patients undergoing TB reported less post-operative pain, both at rest and after Valsalva' maneuver ($p=0.005$ and $p=0.008$, respectively), with less additional analgesics beside standard therapy than in arm B ($p=0.02$)

Conclusion: TB is associated with shorter operative time and less post-operative pain than standard technique (SES) in patients with uterine cancer.

Оценка технических характеристик инструмента THUNDERBEAT

Оценка технических характеристик инструмента THUNDERBEAT: подробный доклад

1

Качество сваривания сосудов инструментом THUNDERBEAT по сравнению с LigaSure V и EnSeal

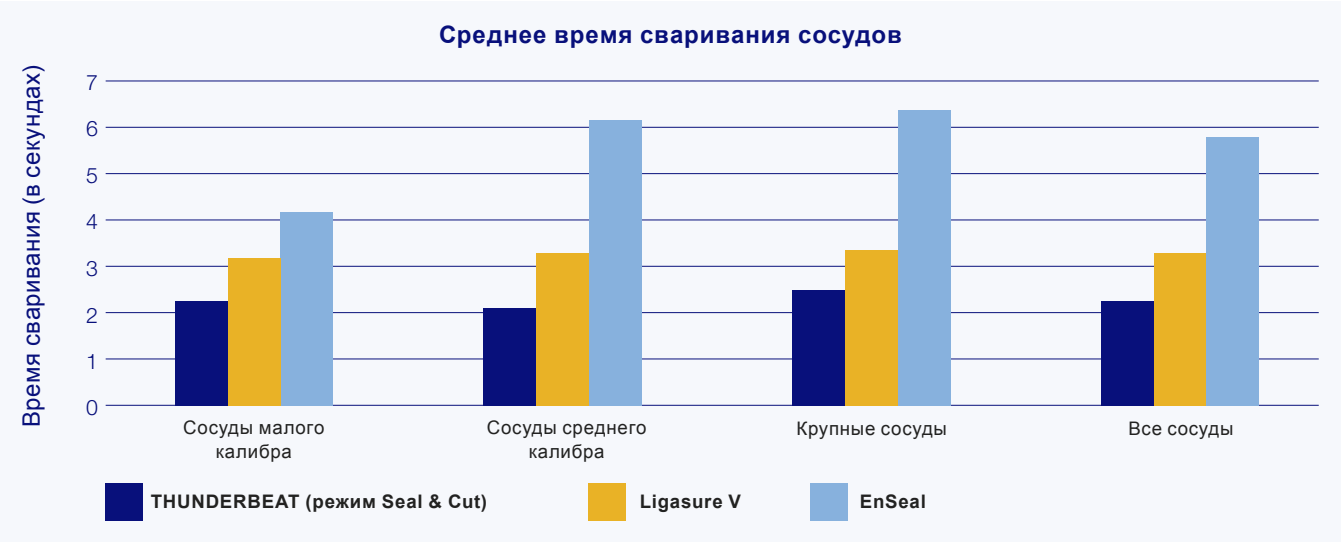
Olympus Medical Systems Corporation, Токио, ноябрь 2012 г.

Цель. Целью исследования являлась оценка качества сваривания сосудов (давление разрыва и скорость сваривания) инструментом THUNDERBEAT по сравнению с существующими на рынке устройствами (LigaSure V и EnSeal).

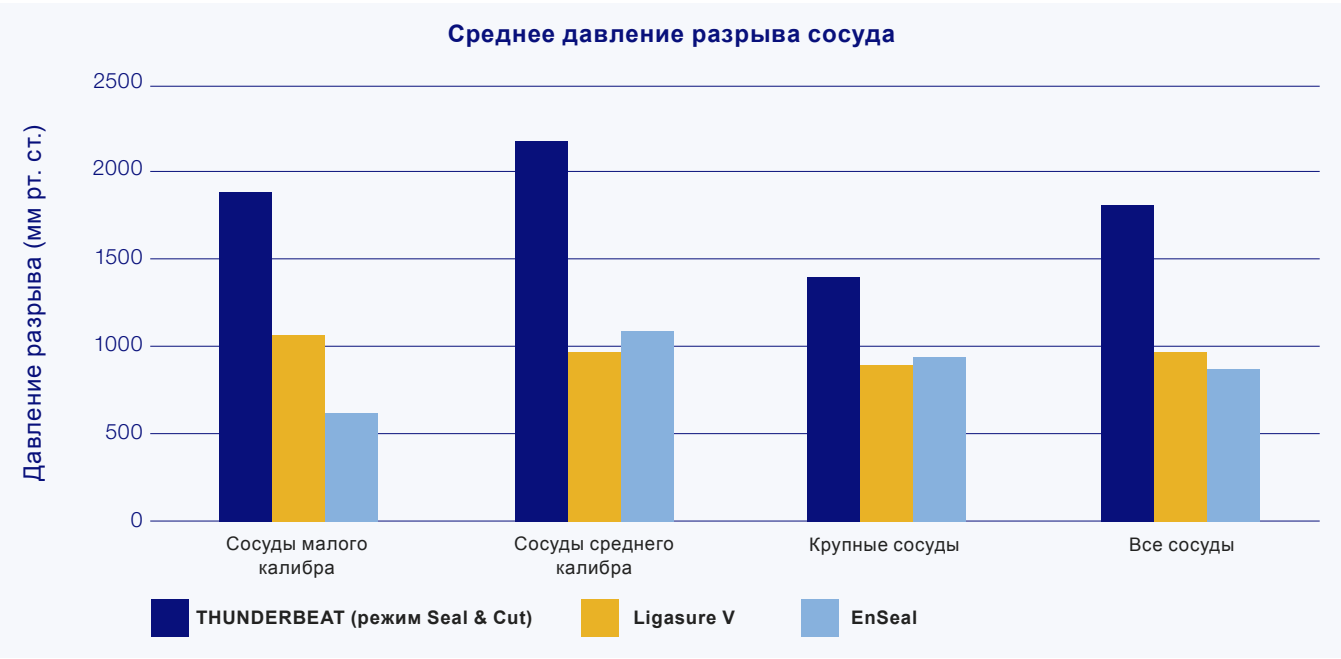
Методы. Испытания сваривания сосудов проводилось на сонных артериях, почечных артериях и селезеночных артериях, выделенных из модели свиньи. В группу кровеносных сосудов малого калибра вошли любые кровеносные сосуды диаметром не более 2,0 мм, сосудами среднего калибра обозначили любые кровеносные сосуды диаметром от 2,0 до 4,0 мм, а крупными — от 4,0 до 7,0 мм. Каждое устройство было применено для сваривания не менее 30 сосудов в каждой размерной категории. Каждый сосуд захватывался каждым проверяемым устройством в точке сваривания. Регистрировалось время, потребовавшееся на сваривание или сваривание и разрезание каждого сосуда. После сваривания сосуда с помощью манометра измеряли и регистрировали давление разрыва.

Результаты

Скорость сваривания сосудов					
Инструменты		Сосуды малого калибра	Сосуды среднего калибра	Крупные сосуды	Все сосуды
THUNDERBEAT (режим Seal & Cut)	Среднее время сваривания (в секундах)	2,48 ± 0,84	2,18 ± 0,34	2,62 ± 0,92	2,43 ± 0,76
	Среднее время сваривания (в секундах)	3,15 ± 0,34	3,24 ± 0,33	3,34 ± 0,28	3,24 ± 0,32
	Среднее время сваривания (в секундах)	4,25 ± 0,38	6,22 ± 0,34	6,39 ± 0,48	5,62 ± 1,05



Давление разрыва сосуда (мм рт. ст.)					
Инструменты		Малый	Средний	Крупный	Все сосуды
THUNDERBEAT (режим Seal & Cut)	Размер выборки	31	30	35	96
	Среднее давление разрыва	1848 ± 567	2150 ± 730	1364 ± 733	1766 ± 751
	Диапазон значений давления разрыва	929–3507	1052–3349	282–2822	282–3507
LigaSure V	Размер выборки	30	30	35	95
	Среднее давление разрыва	1073 ± 364	945 ± 373	869 ± 366	958 ± 373
	Диапазон значений давления разрыва	344–1944	378–2202	360–1902	344–2202
EnSeal	Размер выборки	30	31	34	95
	Среднее давление разрыва	623 ± 276	1074 ± 469	891 ± 355	866 ± 414
	Диапазон значений давления разрыва	213–1306	290–2175	327–1843	213–2175



Выводы. Применение THUNDERBEAT обеспечило более высокое среднее давление разрыва, чем LigaSure V или EnSeal, на всех проверенных калибрах сосудов. Кроме того, для THUNDERBEAT была зарегистрирована более высокая средняя скорость сваривания по сравнению с LigaSure V или EnSeal на всех проверенных калибрах сосудов. Вероятность достижения давления разрыва более 360 мм рт. ст. с помощью инструмента THUNDERBEAT в режиме Seal & Cut (Сварка и резание) составила 96,9 %. Для LigaSure V эта вероятность составила 94,5 %. EnSeal продемонстрировал вероятность достижения давления разрыва более 360 мм рт. ст. равную 88,9 %. Характеристики сваривания сосудов диаметром до 7 мм включительно инструментом THUNDERBEAT эквивалентны таковым для инструментов LigaSure V и EnSeal.

Оценка технических характеристик инструмента

THUNDERBEAT: подробный доклад

2

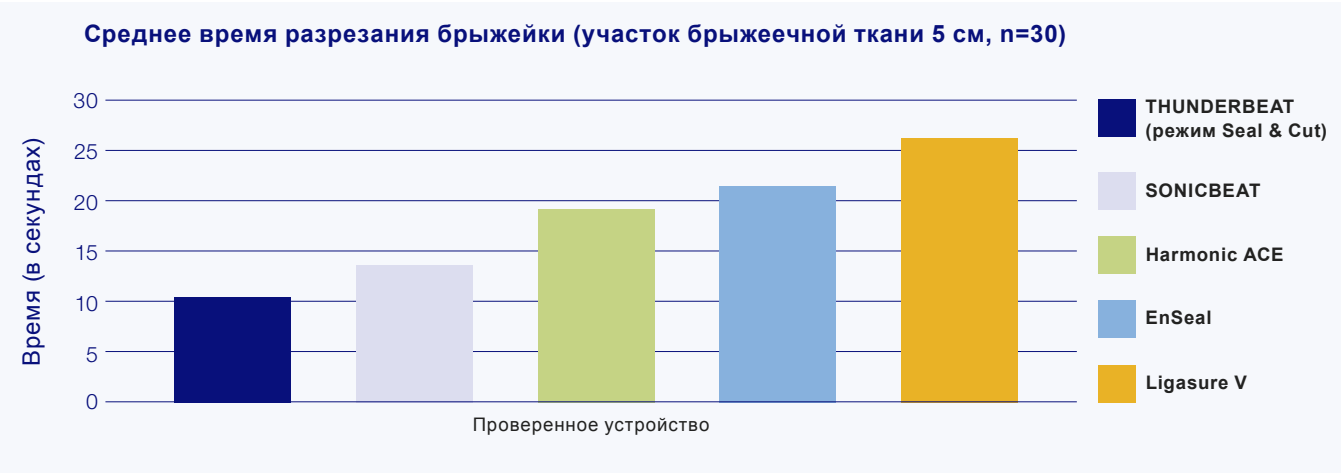
Скорость резания ткани THUNDERBEAT и SONICBEAT по сравнению с LigaSure V, Harmonic ACE и EnSeal
Olympus Medical Systems Corporation, Токио, ноябрь 2012 г.

Цель. Целью данного исследования являлось сравнение скорости разрезания ткани инструментами THUNDERBEAT и SONICBEAT по сравнению с существующими на рынке устройствами с применением общепринятой модели свиной ткани.

Методы. Проверка скорости разрезания ткани выполнялась с применением свиной брыжейки. Для получения надежных данных испытания работа с тканью проводилась таким образом, чтобы максимально близко воспроизвести условия in vivo. Участки ткани отбирались случайным образом, регистрировалось время, потребовавшееся для разрезания участка брыжеечной ткани 5 см. Для каждого устройства размер выборки составил 30 единиц.

Результаты

Скорость разрезания брыжейки в секундах		
THUNDERBEAT (Режим Seal & Cut)	Размер выборки	30
	Средняя скорость разрезания в секундах	10,7 ± 4,50
SONICBEAT	Размер выборки	30
	Средняя скорость разрезания в секундах	13,2 ± 4,18
LigaSure V	Размер выборки	30
	Средняя скорость разрезания в секундах	26,9 ± 8,00
Harmonic ACE	Размер выборки	30
	Средняя скорость разрезания в секундах	18,8 ± 3,80
EnSeal	Размер выборки	30
	Средняя скорость разрезания в секундах	21,6 ± 10,08



Вывод. Средняя продолжительность резания инструментом THUNDERBEAT составляла 10,7 секунды (на 68 % быстрее, чем Harmonic ACE, на 102 % быстрее, чем EnSeal, и на 151 % быстрее, чем LigaSure V). THUNDERBEAT показал значимо ($p < 0,05$) большую скорость разрезания брыжейки по сравнению с LigaSure V, Harmonic ACE и EnSeal. Средняя продолжительность резания инструментом SONICBEAT составила 13,2 секунды (на 42 % быстрее, чем Harmonic ACE, на 64 % быстрее, чем EnSeal, и на 104 % быстрее, чем LigaSure V). SONICBEAT показал значимо ($p < 0,05$) большую скорость разрезания брыжейки по сравнению с LigaSure V.

Оценка технических характеристик инструмента THUNDERBEAT: подробный доклад

3

Образование аэрозоля при использовании инструментов THUNDERBEAT и SONICBEAT по сравнению с Harmonic ACE

Olympus Medical Systems Corporation, Токио, ноябрь 2012 г.

Цель. Использование ультразвукового хирургического инструмента при внутрибрюшных хирургических вмешательствах ведет к образованию аэрозоля в связи с кавитацией, вызываемой ультразвуковой вибрацией зонда. Аэрозоль заполняет брюшную полость, приводя к нечеткому эндоскопическому обзору и затрудняя работу оператора. Чтобы снизить кавитацию, компания OLYMPUS разработала инструменты THUNDERBEAT и SONICBEAT с запатентованной конструкцией браншей. В данном сообщении рассматривается способность образования аэрозоля при использовании устройств THUNDERBEAT и SONICBEAT в сравнении с существующим на рынке ультразвуковым хирургическим инструментом Harmonic ACE.

Методы. Известно, что разрезание жировой ткани с помощью ультразвукового хирургического инструмента приводит к разбрызгиванию мелких капель жира, приводящему к распространению аэрозоля в брюшной полости. Для отражения наиболее неблагоприятного сценария образования аэрозоля в качестве модельной ткани для данного исследования была выбрана жировая ткань свиньи. Количественное измерение уровня образования аэрозоля выполнялось с помощью прибора оценки содержания аэрозоля. В используемой модели количество образованного аэрозоля прямо пропорционально степени ослабления инфракрасного излучения. Ткань для проверки захватывалась средней частью ультразвукового зонда каждого устройства. Каждое устройство приводилось в действие и не выключалось до полного отделения ткани. Регистрировался максимальный уровень образования аэрозоля и уровень образования аэрозоля по прошествии 15 секунд. После каждой проверки выполнялась очистка внутренней поверхности прибора для оценки содержания аэрозоля. Наборы данных формировались на основе десяти испытаний каждого устройства. Для каждого устройства формировали три набора данных, таким образом каждое устройство испытывали 30 раз.

Результаты

Оценка содержания аэрозоля при максимальном уровне ослабления света

Поглощение проникающего ИК-света (%)					
		Испытание 1	Испытание 2	Испытание 3	Среднее
THUNDERBEAT (режим Seal & Cut)	Размер выборки	10	10	10	н/п
	Среднее поглощение	0,96 ± 0,60	0,77 ± 0,24	0,42 ± 0,26	0,72 ± 0,45
SONICBEAT	Размер выборки	10	10	10	н/п
	Среднее поглощение	0,70 ± 0,30	1,00 ± 0,58	0,90 ± 0,78	0,87 ± 0,61
Harmonic ACE	Размер выборки	10	10	10	н/п
	Среднее ослабление	5,54 ± 1,84	5,89 ± 2,52	7,01 ± 2,67	6,15 ± 2,49

Оценка содержания аэрозоля через 15 секунд после начала подачи энергии

Поглощение проникающего ИК-света (%)					
		Испытание 1	Испытание 2	Испытание 3	Среднее
THUNDERBEAT (режим Seal & Cut)	Размер выборки	10	10	10	н/п
	Среднее поглощение	0,33 ± 0,21	0,23 ± 0,18	0,16 ± 0,20	0,24 ± 0,21
SONICBEAT	Размер выборки	10	10	10	н/п
	Среднее поглощение	0,31 ± 0,14	0,23 ± 0,22	0,21 ± 0,15	0,25 ± 0,18
Harmonic ACE	Размер выборки	10	10	10	н/п
	Среднее поглощение	2,69 ± 0,67	3,22 ± 1,44	3,88 ± 1,86	3,26 ± 1,52

Оценка содержания аэрозоля



Вывод. При использовании инструмента THUNDERBEAT образование аэрозоля было значимо ниже по сравнению с Harmonic ACE (p <0,001). При использовании инструмента SONICBEAT образование аэрозоля также было значимо ниже по сравнению с Harmonic ACE (p <0,001). При работе с THUNDERBEAT и SONICBEAT лапароскопическое изображение во время диссекции было более четким, чем при работе с Harmonic ACE. Инструмент Harmonic ACE образует приблизительно в семь раз больше аэрозоля, чем инструменты THUNDERBEAT и SONICBEAT.

Оценка технических характеристик инструмента THUNDERBEAT: подробный доклад

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Качество диссекции инструментами THUNDERBEAT и SONICBEAT по сравнению с LigaSure V, Harmonic ACE и EnSeal

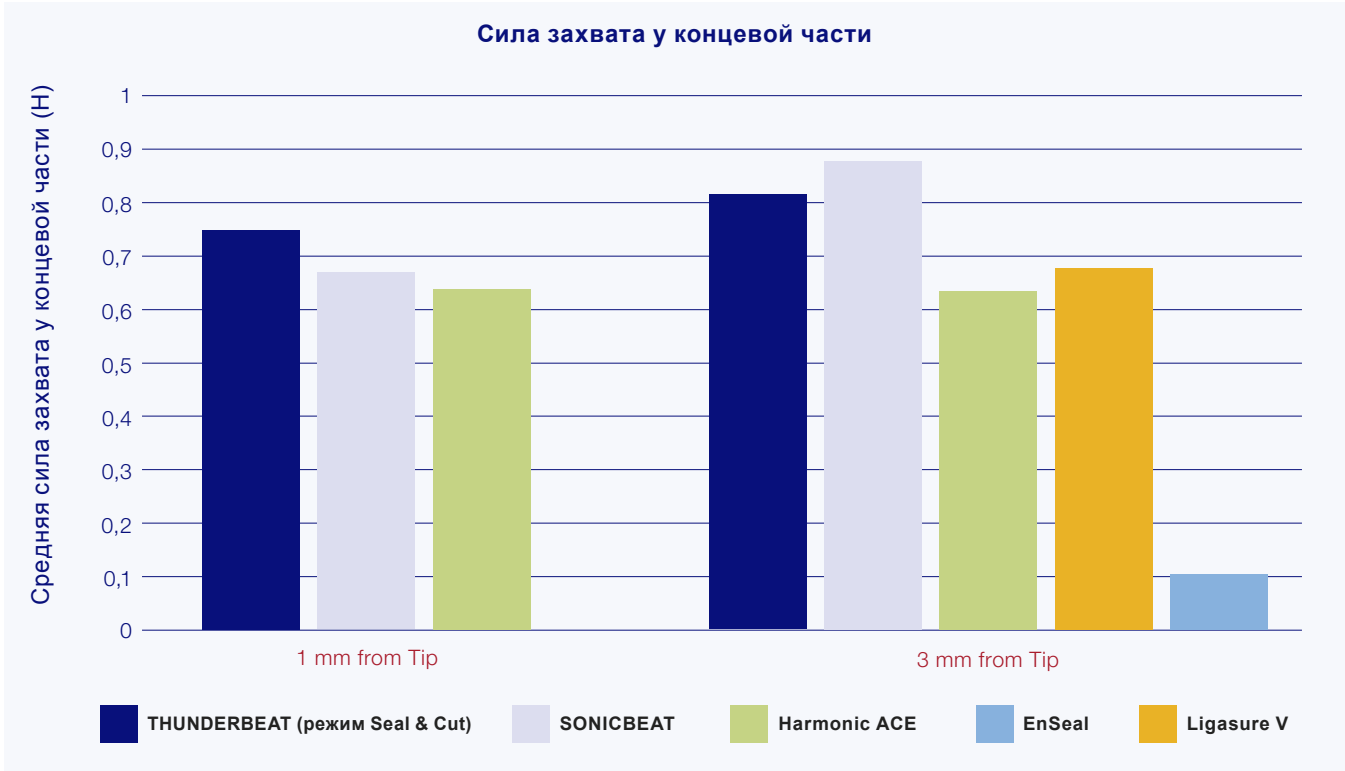
Olympus Medical Systems Corporation, Токио, ноябрь 2012 г.

Цель. Улучшенное качество диссекции с помощью хирургических энергетических устройств может способствовать сокращению времени использования инструмента, числа смены инструментов и перерывов в ходе хирургической процедуры, а также общей экономии времени персонала операционной. Целью данного исследования являлось сравнение качества диссекции инструментами THUNDERBEAT и SONICBEAT по сравнению с существующими на рынке устройствами (LigaSure V, Harmonic ACE® и EnSeal).

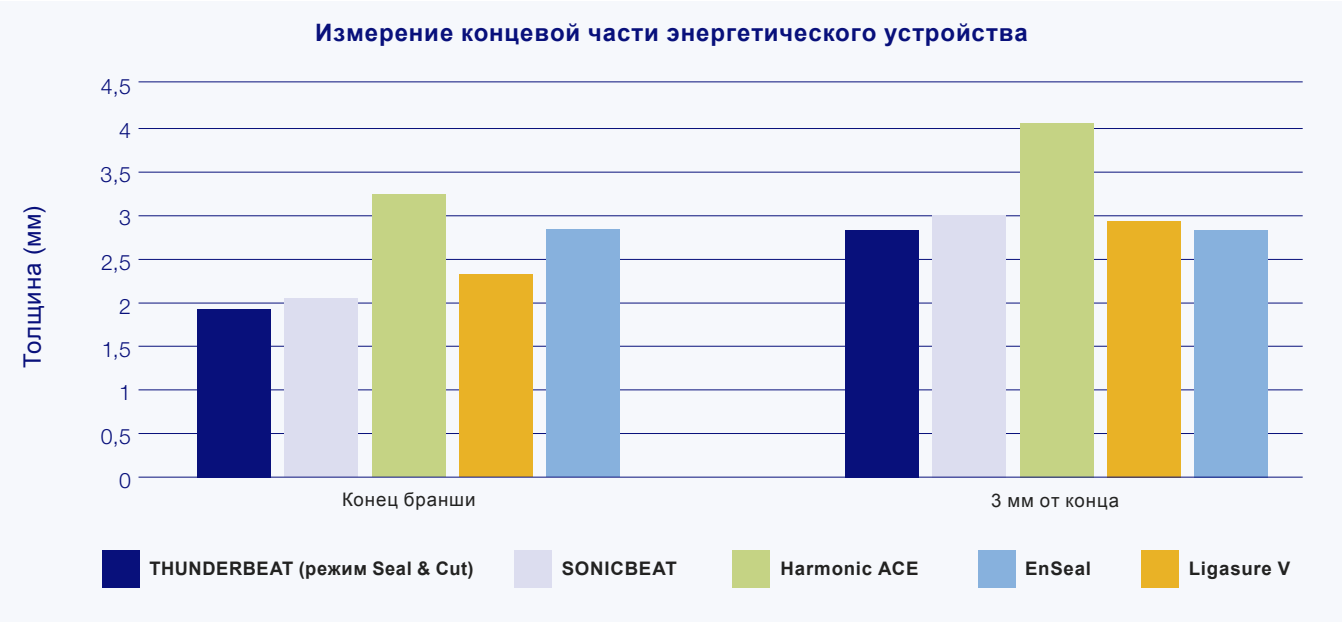
Методы. Качество диссекции оценивалось с учетом ряда факторов, включая силу захвата у концевой части, толщину концевой части и силу диссекции. Сила захвата определялась с использованием бумаги, чувствительной к давлению на расстоянии 1 мм и 3 мм от конца бранши. Толщина концевой части оценивалась путем измерения бранши каждого инструмента в концевой части и на 3 мм проксимальнее. Сила диссекции измерялась путем приложения силы с известными значениями (5 Н, 10 Н и 15 Н) к рукоятке каждого устройства и измерения силы открытия в точке на 3 мм проксимальнее конца бранши.

Результаты

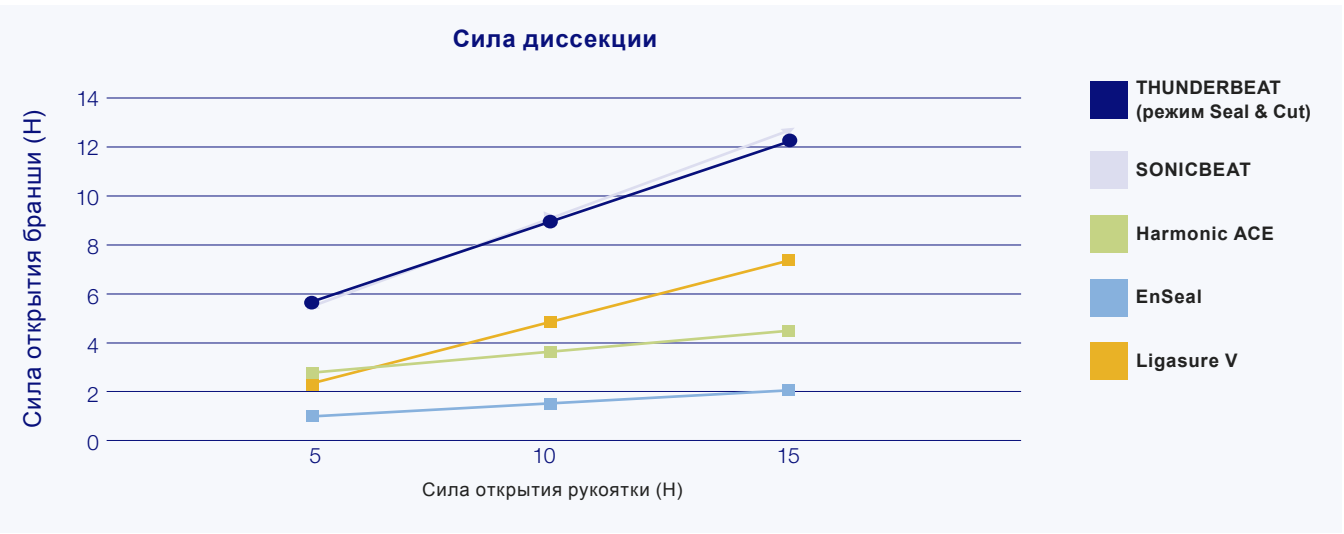
Сила захвата у концевой части



Толщина концевой части



Сила открытия бранши (сила диссекции)



Вывод. Испытание показало, что инструменты THUNDERBEAT и SONICBEAT обладают большей силой захвата у концевой части, более тонкими концевыми частями и большей силой открытия браншей, чем существующие на рынке устройства. Инструменты THUNDERBEAT и SONICBEAT демонстрируют превосходящее качество диссекции по сравнению с существующими на рынке устройствами (LigaSure v, Harmonic ACE и EnSeal).

Опыт применения
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**Clinical Perspectives on Using Advanced Vessel-Sealing Technology:
Experience with the Multifunctional THUNDERBEAT Device**

Опыт работы с многофункциональным устройством THUNDERBEAT

Faculty

Michael J. Fahey, MD, FACS

General Surgeon
Yuba City, California

Jeffrey W. Milsom, MD

Chief, Colon and Rectal Surgery
Jerome J. DeCosse, MD Distinguished
Professor of Surgery
NewYork-Presbyterian Hospital/Weill Cornell
Medical College
New York, New York

Kevin Tri Nguyen, MD, PhD

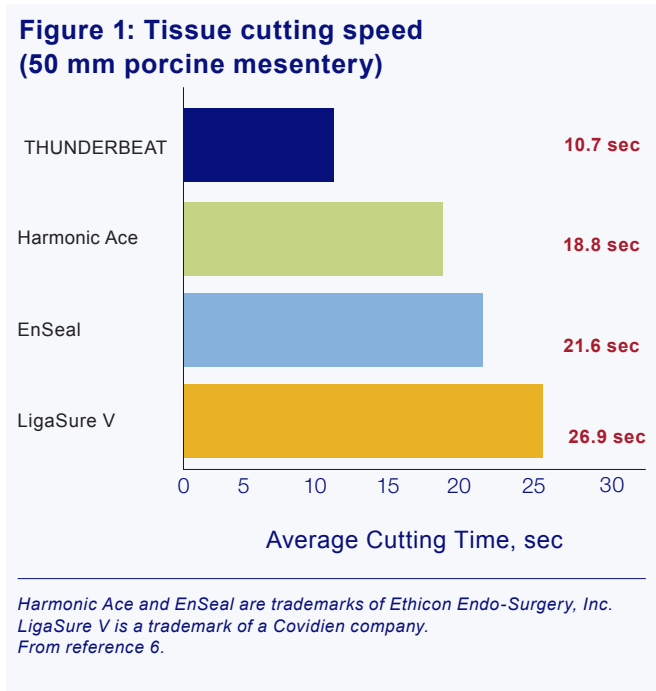
Assistant Professor of Surgery
Division of Hepatopancreatobiliary and Advanced
Gastrointestinal Surgery
University of Michigan Health Systems
Ann Arbor, Michigan

Douglas Olsen, MD, FACS

Associate Clinical Professor of Surgery
Vanderbilt University
Nashville, Tennessee

Since the introduction of energy-based devices into the surgeon’s armamentarium, manufacturers have sought to improve device function and versatility in order to provide surgeons with tools that are effective at both cutting and coagulating tissue.¹ As new models are introduced, manufacturers have added features to advance the use and efficacy of energy-based devices, and not only in their cutting ability. Sealing vessels and providing effective hemostasis, which can be difficult to achieve with methods that solely rely on compression (eg, sutures, clips, and staples), also have improved with each new generation of devices. Although these devices have been developed over time to hone their ability to seal vessels and dissect tissue – as well as provide ease of use and multifunctionality – no device has been able to offer complete efficacy without some risk.

Bipolar devices offer advantages over monopolar instruments in terms of safety and precision as they pass current only between electrodes placed closely together and better control the dispersed current.¹ However, bipolar devices that cut in addition to cauterizing usually rely on the addition of a mechanical blade activated independent of cauterizing. Ultrasonic



energy, which emerged in the 1980s as an alternative to mono- and bipolar devices, relies on friction, rather than radiofrequency energy, to effectively desiccate tissue. Although the risk for electricity to spread through the patient’s body is avoided, ultrasonic devices have been known to reach maximum temperatures of approximately 200 °C or even higher at the jaws (eg, after activation for 10 seconds).^{2,3}

The THUNDERBEAT Platform: Fully Integrated Bipolar and Ultrasonic Technology

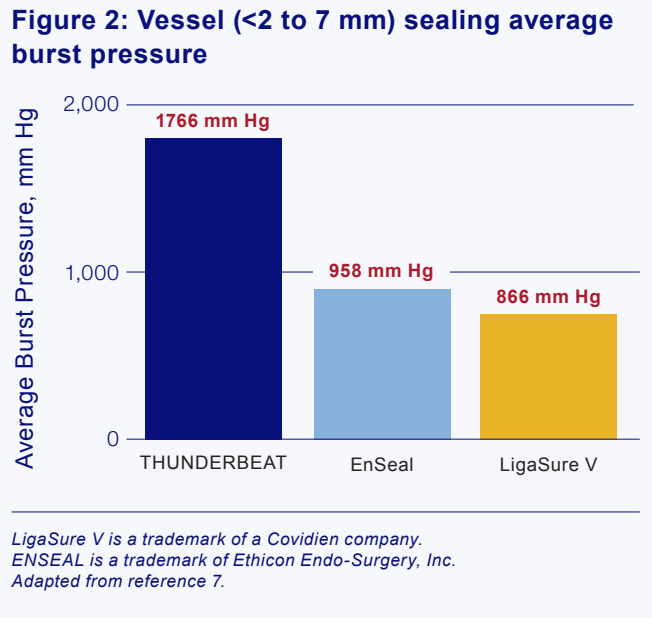
Energy-based vessel-sealing devices have provided surgeons with increasingly sophisticated options, but only the Olympus THUNDERBEAT combines both bipolar and ultrasonic technology in a single multifunctional instrument. Surgeons have found THUNDERBEAT capable of sealing vessels up to and including 7 mm in diameter while also providing fastest-in-class cutting speed.⁴ THUNDERBEAT’s fine jaw design provides precise dissection and forceful grasping, while its always available bipolar energy ensures hemostasis without the need to cut. The 5-mm diameter device can serve surgeons performing open or laparoscopic cases in a variety of disciplines, including general, urologic, gynecologic, bariatric, thoracic, and reconstructive surgery.⁴

Considering Energy-Based Devices

Kevin Tri Nguyen, MD, PhD, assistant professor of surgery in the Division of Hepatopancreatobiliary Surgery and Advanced Gastrointestinal Surgery at the University of Michigan Health Systems in Ann Arbor, experienced both the benefits and drawbacks of competing devices before he began using THUNDERBEAT. “The Harmonic ACE is fast, but I was not comfortable with its ability to adequately seal vessels,” he said. “The LigaSure provided me comfort that it was sealing vessels appropriately, but it was too slow. After I’d seal, I would have to press the cut button multiple times, and even then it didn’t cut completely. So when I was introduced to THUNDERBEAT, I liked that it combined the sealing capability of the LigaSure and the quick-cutting ability of the Harmonic ACE all in one.”

Dr. Nguyen performs approximately 200 major procedures per year and uses THUNDERBEAT exclusively in all his cases that require an energy-

based device. “I’ve now replaced the LigaSure with THUNDERBEAT for all my procedures. I use it for all my pancreas and liver cases, to mobilize the stomach and the colon or divide the pancreas or liver – all my procedures. It’s helped move the cases along, and since I started using it I’ve been really happy with it.” The surgical armamentarium of Jeffrey W. Milsom, MD, chief of colon and rectal surgery and professor of surgery at NewYork-Presbyterian Hospital/Weill Cornell Medical College in New York City, has included various energy-based devices over the past 25 years.



“Monopolar energy, especially in minimally invasive surgery, carries the risk for arcing and for injury by the electrical current straight from the tip. It provides no compression, can result in a build-up of carbon material, and there are a lot of charring issues. It’s less precise than other forms of energy and doesn’t work on all types of tissues equally,” he said. “Bipolar energy requires more specialized equipment and many physicians are not familiar with how to use it. But I think bipolar devices have fewer limitations than monopolar, in general.

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“Ultrasonic energy has the limitation of becoming hot, and it puts off a lot of vapor and mist, which clouds the operative field sometimes. Also, with traditional ultrasonic devices, you are not able to close off major blood vessels compared with bipolar,” Dr. Milsom said. “The THUNDERBEAT represents the latest development of energy use in surgery and it will allowsurgeons to be much more efficient in their procedures.”

THUNDERBEAT Technology and the Benefits of Versatility
Cutting Speed

The area in which THUNDERBEAT offers perhaps its greatest advantage over competing devices is in terms of speed, without sacrificing any vessel-sealing security. Douglas Olsen, MD, FACS, associate clinical professor of surgery at Vanderbilt University in Nashville, Tennessee, has used THUNDERBEAT for bariatric procedures—mostly sleeve gastrectomy, Rouxen-Y gastric bypass, and duodenal switch—and said that he was instrumental in bringing THUNDERBEAT to his institution. “When I first began performing bariatric surgery, I used Harmonic technology and then I used a variety of bipolar devices before finally settling on LigaSure, which I’ve used over the past couple of years,” he said, “But when Olympus began working on THUNDERBEAT, I was very interested.”

Comparing the THUNDERBEAT with its competitors, Dr. Olsen added, “where the THUNDERBEAT wins is as the fastest in class in cutting speed. It beats the rest of them hands down.” Even when the speed of a Harmonic device is optimal, that device sacrifices another element crucial to surgery: “Most surgeons use the fast mode on the Harmonic. They can get through tissues pretty quickly, but the device’s seal ability falls off tremendously,” he said.

In a study by Seehofer et al, THUNDERBEAT surpassed the Harmonic ACE and LigaSure V in terms of cutting and sealing speed.⁵ These researchers also concluded that THUNDERBEAT has the potential to deliver sealing at a speed exceeding that of a solely ultrasonic device.⁵ On 5-cm porcine mesentery, THUNDERBEAT has been shown to be 76% faster than the Harmonic ACE, 102% faster than ENSEAL, and 151% faster than the LigaSure V, which was a significant improvement in speed over all 3 devices (Figure 1).⁶ Additionally, a study conducted by Milsom et al reported that THUNDERBEAT has a higher versatility compared with other energy instruments with faster dissection speed and acceptable thermal spread.⁷

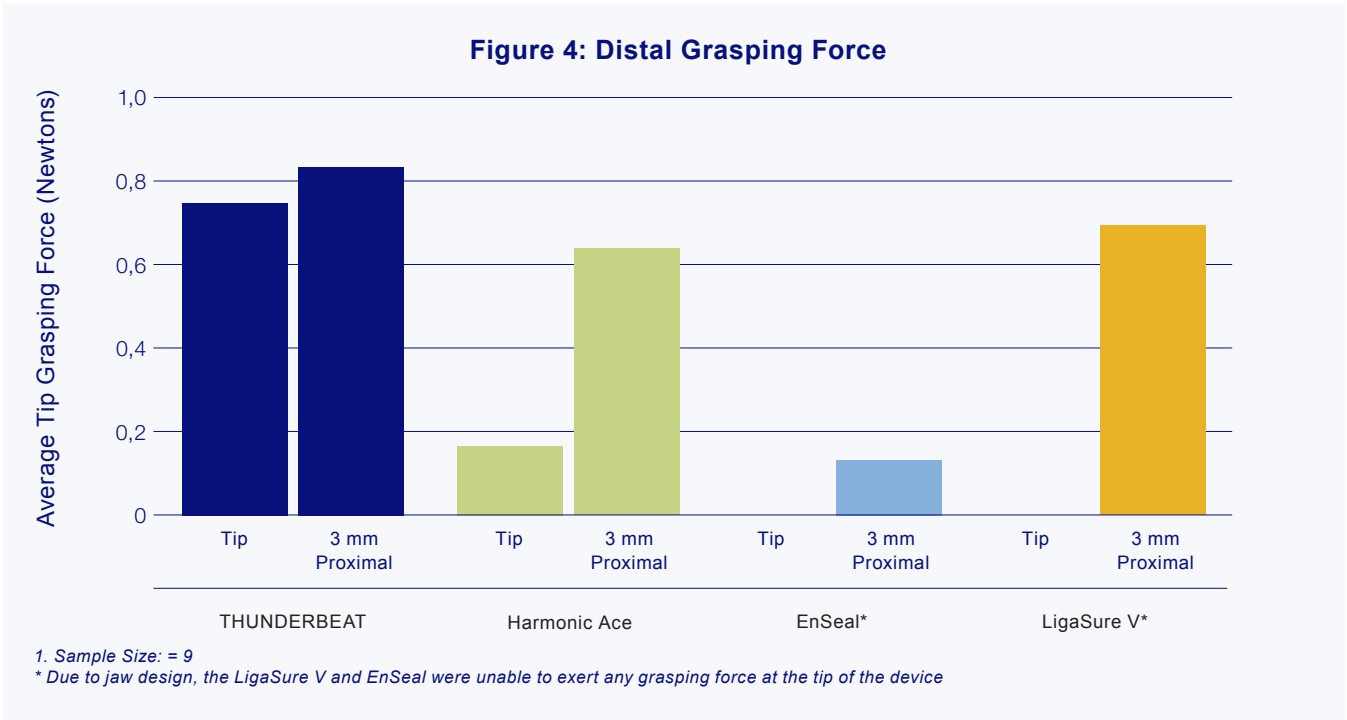
When using THUNDERBEAT during major colorectal procedures, Dr. Milsom said the device speeds up procedures via its multifunctionality, ability to independently seal and divide vessels, and its capacity to be used as a dissector and grasper. “It’s versatile. You can use one instrument for all the tissue dissection you need to do within the abdomen,” he said. “First of all, it lets you use fewer instruments. You can use it for virtually all applications. It gives you the ability to do some very fine dissection compared with other instruments. You can use the grasping function to pick up tissue, which you can’t really do with other instruments. As with all ultrasonic devices, you do have to be careful – it can get hot so you may have to modify things to make sure you don’t touch any neighboring tissues within the first few seconds after using it.”

In addition to reducing the need to exchange instruments, Dr. Milsom finds that THUNDERBEAT allows him to cut and seal various tissues quickly and easily. “I think it will allow [a surgeon] to move along more quickly and efficiently, and in tight spaces like

the pelvis, it will allow you to dissect with a lot of precision,” he said. This greater potential for speed benefits everyone, Dr. Milsom noted. “For a 2-hour procedure, this may save you 10 or 15 minutes, which is really quite significant. The patient has shorter anesthesia and the health care team gets through the procedure more quickly.” Overall, longer surgical times often are associated with increased rate of complications, whereas shorter operating times are associated with better patient outcomes.⁸ Michael J. Fahey, MD, a general, vascular, thoracic, and trauma surgeon in Yuba City, California, performs a wide variety of noncardiac chest, general surgical, and hernia procedures every year. He has worked with every generation of ultrasonic and bipolar device in both open and laparoscopic procedures. “Probably the biggest limitation with the LigaSure™ [device] is that it’s a little slow to work, a little unpredictable in maintaining a seal on a 7-mm vessel, and there’s a fair amount of charring and instrument jaw cleaning that goes on in some cases. Sometimes, the blade is

either not as reproducibly sharp as it should be or it dulls quickly,” he said. “The precision of the Harmonic® [device] is nice, and it can be used in areas where a stapling device has left staples, which you can’t do with the LigaSure™. But its secondary use as a grasper is not very good; things slip through its jaws more easily than they do with the LigaSure™.”

Thus, the drawbacks of using those instruments can lengthen the duration of a procedure. “If you have to go back and control bleeding that should have been controlled the first time from the device you’re using, whether it’s an energy device or a stapler, that’s a big increase in time,” Dr. Fahey explained. “Also, if you’re using a bipolar or ultrasonic device, you have to wait for the tissue to be functionally desiccated. These are 5-mm devices; if you need to divide 10 inches or 20 cm of tissue, there’s a true wait time for each opening and closing of the jaws. If you can turn to a device in which each division is faster and more hemostatic, you’ll have a smoother case, rather than constantly



Опыт работы с многофункциональным устройством THUNDERBEAT

having to backtrack to control bleeding or waiting (for an instrument to perform) before moving forward to your next step.”

THUNDERBEAT seems to have resolved these time-consuming problems, Dr. Fahey explained. “Overall, it’s faster and more accurate. As you move through the case, it saves you time without the risk for increased bleeding. Usually I was pushing the other technologies to move a little faster, or having to wait on them,” he said. “Also, the jaws of THUNDERBEAT have fairly good grasping capability, the clarity of the division of tissue is good, and the jaws require minimal cleaning.”

Reliable Vessel Sealing

The same integration of ultrasonic and bipolar energy that makes THUNDERBEAT fast also enhances its reliability in sealing vessels up to and including 7 mm in diameter,⁴ making it equivalent in sealing capacity to the leading pure bipolar devices (Figure 2).⁷

In the comparison of THUNDERBEAT to Harmonic ACE and LigaSure V by Seehofer et al, researchers found that all 3 instruments were capable of safely dividing vessels up to 4 mm in size, but the burst pressure of larger vessels, 5 to 7 mm, was significantly higher (734±64 mm Hg) in those sealed with THUNDERBEAT than in those sealed with the Harmonic ACE (453±50 mm Hg).⁵

“Speed and the dependability of the seal are important factors,” Dr. Olsen said. “From a surgeon’s standpoint, THUNDERBEAT’s speed is certainly nice. When I’m doing something like a sleeve gastrectomy, taking down the greater curvature of the stomach and I have multiple vascular pedicles to divide, I want to be able to move through that quickly and know with confidence that I have the vessels sealed.” In bariatric surgery, Dr. Olsen often encounters mixed tissues,

such as pedicle or adipose tissue, all with vessels throughout. He found both Harmonic and LigaSure devices good at sealing some, but not all, types of tissues. “Harmonic is very good at sealing larger vessels, but is not good at sealing the little capillaries in the adipose tissue; same with the LigaSure,” he said. “I feel THUNDERBEAT gets better hemostasis through those tissues completely.”

In Seal mode, THUNDERBEAT uses only advanced bipolar energy for vessel sealing and tissue coagulation, a feature that other ultrasonic devices cannot provide. Dr. Fahey noted that hemostasis provided by THUNDERBEAT was superior to the sealing capabilities of competing devices. “We always test (new) devices on the open mesentery of colon in the open portions of cases before we start trusting them in closed, laparoscopic procedures, and the ability of the THUNDERBEAT to divide sigmoid colon or rectal lateral stocks was much more efficacious in terms of hemostasis than the 2 competitors,” he said. “The larger vessels seemed to be controlled. THUNDERBEAT still runs into the same limitations all devices have in people with atherosclerotic arteries, where they don’t work best. But because it features an ultrasonic side, you can use it around staples, whereas with LigaSure, you would have to change modalities to monopolar devices or clips.”

Dr. Fahey advises that surgeons spend some time becoming familiar with the instrument. “You have to play with it, be appropriately instructed, and take some time with your first few cases so that you appreciate the range of settings that are available on THUNDERBEAT,” Dr. Fahey said.

Also, his colleagues in gynecologic surgery who perform laparoscopic hysterectomy – a procedure historically associated with postoperative bleeding

Figure 5: NEW Handle

Front Actuated handle designed to help minimize hand fatigue through improved ergonomics



– have migrated to THUNDERBEAT as their device of choice for uterine vessel division. “Clearly the other service lines have decided that between competing technologies, this is the one that gives them the best hemostasis,” Dr. Fahey said.

Dr. Nguyen added that THUNDERBEAT saves him time in procedures. “There are certain parts of procedures that just move a lot faster. For example, mobilizing the greater curve of the stomach,” he said. Also, having confidence that THUNDERBEAT provides a reliable seal contributes to operative time savings. “There are a lot of major blood vessels that I dissect around and divide in my surgeries, and I feel comfortable sealing and dividing with THUNDERBEAT,” Dr. Nguyen said. In the past, when he wasn’t confident about the seal a device provided, he would, “either clip or tie, which is more time-consuming.”

Precise Dissection and Optimized Grasping

In addition to providing superior speed and equivalent

hemostasis compared with its leading competitors, THUNDERBEAT offers several other features that make it a truly multifunctional instrument: a fine-tip design, strong jaw-opening force, wide jaw-opening aperture, high grasping force at the tip, and stability of the jaw. All of these features are designed to ease the surgeon’s ability to access and separate tissue planes (Figure 3).

Employing an advanced “wiper jaw” mechanism, THUNDERBEAT provides a high grasping force throughout the length of the jaw, which creates the potential for the device to be used as an alternative to generic graspers (Figure 4).⁹ THUNDERBEAT’s dissecting and grasping capabilities together may result in a reduction of instruments used in the operating room, which in turn may lead to shorter procedure duration. When he was using LigaSure, Dr. Olsen found the bulky jaw design to be a subpar dissector, which he said often is the case with pure

Опыт работы с многофункциональным устройством THUNDERBEAT

bipolar devices. “That meant that you’d often need to use a second instrument to develop a tissue plane so that you could bring your (bipolar) device in across that tissue, close it, divide and seal,” he said. “So that would slow down surgery because you would have to stop and bring in a dissecting instrument to develop that tissue plane.

“Harmonic and THUNDERBEAT, on the other hand, have the ability to be excellent dissectors; the active blade on THUNDERBEAT, which is the same as the active blade on the Harmonic, is a long, thin rod, so you can use it to tease into tissues, develop the tissue plane, then close the instrument and fire it,” Dr. Olsen added. Now that he uses THUNDERBEAT in his procedures predominantly, Dr. Olsen said that he rarely needs to employ other dissectors, and in most cases does not need a curved dissector, which has streamlined his operating efficiency. Dr. Milsom also finds that using THUNDERBEAT allows him to cut down on the number of additional instruments he might use. “It gives you the ability to do some very fine dissection compared with other instruments, and you can use the grasping function to pick up tissue— with other instruments you can’t really do that,” he said.

Dr. Fahey has found the integration of fine dissection and reliable grasping to contribute to THUNDERBEAT’s ability to save surgical time and reduce instrument use. “Olympus has listened, I think, to surgical discussions that you don’t need just fine dissection, but you also need to be able to grasp tissue and hold it. Otherwise, you’re having to add other ports or other instruments—so the combination of fine dissection and grasping has been a nice integration,” Dr. Fahey said.

In the past, during complex paraesophageal or redo antireflux procedures, Dr. Fahey found that he would need to use 2 energy-based technologies to complete

the surgery. “We’d use a Harmonic (device) for dissection and a LigaSure (device) for vessel control. Or, we’d plan to staple everything else to save on energy source in terms of cost,” he said. “But now in those cases we tend to use only THUNDERBEAT. This is probably why it is more reproducible to say it takes only 20 minutes or less to take down the splenic flexure of the colon, because we don’t run into a vessel or omental bleeding that is not controlled by the device.”

The THUNDERBEAT Platform

By integrating ultrasonic and bipolar energy into one multifunctional device, THUNDERBEAT gives surgeons the option of selecting the technology option most appropriate to their specific procedural needs. THUNDERBEAT also is compatible with the Olympus Integrated OR System, is hand- and/or foot-switch compatible, and features 3 handle designs (inline, pistol, and the new front-actuated grip (Figure 5) and 4 working lengths (10, 20, 35, and 45 cm).^{9,10}

Furthermore, the THUNDERBEAT Platform also is the only surgical tissue management system that delivers every common form of energy used in surgery today (ie, monopolar, bipolar, ultrasonic, and advanced bipolar) as well as the revolutionary combination of advanced bipolar and ultrasonic energies. “For institutions that are looking for a cost-efficient way to add an entire energy platform, it makes a lot of sense,” Dr. Olsen said.

For those who prefer to use an ultrasonic energy – only device, Olympus offers SONICBEAT: Like THUNDERBEAT, SONICBEAT cuts tissue faster and provides a stronger grasping force than the Harmonic ACE; it also produces 85% less smoke and mist.^{11,12} Per Dr. Olsen, “If they’re comfortable just with the ultrasonic [devices], they can use the SONICBEAT, and for more advanced procedures when they want to add bipolar energy, they can plug in THUNDERBEAT.”

Conclusion: THUNDERBEAT is the first device available that combines the speed of ultrasonic energy with the reliability of bipolar energy into a single instrument. It allows surgeons to cleanly divide tissue and effectively seal blood vessels up to 7 mm in size.⁴ Also, THUNDERBEAT acts as precise dissecting and powerful grasping tool, allowing surgeons to cut down on instrument exchange. “Certainly, the management of tissue division is in evolution and this product represents the future of the use of energy in safely dividing tissues,” Dr. Milsom said. “Surgeons who want to be a part of futuristic energy management in tissue division have to get their hands on this.”

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Система работы с тканью THUNDERBEAT

Инструмент THUNDERBEAT: непревзойденная универсальность в работе

Цель данной брошюры – представить техническое описание проведенных испытаний (на доклиническом этапе и при клиническом применении), а также отзывы пользователей о применении системы работы с тканью THUNDERBEAT.

По настоящему универсальный лапароскопический инструмент с применением энергии в наиболее современных формах это устройство, которое высоко оценивается по следующим параметрам. (Источник: Market Acceptance Study (Исследование восприятия рынком), Olympus Europe, 2011 г.)

- Скорость резания
- Надежность сваривания крупных сосудов (до 7 мм включительно)
- Возможность проведения вторичного гемостаза с использованием передовой биполярной энергии
- Возможность захвата, удержания, перемещения и диссекции ткани

THUNDERBEAT соответствует этим требованиям. Согласно ряду модельных экспериментов, его качество превосходит качество других устройств, представленных на рынке.

Опыт применения

Профессор Карл-Херманн Фукс (Karl-Hermann Fuchs), дипломированный врач; Agaplesion Markus Krankenhaus, главный врач, ведущий хирург; отделение общей, висцеральной и торакальной хирургии

Мы начали исследование с проведением объективных измерений по оценке возможных преимуществ системы THUNDERBEAT. На основе полученных данных мы можем утверждать, что платформа THUNDERBEAT является быстрой и безопасной, что дает нам преимущество при работе в операционной, сокращая расход времени как минимум на 15 %. Экономия времени является результатом уверенной коагуляции и быстрого рассечения любых тканей без необходимости смены инструментов даже при тупой диссекции и зажиме тканей (май 2014 г.).

Пейман Порнорози (Peïman Poornoozy), дипломированный врач, университетская клиника г. Оденсе, ведущий хирург; отделение гастроинтестинальной хирургии

THUNDERBEAT выполняет все операции по диссекции и ушиванию сосудов. Смена инструментов больше не требуется. Система THUNDERBEAT отличается высокой безопасностью и быстротой. Кроме того, в ней образуется меньше конденсата по сравнению с системой Harmonic (май 2014 г.).

Петер Разек (Peter Razek), дипломированный врач, Sozialmedizinisches Zentrum Floridsdorf – больница и центр гериатрической медицины, консультирующий хирург; хирургическое отделение

THUNDERBEAT превосходит все остальные инструменты. Швы очень надежные, а скорость работы инструмента действительно впечатляет (май 2014 г.).

Андреас Керл (Andreas Keerl), дипломированный врач, госпиталь кантона Баден, ведущий врач; хирургическое отделение

Я предпочитаю использовать THUNDERBEAT в качестве основного инструмента при колоректальной хирургии, поскольку комбинированные технологии позволяют выполнять точные диссекции, а также быстро и безопасно ушивать сосуды. Я использую систему THUNDERBEAT, так как она является безопасной, простой и быстрой (май 2014 г.).

Андреас Церц (Andreas Zerz), дипломированный врач, госпиталь кантона Базель-Ланд, главный консультирующий врач; хирургическое отделение

THUNDERBEAT – безопасный, быстрый и самый универсальный инструмент (май 2014 г.).

Профессор Ив ван Нийовенхове (Yves van Nieuwenhove), дипломированный врач, университетская клиника г. Гент, директор больницы; отделение гастроинтестинальной хирургии

THUNDERBEAT: быстрые и сухие операции. THUNDERBEAT: тотальная колэктомия без единой капли крови (май 2014 г.).

Технические условия, конструкция и вспомогательное оборудование могут быть изменены производителем без предварительного уведомления или каких-либо обязательств.

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ООО ОЛИМПАС МОСКВА

Россия, 107023, г. Москва
ул. Электрозаводская, д.27, стр. 8
тел.: +7 (495) 926 70 77
факс: +7 (495) 926 70 72
www.olympus.com.ru

Россия, 199178, г. Санкт-Петербург
3-я линия В.О. д. 62, Лит. А.
тел.: +7 (812) 385-47-90
факс: +7 (812) 385-47-93
www.olympus.com.ru

Украина, 01032, г. Киев
бул. Т. Шевченко, д. 336
тел.: +38 (044) 730-21-57
факс: +38 (044) 594-48-01
www.olympus.com.ru

Казахстан, 050012
г. Алматы, ул. Шевченко
д. 118, оф. 217
тел.: +7 (777) 399-74-96
www.olympus.com.ru