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Implementation of a novel efficacy score to compare sealing and cutting devices in a porcine model

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Abstract
Background In general surgery, minimally invasive laparoscopic procedures have been steadily increasing over the last decade. The application of advanced bipolar and ultrasonic energy devices for sealing and cutting of blood vessels plays a vital role in routine clinical procedures. The advantages of energy-based instruments are enhanced sealing capability combined with both fast sealing time and minimal thermal injury. The purpose of this study was to compare the safety and efficacy profiles of nine laparoscopic sealing and cutting devices in a porcine model, with a new scoring system.
Methods Comparative studies in a porcine model were performed to assess vessel sealing, burst pressure, thermal spread, maximum heat, sealing/cooling time, and compression strength over the full jaw. Nine different devices from five manufacturers were tested in this study. The sealing and cutting devices (SCD) score has been developed to enable standardized comparisons of various devices. For this purpose, the most important parameters were identified through a consensus approach.
Results All sealed vessels with different devices could withstand a median pressure of more than 300 mmHg (range 112–2046 mmHg). The time for the sealing procedure was 7.705 s (range 5.305–18.38 s) for the ultrasonic and 7.860 s (range 5.08–10.17 s) for the bipolar devices. The ultrasonic instruments reached a median temperature of 218.1 °C (range 81.3–349.75 °C) and the bipolar devices a temperature of 125.5 °C (range 94.1–133.35 °C). The tissue reached a median temperature of 61.9 (range 47.1–80.6 °C) after ultrasonic sealing and 76.7 °C (range 63.1–94.2 °C) after bipolar sealing. The median SCD score was 10.47 (range 7.16–13.72).
Conclusion All the instruments used seemed safe for use on the patient. The SCD score allows an indirect comparability of the instruments.

Keywords Endoscopy · Sealing and cutting devices · Burst pressure · Sealing time · SCD score

In gynecological surgery, minimally invasive laparoscopic procedures have been steadily increasing over the last decade [1, 2]. The application of advanced bipolar and ultrasonic energy devices for sealing and cutting of blood vessels plays a vital role in routine clinical procedures [3, 4]. The challenge lies in combining multiple functions in the same instrument for coagulation and dissection without worsening the handling. The underlying mechanism is to achieve thermal hemostasis by protein denaturation, which occurs at a temperature of 45 °C onward [5]. The sealing with bipolar instruments can

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withstand high intraluminal pressures and is an alternative to the classical vessel occlusions such as ligature or clips [6–12]. The sealing takes place within the vessel wall structure and cannot dislodge [8, 13]. The closure is not always optimal and can be adversely affected for many different reasons [2, 11, 14]. Advantages of state-of-the-art energy-based instruments are enhanced sealing capability combined with both fast sealing time and minimal thermal injury [15]. The increasing popularity of these instruments has led to a wide arsenal of devices with different energy bases. Despite the safety- and efficacy-related aspects, the likely disadvantages are mainly lateral thermal spread, relatively high disposal cost, and variable burst pressures [16]. Excessive energy delivery to the tissue may result in larger necrosis and thus a higher risk of secondary bleeding and more frequent damage to sensitive structures such as the intestines or ureters [2, 17–19]. Previous studies identified homogeneous compression on the sealing area, controlled energy on the vessel, and a strong vascular sealing as important parameters to avoid collateral damages and comorbidity such as necrosis-associated adhesions [20–23]. Based on the studies of Wallwiener et al. and Soderstrom et al., we generated an easily reproducible porcine model to assess the effects of sealing and cutting devices [24, 25].

The purpose of this study was to compare the safety and efficacy profiles of nine laparoscopic sealing and cutting devices in a porcine model with the new sealing and cutting devices (SCD) score, which was developed to enable standardized comparisons of various devices. Instruments were compared in regard to thermal spread, burst and compression pressure, and sealing and cooling time.

Materials and methods

Comparative studies were performed to assess vessel sealing and burst pressure (BP), thermal spread (TS), maximum heat, sealing/cooling time (ST/CT), and compression strength over the full jaw. Nine different devices from five manufacturers were tested in this study. During these in vitro experimental procedures, some instruments were either updated (Ethicon Harmonic ACE was updated to Harmonic ACE + 7®) or withdrawn (Aesculap Caiman® was withdrawn by the manufacturer from the study) and were thus not taken into account in the further evaluation. The energy-based devices used in this study are shown in Table 1.

The tissues for TS and BP experiments were taken from German domestic pigs weighing 40–60 kg. Immediately after the slaughter of the pigs in a slaughterhouse, the carotid arteries and small intestine were removed (OP organization and animal welfare, the competence center "MEDIZIN IM GRUNEN" in Wendisch Rietz, Germany). After skeletonizing the vessels and bowels, both were placed in normal saline (0.9%) and frozen at −20 °C. Before the experiments were started, the tissue was thawed to 4 °C and then warmed to body temperature (37 °C) in heat baths. In a previous study, it was demonstrated that freshly thawed frozen vessels reacted similar to fresh vessels [26].

Sealing and burst pressure

Burst pressure measurements are important endpoints and evaluation parameters, because they reflect the sealing quality of the devices. The normal blood pressure is 140/90 mmHg and reaches values >160/100 mmHg in hypertensive patients. In male athletes, the mean blood pressure reaches 311/284 mmHg during double-leg press sets at 85 and 100% of maximum with closed glottis Valsalva. The highest measured blood pressure in an individual during these tests was 370/360 mmHg [27]. During and after the exercises, values of more than 300 mmHg are not reached; since a safety distance must be maintained to the limits actually attainable, in this work the limit was set at 250 mmHg.

The sealing and BP experiments were conducted on the carotid arteries (diameter: 4–7 mm). The vessel diameter was measured with a digital caliper with a filled vessel and a pressure of 100 mmHg. The burst pressure measurements were carried out with a measuring device from Medimotec, Germany, which was provided by Ethicon, Germany. The experiments were controlled and recorded by a computer program. At the beginning of each day, the measuring instrument had to be rinsed with a 70% solution of 2-propanol to dissolve any possible gluing in the lines and check the continuity. The system was then rinsed with a 0.9% sodium chloride solution so that no propanol could subsequently come into contact with the vessels and eventually damage them. The following steps had to be done with each measurement: (1) Connecting vessel, (2) Vessel cleaning, (3) Leakage test, (4) Sealing and cutting the vessel, (5) Placing cover, (6) Cleaning the buffer, and (7) Activation. The bipolar instruments gave a feedback to the point of completion of the seal. For the ultrasonic instruments, the end of the seal was equated with the time of the vessel dissection. After each test, the sealed zone was removed with a surgical scissor while maintaining sufficient safety margins and the vessel was reused. In case of a defect on the vessel or insufficient length, it was replaced by a new carotid artery.

At least six measurements per device were carried out; in case of obvious failures such as leakage or slipping of the vessel, the experiment was repeated.

Maximum heat and sealing and cooling time

For the measurement of maximum heat and cooling time, the "testo 885" camera (Serial number: 02323152) from Testo (Testo SE & Co. KGaA, Lenzkirch, Germany) was used. The intestine was cleaned of residual fecal matter with physiological sodium chloride solution at 37 °C. In order to minimize unwanted reflections and thus inaccurate measurements, all reflecting areas were covered. All measurements were carried out uniformly with a camera distance of 28 cm. The intestine was fixed to avoid tension during the sealing and cutting procedure. The recording was stopped as soon as the tissue cooled down to 38 °C. The tissue temperature was measured directly on the dissection edge after removal of the device. The devices were carefully cleaned after each measurement. The scan area of the camera was in the range of 0–350 °C. To evaluate video recordings, the Testo software IR Soft 3.2 and 3.6 were used. Maximum heat, duration of coagulation, and cooling to 38 °C were measured. We defined 38 °C as nearly normal body temperature without any further damage to the collateral tissue. In order to determine the exact moment of the sealing and the time course of the temperature, the respective video was scanned in approximately 4-hundredths of a second step. The sealing time was defined as the time between the start ofsealing until the bipolar instruments gave a feedback or the ultrasonic devices divided the vessels. In devices with dissimilar jaws (ultrasonic devices), which have an active blade and a passive jaw, both sides were separately measured.

Compression strength

For the measurement of compression forces of the sealing and cutting devices, a sensor (Tekscan 5027@500psi™, Tekscan Inc., CMV Hoven GmbH, Germany) was placed between two thin layers of a silicone membrane (each side: 0.8 mm). Closed-jaw pressures were recorded with I-Scan™ software (Tekscan™ Inc., CMV Hoven GmbH, Germany).

No unit was used to measure the compression strength; the results represent the relative clamping pressure values of the instruments (along the closed jaw, from the tip to the base, Fig. 1). The compression pressure of the individual instruments must be seen in relation to the other instruments. Each device was measured with the maximum possible closing pressure, and this corresponded to the clicked close of some instruments. Each device was tested only once.

Necrosis zone

By measuring the necrosis zone, the cell damage can be measured lateral to the branches. Coagulated and dissected vessels were prepared for further histochemical hematoxylin and eosin staining. The necrosis zone was then microscopically measured on the stump of the vessel. For the two non-dissecting instruments BiClamp® fenestrated and BiClamp® Maryland (ERBE Elektromedizin GmbH, Germany), the measured necrosis zone was used to indicate half the distance in order to be able to make a comparison with the other instruments.

SCD score

The sealing and cutting devices (SCD) score was developed to enable standardized comparisons of various devices. For this purpose, the most important parameters ST, BP, and maximum temperature of the jaws of each device (T) were identified through a consensus approach, and the median value scaled. Next, the scaled values (T_s, BP_s, ST_s) were added and then divided by the number of parameters. Because BP is the most important parameter for clinical application, its value was doubled.

$$\text{SCD score formula } = ((20 - T_s) + 2 * \text{BP}_s + (20 - \text{ST}_s))/4$$

The respective span width of the parameters was divided by 20, and the values were converted into a score. For BP, a higher score was assigned for a higher value, whereas for ST and T a lower score was assigned for higher values. Devices with a bursting force below 250 mmHg are not recommended for use owing to a poor safety profile. The relevant parameters were scaled as follows:

$$\text{BP}_s = (\text{median BP} - 250)/87.5\,(\text{range } 250{-}2000 \text{ mmHg})$$

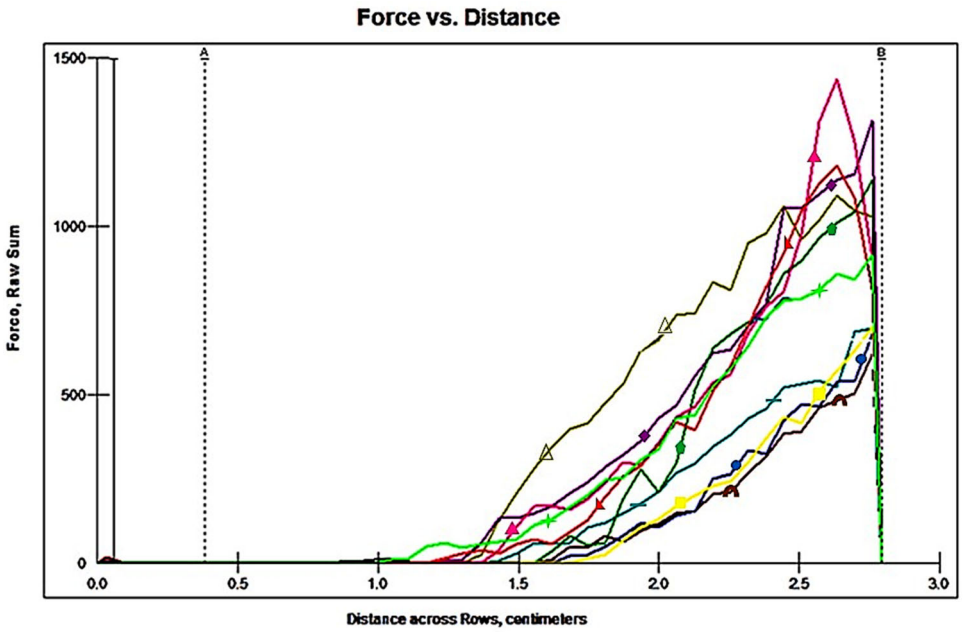
$$\text{ST}_s = \text{median ST}/1\,(\text{range } 0{-}20 \text{ s})$$

$$T_s = \text{median T}/17.5^{\circ}\,(\text{range } 0{-}350^{\circ}\text{C}).$$

The range was determined for the possible measured values of the respective measuring instruments. The minimum value of the score was 0, while the maximum value was 20.

Statistical analysis

This is an explorative analysis and hence the analysis of data was of a descriptive nature. Depending on the scale level of the variable and with respect to the small number



Device	Color	Symbol	Device	Color	Symbol
ERBE Biclamp Maryland®	red		Ethicon Enseal®	dark green	
Ethicon Harmonic ACE+7®	blue		Gebrüder Martin MarSeal®	green brown	
Covidien Ligasure™	purple		ERBE Biclamp®	pink	
Olympus THUNDERBEAT	mint		ERBE Bicision®	light green	
Covidien Sonicision™	red brown				

Fig. 1 Pressure versus distance. Covidien LigaSure™: *purple*; Covidien Sonicision™: *red brown*; ERBE BiCision®: *light green*; ERBE BiClamp® *pink*; ERBE BiClamp Maryland®: *red*; Ethicon Enseal®: *dark green*; Ethicon Harmonic ACE + 7®: *blue*; Gebrüder Martin marSeal®: *green brown*; Olympus THUNDERBEAT: *mint* (Color figure online)

Table 1 Tested laparoscopic sealing and cutting devices

Manufacturer	Product	Energy	Generator settings	Dissection function	Applicability
Covidien	LigaSure™	Bipolar	Level 2	Yes	Single-use
	Sonicision™	Ultrasonic	Minimal, maximal	Yes	Single-use
ERBE	BiCision®	Bipolar	Level 2	Yes	Single-use
	BiClamp® Fenestrated	Bipolar	Level 2	No	Reusable
	BiClamp Maryland®	Bipolar	Level 2	No	Reusable
Ethicon	Enseal®	Bipolar	Standard	Yes	Single-use
	Harmonic ACE + 7® (HARH36)	Ultrasonic	Levels 3 and 5, Advanced hemostasis	Yes	Single-use
Gebrüder Martin	MarSeal®	Bipolar	Level G3	Yes	Reusable
Olympus[a]	THUNDERBEAT	Bipolar and Ultrasonic	Standard	Yes	Single-use

[a] The Olympus THUNDERBEAT uses bipolar coagulation in the beginning and after a short period the ultrasonic mechanism starts. This instrument is the only device using both energies and needs to be considered separately

Table 2 Burst pressure measurements

Product	Generator settings	Evaluable coagulations	External median vessel diameter in mm (range)	Median BP in mmHg (SD; range)	Median length of necrosis zone in µm[b]
Covidien	Level 2	10	5.5	749	1054.4
LigaSure™			(5–6)	(228; 460–1019)	
Covidien	Minimal	6	4	1187.5	3632.7
Sonicision™			4	(416; 583–1702)	
	Maximal	10	4.5	680.5	320.3
			(4–7)	(264; 112–1015)	
ERBE	Level 2	6	6	916	1698.7
BiCision®			6	(459; 421–1691)	
ERBE	Level 2	10	5	303	2083.7
BiClamp®[a] Fenestration			(5–9)	(309; 168–1109)	
ERBE	Level 2	10	5	470	813.9
BiClamp Maryland®[a]			(5–7)	(579; 200–1924)	
Ethicon	Standard	9	5	465	547.4
Enseal®			5	(680; 228–2040)	
Ethicon	Level 3	6	6	1021.5	986.7
Harmonic ACE + 7®			(5–10)	(644; 394–2046)	
	Level 5	6	4	1147	5024.5
			4	(418; 723–1945)	
	Advanced hemostasis	6	6	2007.5	1666.7
			(5–7)	(532; 915–2046)	
Gebrüder Martin	Level G3	9	6	723	1570.9
marSeal®			(5–6)	(245; 413–1125)	
Olympus	Standard	11	5	1238	1357.74
THUNDERBEAT			5	(563; 209–1997)	

SD standard deviation

[a] No dissection function

[b] As only one measurement was performed, no range can be shown

of measurements, median and range or frequencies were provided. Data were analyzed with the SPSS software (IBM SPSS Statistics 24, Ehningen, Germany).

Results

The vessel caliber and anatomic origin of the vessel or the intestine did not have any influence on the experimental outcomes. The median vessel diameter was 5 mm (range 4–10 mm).

Sealing and burst pressure

A summary of the measured BP is shown in Table 2. All devices were measured until at least six coagulations were evaluable. The main reason for non-evaluable measurements was errors in the measuring device and individual vessel ramifications. We observed that all sealed vessels with different devices could withstand a median BP of more than 300 mmHg (range 112–2046 mmHg).

Maximum tissue temperature and cooling time

The time for the sealing procedure was 7.705 s (range 5.305–18.38 s) for the ultrasonic (including THUNDERBEAT) and 7.86 s (range 5.08–10.17 s) for the bipolar devices. The ultrasonic instruments reached a median temperature of 218.1 °C (range 81.3–349.75 °C) and the bipolar devices a temperature of 125.5 °C (range 94.1–133.35 °C). The tissue reached a median temperature of 61.9 °C (range 47.1–80.6 °C) after ultrasonic sealing and 76.7 °C (range 63.1–94.2 °C) after bipolar sealing. The median time till the tissue cooled down to 38 °C was

Table 3 Sealing time, maximum tissue temperature, and time for cooling down

Device	Median sealing time in s (range)	Median temperature of device in °C (range)	Median temperature of the tissue in °C (range)	Median time for tissue cooling down in s (range)
Covidien	5.015	94.1	76.7	31.330
LigaSure™ 2	(4.19–6.5)	(86.8–94.9)	(64–81.6)	(26.09–36.23)
Covidien	9.215	270	63.45	10.480
Sonicision™ half active side up	(8.44–10.52)	(256.6–293.8)	(52.1–88.7)	(5.51–14.77)
Covidien	8.755	136.150	71.35	12.775
Sonicision™ half passive side up	(7.87–10.81)	(119.6–191.8)	(60.1–107.9)	(11.82–23.48)
Covidien	6.925	350	60.35	13.500
Sonisicion™ full active side up	(3.42–8.66)	(281.5–350)	(54.5–98.9)	(7.8–22.38)
Covidien	5.955	168.35	58.65	9.250
Sonisicion™ full passive side up	(5.28–6.6)	(131.5–278.1)	(46.8–64.4)	(5.3–14.04)
ERBE	10.135	125.5	78.15	38.2
BiCision® 2	(9.21–11.14)	(121.2–130.4)	(65.9–86.1)	(35.04–42)
ERBE	5.220	133.35	94.2	82.150
BiClamp® Fenestration	(4.94–5.84)	(111.9–182.4)	(90–96.4)	(42.33–85.32)
ERBE	5.080	125.55	87.4	70.966
BiClamp Maryland®	(4.32–6.74)	(120.4–136.8)	(79–92.9)	(42.33–85.32)
Ethicon	10.000	96.1	63.1	30.350
Enseal® G2	(9.23–11.73)	(72.7–99)	(45.3–70.1)	(10.75–34.44)
Ethicon	13.505	233.5	51.15	15.490
Harmonic ACE + 7® Level 3, active side up	(13.33–14.95)	(205.5–242.1)	(44–71.5)	(11.27–24)
Ethicon	8.485	95.1	75.9	15.510
Harmonic ACE + 7® Level 3, passive side up	(7.32–11.27)	(77.8–132.4)	(52.5–104.8)	(9.0–21.79)
Ethicon	6.670	218.1	47.1	7.445
Harmonic ACE + 7® Level 5, active side up	(5.65–7.58)	(190.6–228)	(39.9–52.8)	(1.92–10.86)
Ethicon	5.070	81.3	50.8	4.445
Harmonic ACE + 7® Level 5, passive side up	(4.63–7.19)	(75.9–95.2)	(47.7–65)	(2.98–7.87)
Ethicon	17.695	233.25	64.65	28.480
Harmonic ACE + 7 ®advanced hemostasis, active side up	(15.54–24.42)	(198.5–350)	(59.8–76.2)	(24.56–35.31)
Ethicon	18.380	181.05	54	31.025
Harmonic ACE + 7® advanced hemostasis, passive side up	(13.74–22.08)	(141.4–243.7)	(50.2–70)	(23.65–33.35)
Gebrüder Martin	7.860	129.8	73.55	44.500
marSeal® G3	(6.8–8.63)	(106.8–134.2)	(66.1–85)	(33.11–49.29)
Olympus	5.340	232.2	68.65	23.275
THUNDERBEAT, active side up	(3.91–9.03)	(219.9–280.1)	(62.8–78.2)	(14.58–26.63)
Olympus	5.305	129.55	80.6	22.520
THUNDERBEAT, passive side up	(3.55–7.39)	(100.9–268.7)	(63.9–118.6)	(20.02–36.14)

14.50 s (range 4.445–31.025 s) for the ultrasonic and 38.27 s (range 30.35–82.15 s) for bipolar sealing. The sealing and cooling down times and the temperature of the tissue and the devices are shown in Table 3.

Compression strength

The median compression area for the ultrasonic devices was 67 mm^2 (range 50–63 mm^2) and that for the bipolar

Table 4 Compression area and pressure strength

Devices	Compression area in mm^2	Length of compression zone in mm	Maximum pressure[a]	Pressure strength after 5 mm in %	Pressure strength after 10 mm in %
Covidien LigaSure™	98	16.15	94.57	66.67	29.89
Covidien Sonicision™	50	12.31	57.61	62.26	24.53
ERBE BiCision®	98	18.08	70.65	80	38.46
ERBE BiClamp®	99	14.23	110.87	50.98	19.61
ERBE BiClamp Maryland®	77	16.15	93.48	74.42	41.86
Ethicon Enseal®[b]	83	12.31	94.57	57.47	10.34
Ethicon Harmonic ACE + 7®	53	11.67	67.39	59.68	14.52
Gebrüder Martin marSeal®	102	14.87	86.96	96.25	50
Olympus THUNDERBEAT	61	14.1	63.04	43.14	18.63

[a] No unit of measurement was assigned to the pressure strength during the evaluation

[b] Ethicon Enseal increases the pressure strength during the cutting process. Our experiment was performed without cutting and hence the values are limited

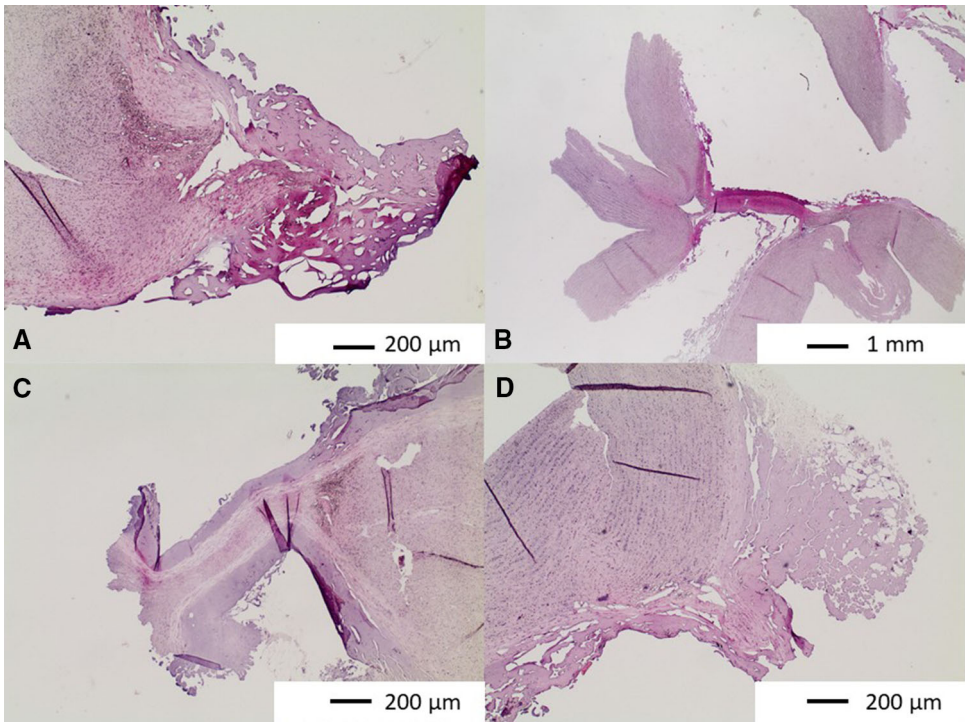


Fig. 2 Histological images: **A** Olympus THUNDERBEAT, **B** ERBE BiClamp Maryland®, **C** Covidien LigaSure™, and **D** Ethicon Harmonic ACE + 7® 3

devices was 98 mm^2 (range 77–102 mm^2). The compression force decreased with the ultrasound devices by 50% in the median after a centimeter, and by 60% with the bipolar devices (Table 4). Figure 1 demonstrates the relation of the compression strength to distance of the jaws.

Necrosis zone

The necrosis zone ranged from 320.30 µm (Sonicision high) being the lowest to 5024.50 µm (Harmonic ACE + 7® Level 5) being the highest (Table 2). Figure 2 shows the histological sections of Olympus

Table 5 Calculation of the SCD score

	Temperature of the device (scaled)	Burst pressure (scaled)	Sealing time (scaled)	SCD score
Harmonic ACE + 7® advanced hemostasis	13.33	20	17.7	12.24
THUNDERBEAT	13.27	11.29	5.34	10.99
Harmonic ACE + 7® Level 5	12.46	10.25	6.67	10.34
LigaSure™	5.38	5.7	5.02	10.25
BiCision®	7.17	7.61	10.14	9.48
Sonicision™ half	15.43	10.71	9.22	9.19
marSeal®	7.42	5.41	7.86	8.88
BiClamp Maryland®	7.17	2.51	5.08	8.19
Harmonic ACE + 7® Level 3	13.34	8.82	13.51	7.7
Enseal®	5.49	2.46	10	7.36
BiClamp®	7.62	0.61	5.22	7.09
Sonisicion™ full	20	4.92	6.93	5.73

THUNDERBEAT (ultrasonic and bipolar, A), ERBE BiClamp® (bipolar without dissection function, B), Covidien LigaSure™ (bipolar, C), and Ethicon Harmonic ACE + 7® Level 3 (ultrasonic, D).

SCD Score

The median SCD score was 9.04 (range 5.73–12.24). The values calculated for the score are shown in Table 5.

Discussion

The number of sealing and cutting devices for laparoscopic procedures is constantly increasing; however, in vitro models for evaluation of efficacy and safety parameters are scarce and only limited to individual parameters. Moreover, properties have been compared only in small groups. In this study, we compared nine different laparoscopic devices from four different categories. The aim of this work was to compare the safety and efficacy profiles of nine laparoscopic sealing and cutting devices in a porcine model with a new scoring system. Each device was tested for compressive pressure, thermal development and energy release, BP after vessel sealing, and the resulting necrosis zone.

The devices used in recent times undergo continuous development, as surgeons demand these instruments for more difficult and complex procedures [28, 29]. The porcine model is suitable as the calibers of the sealed porcine vessels (carotid arteries [median: 5 mm]) were comparable with the human uterine artery, which ranges from 3 to 5 mm in diameter [30]. The purified porcine small bowels have a homogeneous and evenly thick tissue that is most suitable for experiments on thermal measurement. Hence, it can be concluded that all instruments evaluated in this study safely sealed the vessel, as no median burst values below 300 mmHg were recorded. In accordance to our findings, the BP measurements showed reliable sealing results on explanted porcine arteries. Our results are in the range of reported values in the literature [3, 4, 8, 21, 31–35]. An important clinical aspect is the collagen–elastin ratio in vessels, which predicts the BP of arteries using bipolar sealing [36].

In this work, the thermal behavior of the instruments and the energy output to the tissue were measured. Even if one of the instruments reached temperatures above 350 °C, the temperature of the tissue did not exceed 94 °C. Sealed tissue takes up to 80 s to reattain body temperature. The closing pressures are higher than that on bipolar instruments.

Tissue necrosis due to thermal damage is an important factor for vessel sealing. The detection and evaluation of the thermal damage is reportedly difficult [37, 38].

Not only the maximum temperature but also the duration of heat application is responsible for the extent of permanent damage [39].

In literature, the process and quality of the sealing are described as strongly dependent on the pressure distribution and the actual pressure between the jaws [21, 22]. Another issue worth mentioning is the closure pressure on the instruments.

All instruments showed similar closing pressure and a decrease of this pressure from the base to the tip. To our best knowledge, this study evaluates the largest number of different instruments and measurements. We acknowledge that the significance of this study is presently limited, as no statistical association could be derived owing to the low number of cases. However, all properties were measured with high reproducibility. Additionally, the aim of the study was to

demonstrate that all the instruments could reach values that are safe for everyday clinical practice. The choice of the instrument depends on the user and convenience of handling. The lateral thermal spread in the tissue remains a major issue for clinical handling and shall be investigated in future studies that address the impact of the devices' proximity to sensitive organs and structures. It is important to consider the moisture levels in the tissue during these tests, because water vapor, which is produced during the sealing, spreads laterally and can cause collateral damage.

This parameter could also be inserted into the SCD score. Future studies should aim to perform more measurements during the thermal imaging stage. Using the SCD score described herein, instruments can be easily compared with each other and their safety represented in a comprehensible manner.

Conclusion

To our best knowledge, this is the largest comparison of laparoscopic cutting and sealing devices that showed that all the instruments used are safe for daily clinical routine. The new SCD scoring system allows an indirect comparison of the instruments.

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Compliance with ethical standards

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