



A novel device designed to improve the operability of energy devices with foot pedals in endoscopic surgery: the Foot-Site Monitor

Akihiro Kondo^{1,2} · Yuji Nishizawa² · Yasumasa Horikiri³ · Hiroki Amemori⁴ · Yuichiro Tsukada² · Takeshi Sasaki² · Toshikazu Kawai⁴ · Hiroyuki Daiko⁵ · Masaaki Ito²

Received: 5 February 2019 / Accepted: 14 May 2019 / Published online: 27 May 2019
© Springer Nature Singapore Pte Ltd. 2019

Abstract

Purpose We developed the “Foot-Site Monitor” (FSM) to permit easy identification of multiple foot pedals of energy devices in endoscopic surgery. The purpose of this study was to evaluate the effectiveness of the use of the FSM.

Methods Using a training box, 20 surgeons performed a task consisting of pressing foot pedals with and without the FSM. The time from showing a color on a PC monitor to pressing the foot pedal that corresponded to this color (defined as the completion time), and the distance of the movement of the tip of the surgeon’s forceps from the beginning to the end of the task (defined as shaking of the forceps) were measured.

Results The use of the FSM was associated with significantly reduced shaking of the forceps (1.95 vs. 2.47 mm; $p=0.014$), and a tendency toward a shorter completion time (1.39 vs. 1.51 s; $p=0.053$).

Conclusions The use of the FSM in endoscopic surgery contributes to reduced shaking of the forceps and may shorten the operative time.

Keywords Endoscopic surgery · Foot-Site Monitor · Energy device · Interface · Foot pedal

Introduction

Endoscopic surgery has recently come into wider use in the treatment of thoracic and abdominal diseases. One reason for this change is the development of endoscopic device technologies such as monopolar, ultrasonically activated, and

bipolar or vessel sealing devices. The use of these energy devices (EDs) is beneficial for use in endoscopic surgery [1–15] due to their potential to reduce operative times [3, 9, 11–14] and blood loss [8]. With the development of EDs, there has been a parallel increase in human–machine (surgeon–ED) interfaces, in the form of hand switches or foot pedals. Multiple interfaces in endoscopic surgery result in complicated and uncomfortable maneuvers, particularly when multiple foot pedals are used, which may lead to unintended movement of the surgical forceps in the surgeon’s hands because the surgeon is looking for the correct foot pedal. This extends the operative time and may cause organ injury organs. Thus, there is a need for surgeons to be able to identify foot pedals in a simple way. For this purpose, we developed the “Foot-Site Monitor” (FSM) as a novel device to allow the simple use of multiple foot pedals in endoscopic surgery. The purpose of this study was to evaluate whether the FSM is beneficial for the stability of surgical forceps while controlling foot pedals and whether its use contributes to reducing the operative time.

✉ Yuji Nishizawa
yunishiz@east.ncc.go.jp

¹ Department of Surgery, KKR Takamatsu Hospital, Federation of National Public Service Personnel Mutual Aid Associations, 4-18 Tenjinmae, Takamatsu, Kagawa 760-0018, Japan

² Department of Colorectal Surgery, National Cancer Center Hospital East, 6-5-1 Kashiwanoha, Kashiwa, Chiba 277-8577, Japan

³ Department of Esophageal Surgery, National Cancer Center Hospital East, 6-5-1 Kashiwanoha, Kashiwa, Chiba 277-8577, Japan

⁴ Graduate School of Robotics and Design, Osaka Institute of Technology, 1-45 Chayamachi, Kita-ku, Osaka, Osaka 530-8568, Japan

⁵ Department of Esophageal Surgery, National Cancer Center Hospital, 5-1-1 Tsukiji, Chuo-ku, Tokyo 104-0045, Japan

Methods

The FSM was developed as a camera unit with a wide-angle

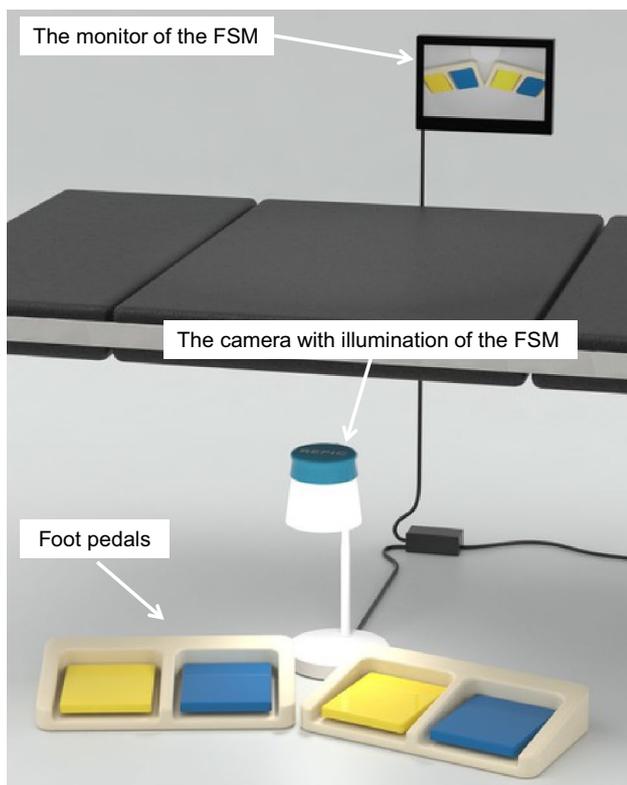
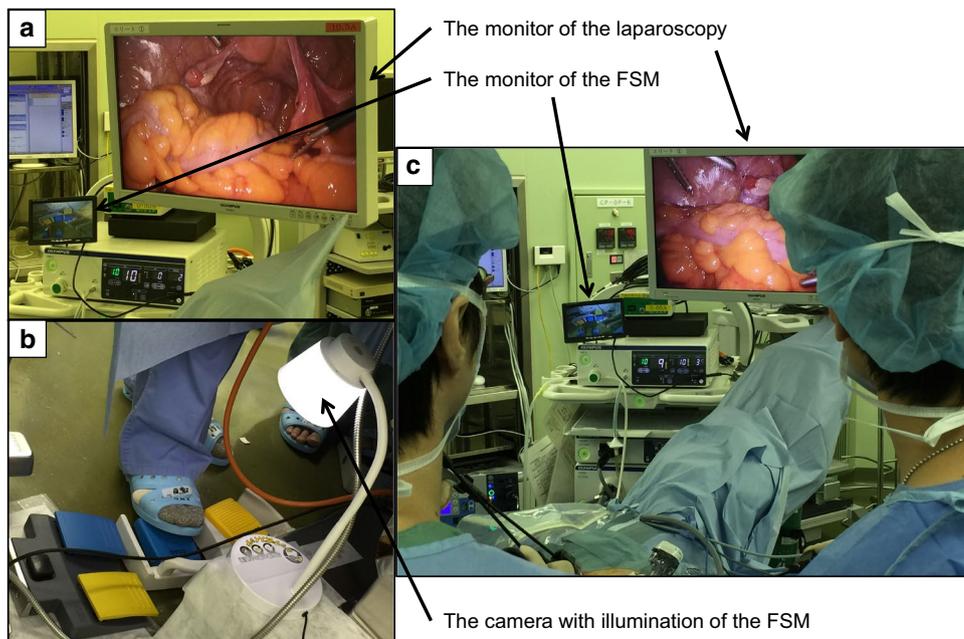


Fig. 1 The Foot-Site Monitor was developed as a novel peripheral device for use during endoscopic surgery

Fig. 2 Clinical positioning of the Foot-Site Monitor (FSM). **a** The monitor of the FSM is placed near the endoscopic monitor. **b** The camera of the FSM with illumination is positioned close to the foot pedals. **c** The surgeon could see both the endoscopic monitor and the FSM in the same view



lens and an integrated light source. A real-time image is taken by the camera and fed to a monitor (Fig. 1). In the clinical setting, the camera is placed by the foot pedals and the monitor is positioned near the endoscopic monitor (Fig. 2). A surgeon can identify the position of the foot pedals by looking at the monitor without the need to look down or change position.

Twenty surgeons with different levels of experience in endoscopic surgery at National Cancer Center Hospital East agreed to participate in the study. The number of participants included in the study determined the study size. Using a training box, each surgeon performed a task consisting of pressing a foot pedal with and without the FSM. An overview of the experiment is shown in Fig. 3. The FSM camera was placed close to four foot pedals and the FSM monitor was positioned near the endoscopic monitor. The area of each foot pedal was 100 × 60 mm and each had a different color. The distance between the foot pedals was 60 mm, which was equal to the transverse diameter of each foot pedal. One of the four foot pedal colors was shown on the PC monitor, and the surgeon pressed the corresponding pedal. The endoscopy monitor was used to measure the movement of the forceps during this process. Each surgeon practiced this procedure five times with and without the FSM, and then the real experiment was performed ten times in the same manner. The color shown on the PC monitor and the use or non-use of the FSM were randomized for each foot pedal press to minimize the selection bias.

Two measurements were made: the time from showing a color on the PC monitor to pressing the foot pedal of the same color (completion time), and the distance of movement of the tip of the forceps during this time (tip movement). The

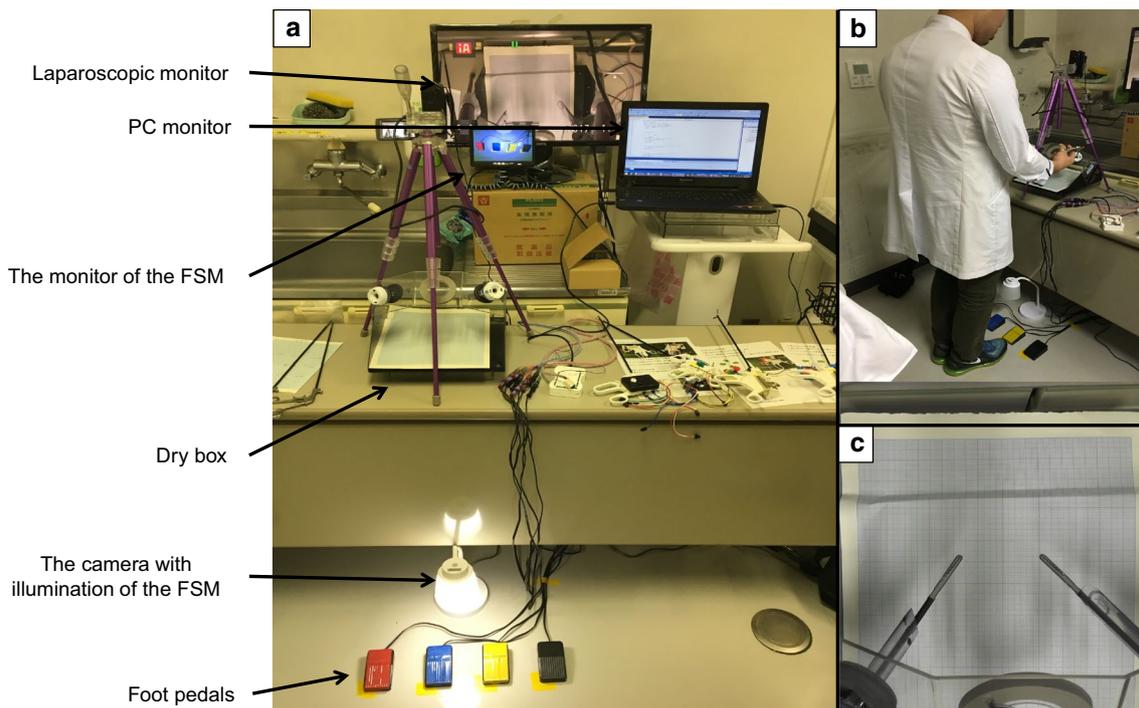


Fig. 3 Overview of the study. **a, b** The procedure used in the study. **c** Plotting paper was placed on the bottom of the training box to measure the movement of the tip of the forceps

completion time was measured by a microcontroller positioned between the foot pedals and the PC monitor (Fig. 4). The tip movement was measured in a video recorded by the endoscopy system. Plotting paper was placed on the bottom of the training box to measure this distance (Fig. 3c). Shaking of the forceps was calculated with the following formula: (vertical tip movement of the right forceps + vertical tip movement of the left forceps + horizontal tip movement of the right forceps + horizontal tip movement of the left forceps)/4. The tip of the forceps was placed in a stable position for each participant, in order to eliminate individual variability in the position of the tip, which minimized bias in shaking of the forceps. With regard to the pressing of the pedal, the surgeon is free to choose which foot should be used to press the pedal in clinical practice; thus, the protocol of this study did not prescribe the use of the right or left foot or both feet. The mean completion time and the shaking of the forceps were calculated for each participant. These continuous variables were compared between procedures with and without the use of the FSM by a Wilcoxon signed rank test. All statistical analyses were performed using the SPSS software program (SPSS, version 22; IBM Statistics, Chicago, IL, USA). p values of <0.05 were considered to indicate statistical significance.

This study was reviewed by the Institutional Review Board (IRB) of National Cancer Center Hospital, Chiba,

Japan, which determined that it did not require ethical approval (No. NCC6000-009). The report of the work adheres to the STROBE guidelines for an observational study, and the study was carried out in accordance with the 1964 Declaration of Helsinki and its later amendments.

Results

The mean completion times and shaking of the forceps for 20 participants (male, $n = 18$; female, $n = 2$) are shown in Table 1. The median career length as a surgeon was 8 years (range 6–15 years). Eighteen participants (90%) used the bilateral feet to press the pedal; two used only one foot. Of the 20 participants, 13 (65%) had a shortened completion time and 15 (75%) had reduced shaking of the forceps with use of the FSM. With the use of the FSM, the median completion time was shortened by 0.12 s and the median shaking of the forceps was reduced by 0.52 mm. The use of the FSM significantly reduced shaking of the forceps (1.95 mm, range 0.48–4.60 vs. 2.47 mm, range 0.90–4.60; $p = 0.014$) and tended to be associated with a decreased completion time (1.39 s, range 0.91–2.29 vs. 1.51 s, range 0.92–2.63; $p = 0.053$).

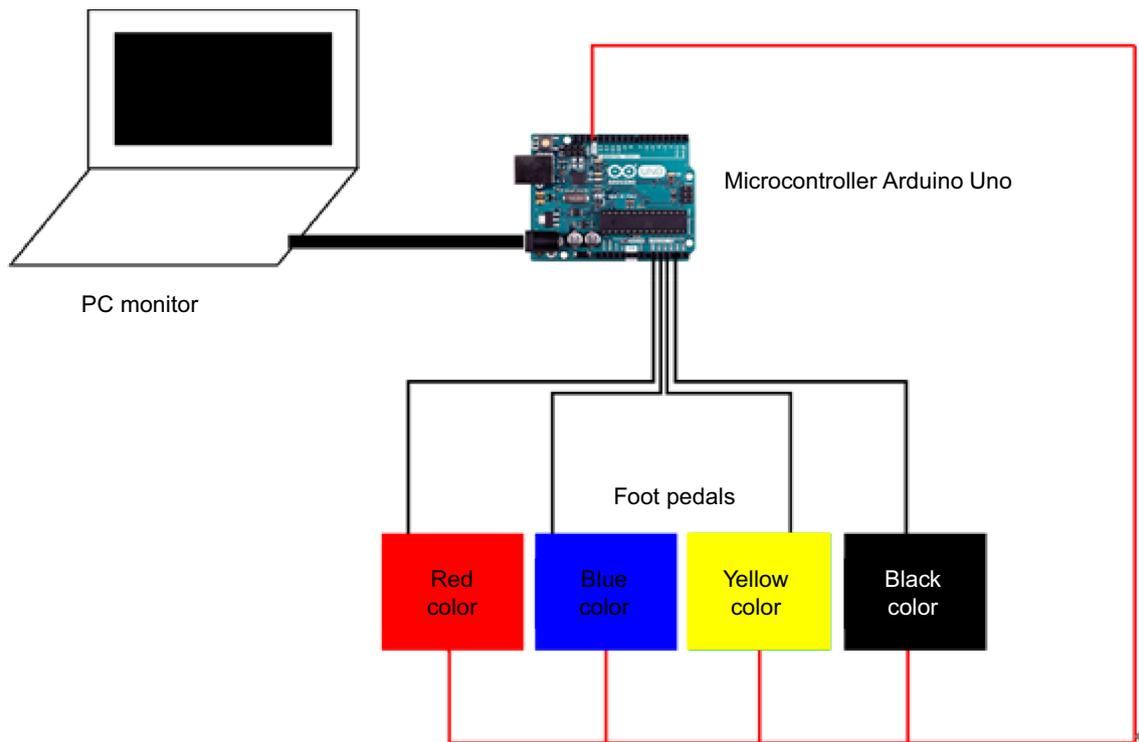


Fig. 4 Method of measuring the completion time

Table 1 Characteristics of the participants and the results of the experience

Participants	Experience (years)	Use of the foot	Completion time (s, mean)		Shaking of the forceps (mm, mean)	
			FSM (–)	FSM (+)	FSM (–)	FSM (+)
1	8	Unilateral	0.9156	0.9085	1.05	1.75
2	15	Bilateral	1.6850	1.2590	2.30	2.85
3	6	Bilateral	2.3679	1.6608	2.15	1.08
4	6	Bilateral	1.5363	1.3902	3.93	4.60
5	6	Bilateral	1.2367	1.1736	2.13	2.03
6	6	Bilateral	1.5014	1.3096	3.08	2.93
7	8	Bilateral	1.0037	1.0305	2.63	2.95
8	8	Bilateral	1.2438	1.2468	3.27	2.28
9	9	Bilateral	1.3601	1.3534	2.08	1.98
10	7	Bilateral	1.1649	0.9634	2.08	0.98
11	10	Bilateral	1.3508	1.4829	3.80	2.83
12	11	Bilateral	1.6495	1.2817	2.05	0.85
13	10	Bilateral	1.8183	1.405	1.33	0.48
14	6	Bilateral	1.2525	2.0548	1.38	1.50
15	9	Bilateral	1.6415	1.2514	4.60	1.70
16	8	Bilateral	1.4224	1.4611	2.10	1.68
17	8	Unilateral	1.8771	1.6037	2.55	1.55
18	10	Bilateral	1.4248	1.5552	3.30	2.80
19	7	Bilateral	2.6272	2.2993	2.63	1.70
20	9	Bilateral	1.1346	1.1506	0.90	0.58
	<i>p</i> value		0.053		0.014	

FSM Foot-Site Monitor

Discussion

The FSM was developed to facilitate the easy identification of multiple foot pedals of EDs used in endoscopic surgery. The results of this study indicate that the use of the FSM significantly reduced shaking of the forceps and tended to reduce the time required to press the pedal.

Recent advances in EDs and forceps have markedly changed endoscopic surgery, and the appropriate use of these instruments enables effective and safe endoscopic surgery. This usage includes the delicate manipulation of EDs and forceps during endoscopic surgery. Several studies have examined methods to improve the manipulation of these laparoscopic devices. Matsunaga et al. showed that the use of 3D images enables the more accurate use of laparoscopic forceps in comparison to the use of 2D images [16]. Rashid et al. found that a robotically assisted laparoscopic system offers improved accuracy in comparison to laparoscopy for trainees [17]. Such systems are not always available, but the improved accuracy of surgical manipulation is always important for precise and safe surgery.

For the delicate control of EDs, the devices need to be consistent with the surgical techniques and user-friendly during endoscopic surgery, which requires a good surgeon-device interface. In robotic systems that assist or control the devices or endoscope, various types of human-machine interface have been suggested, such as remote hand switches [18], instrument-mounted joysticks [19], foot pedals [20], voice recognition [21], head/face control and instrument tracking, and the effectiveness of each of these interfaces has been examined. The EDs in endoscopic surgery mainly involve the use hand switches or foot pedals as human-machine interfaces. Surgeons use different devices in endoscopic surgery, but only simple foot motion is possible because of the requirement for delicate maneuvers of the bilateral hands and concentration of the eyes on the endoscopic monitor. Thus, the development of an operative peripheral device with improved user-friendliness with regard to foot pedals is important for improving the operability of EDs.

The FSM was developed to avoid misdirected pressing of the foot pedals, to avoid the surgeon dropping from having to drop his or her eyes from the endoscopic monitor while pressing the foot pedals, and to reduce shaking of the tip of the forceps. In our experience in the use of the FSM prevents the surgeon from having to look down from the laparoscopic monitor when pressing the foot pedals, and significantly reduces shaking of the forceps tip. These results suggest that the use of the FSM could avoid harm to patients in endoscopic operations, including electrosurgery-related adverse events, such as surgical burn and bowel injuries [22]. The time required to press

the foot pedal also tended to be reduced when using the FSM. This indicates that the use of the FSM can shorten the total operative time, since the foot pedals are pressed many times in a single endoscopic surgery. In this study, 18 participants used the bilateral feet to press the pedal, while two used only one foot. This difference may have affected the results. However, in clinical practice, each surgeon should be free to use either foot or both feet, based on the ease of operation, and for this reason the study protocol did not prescribe the use of a particular foot or both feet. Furthermore, the results obtained when one foot or both feet were used did not seem to differ to a statistically significant extent.

There are some possible problems associated with the introduction of this device into clinical practice. The size of the monitor of the FSM is smaller than that of a laparoscopic monitor, and this difference in size may affect the surgeon's vision. Also, the use of the FSM by the laparoscopic surgeon may be associated with lower limb fatigue, which Nishimoto et al. found to be significant during an operation [23]. However, if the smooth pressing of the foot pedal with the use of the FSM can be achieved in clinical practice, this fatigue may be decreased. An ergonomic assessment was not performed in this study, and a further study is needed to evaluate the ergonomics of the FSM.

The present study was associated with several limitations. First, it had a single-center design and a relatively small study population. Second, the experience of the surgeons, especially in endoscopic surgery, may have affected the results, but we did not evaluate this effect. Third, most participants used the bilateral feet to press the pedal, while two used only one foot. The use of one foot or both feet was not restricted in the study, and the surgeon's choice might have affected the results. Finally, this was a simulated study, and a clinical study is required to evaluate the use of the FSM in endoscopic surgery. Despite these limitations, the findings suggest that the use of the FSM as a novel operative peripheral device may improve the outcomes of endoscopic surgery by increasing the stability of the forceps and reducing the total operative time. Furthermore, this study can serve as a model for general endoscopic surgeons because participants with various levels of experience were included.

Author contributions AK, YN, YH and HA collected and interpreted the data. AK and YN interpreted data and wrote the paper, and contributed equally to the manuscript. YH, HA, YT, TS, TK, HD and MI made substantial contributions to the conception and design of the study, and were involved in drafting the manuscript and revising it critically for important intellectual content. All authors declare that they contributed to this article and that they all approve the final submitted version.

Funding Funding for this study was provided by Hayashi-Repic Co., Ltd. which is developing products related to the research described in this publication.

Data availability Raw data were generated at National Cancer Center Hospital East. Derived data supporting the findings of this study are available from the corresponding author (YN) on request.

Compliance with ethical standards

Conflict of interest Dr. Nishizawa received Grants from Hayashi-Republic Co., Ltd.

References

- Kamiyoshihara M, Igai H, Ibe T, Kawatani N, Ohtaki Y, Shimizu K, et al. Right superior mediastinal lymph node dissection in thoracoscopic surgery using a bipolar sealing device. *Innovations*. 2013;8:258–63.
- Dural C, Akyuz M, Yazici P, Aksoy E, Aucejo F, Quintini C, et al. Safety and efficacy of a new bipolar energy device for parenchymal dissection in laparoscopic liver resection. *Surg Laparosc Endosc Percutan Tech*. 2016;26:21–4.
- Weyhe D, Uslae VN, Tabriz N, Burkowski I, Heinzel R, Muller A, et al. Experience and dissection device are more relevant than patient-related factors for operation time in laparoscopic sigmoid resection—a retrospective 8-year observational study. *Int J Colorectal Dis*. 2017;32:1703–10.
- Choussein S, Srouji SS, Farland LV, Gargiulo AR. Flexible carbon dioxide laser fiber versus ultrasonic scalpel in robot-assisted laparoscopic myomectomy. *J Minim Invasive Gynecol*. 2015;22:1183–90.
- Gotohda N, Yamanaka T, Saiura A, Uesaka K, Hashimoto M, Konishi M, et al. Impact of energy devices during liver parenchymal transection: a multicenter randomized controlled trial. *World J Surg*. 2015;39:1543–9.
- Richter S, Kollmar O, Schuld J, Moussavian MR, Igna D, Schilling MK, Chirurgische Arbeitsgemeinschaft OP-Technik und OP-Strukturen (CAOP) of the Deutsche Gesellschaft für Allgemein- und Viszeralchirurgie. Randomized clinical trial of efficacy and costs of three dissection devices in liver resection. *Br J Surg*. 2009;96:593–601.
- Ikeda M, Hasegawa K, Seno K, Imamura H, Beck Y, Sugawara Y, et al. The vessel sealing system (LigaSure) in hepatic resection: a randomized controlled trial. *Ann Surg*. 2009;250:199–203.
- Targarona EM, Balague C, Marin J, Neto RB, Martinez C, Garriga J, et al. Energy sources for laparoscopic colectomy: a prospective randomized comparison of conventional electrosurgery, bipolar computer-controlled electrosurgery and ultrasonic dissection. Operative outcome and costs analysis. *Surg Innov*. 2005;12:339–44.
- Kossi J, Luostarinen M, Kontula I, Laato M. Laparoscopic sigmoid and rectal resection using an electrothermal bipolar vessel sealing device. *J Laparoendosc Adv Surg Tech A*. 2007;17:719–22.
- Milsom J, Trencheva K, Menette S, Pavoov R, Shukla P, Ma J, et al. Evaluation of the safety, efficacy, and versatility of a new surgical device (THUNDERBEAT) in comparison with Harmonic ACE, LigaSure V, and EnSeal devices in a porcine model. *J Laparoendosc Adv Surg Tech A*. 2012;22:378–86.
- Garfinkle R, Boutros M, Hippalgaonkar N, Maimon G, da Silva G, Potenti F, et al. Electrothermal bipolar vessel ligation improves operative time during laparoscopic total proctocolectomy: a large single-center experience. *Surg Endosc*. 2016;30:2840–7.
- Kim YN, Yoo YC, Guner A, Cho I, Kwon IG, Kim YN, et al. Comparison of perioperative surgical outcomes between a bipolar device and an ultrasonic device during laparoscopic gastrectomy for gastric cancer. *Surg Endosc*. 2015;29:589–95.
- Vizzielli G, Conte C, Romano M, Fagotti A, Constantini B, Lodoli C, et al. Clinical impact of a surgical energy device in advanced ovarian cancer surgery including bowel resection. *In Vivo*. 2018;32:359–64.
- Stotz L, Joukhdar R, Hamza A, Thangarajah F, Bardens D, Juhasz-Boss I, et al. Instrument usage in laparoscopic gynecologic surgery: a prospective clinical trial. *Arch Gynecol Obstet*. 2018;298:773–9.
- Jaiswal A, Huang KG. Energy devices in gynecological laparoscopy—archaic to modern era. *Gynecol Minim Invasive Ther*. 2017;6:147–51.
- Matsunaga R, Nishizawa Y, Saito N, Kobayashi A, Ohdaira T, Ito M. Quantitative evaluation of 3D imaging in laparoscopic surgery. *Surg Today*. 2017;47:440–4.
- Rashid TG, Kini M, Ind TE. Comparing the learning curve for robotically assisted and straight stick laparoscopic procedures in surgical novices. *Int J Med Robot*. 2010;6:306–10.
- Sackier J, Wang Y. Robotically assisted laparoscopic surgery: From concept to development. *Surg Endosc*. 1994;8:63–6.
- Buess G, Arezzo A, Schurr M, Ulmer F, Fisher H, Gumb L, et al. A new remote-controlled endoscope positioning system for endoscopic solo surgery: the FIPS endoarm. *Surg Endosc*. 2000;14:395–9.
- Allaf M, Jackman S, Schulam P, Cadeddu J, Lee B, Moore R, et al. Laparoscopic visual field: voice vs foot pedal interfaces for control of the AESOP robot. *Surg Endosc*. 1998;12:1415–8.
- Vara-Thorbeck C, Munoz V, Toscano R, Gomez J, Fernandez J, Felices M, et al. A new robotic endoscope manipulator: a preliminary trial to evaluate the performance of a voice-operated industrial robot and a human assistant in several simulated and real endoscopic operation. *Surg Endosc*. 2001;15:924–7.
- van der Voort M, Heijnsdijk EA, Gouma DJ. Bowel injury as a complication of laparoscopy. *Br J Surg*. 2004;91:1253–8.
- Nishimoto W, Kawahira H, Shimomura Y, Nishizawa Y, Ito M. A standing posture support device that reduces laparoscopic surgeons' occupational lower limb stress. *Minim Invasive Ther Allied Technol*. 2018;28:151–6. <https://doi.org/10.1080/13645706.2018.1491407>.

Publisher's Note Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.