

Comparison of Gyrus PKS™ PlasmaSpatula Versus Vectec™ Monopolar L-Hook During Colpotomy Step in Total Laparoscopic Hysterectomy in Terms of Vaginal Cuff Thermal Damage

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Abstract

Objective: Thermal injury is a complication that can develop during laparoscopic hysterectomy. The ureter, which is located close to the surgical margin, may be damaged, especially due to the thermal effect created by the electrosurgical devices used in the colpotomy step. The aim of this study is to compare the vaginal cuff thermal injury caused by 2 different energy-based surgical devices used in the colpotomy step in total laparoscopic hysterectomy.

Methods: The study included 55 patients who underwent laparoscopic hysterectomy. Patients were randomly assigned to the Bipolar Gyrus® PKS PlasmaSpatula (Gyrus-ACMI, Maple Grove, MA) cutting device group (n = 27) or the Monopolar L-Hook (VECTEC, Bioparc, Hauterive, France) cutting device group (n = 28), and colpotomy was performed using the assigned energy-based surgical device for each group. The removed uterus was examined by the same pathologist in the pathology department. During the colpotomy stage, the thermally damaged area was measured and photographed in millimeters from the application point of the electrosurgical device at the cervix–vaginal border. The extent of lateral thermal damage was measured in width using a light microscope from the point of instrument application to the margin of unchanged nearby tissue.

Results: Thermal damage was significantly greater in the Monopolar L-Hook group than in the Bipolar Gyrus® PKS PlasmaSpatula cutting device group (8.1 mm [range 6.6-9.1 mm] vs. 4.7 mm [range 4.1-5.6 mm], $P = .000$). However, Bipolar Gyrus® PKS PlasmaSpatula provided a better surgical field as it did not produce excessive smoke and caused less thermal damage. The colpotomy time, cuff closure time, total operative time, blood loss, and cuff cellulite were similar between the 2 groups.

Conclusion: Bipolar Gyrus® PKS PlasmaSpatula caused less lateral thermal damage and provided a better non-smoked surgical view compared to the Monopolar L-Hook cutting device.

Keywords: Bipolar, colpotomy, monopolar, thermal damage

Energy-based surgical devices (ESDs) facilitate complex laparoscopic procedures such as endoscopic gynecological surgery. Vessel-sealing and cutting devices have been shown to be superior to other electrothermal devices in some abdominal or laparoscopic procedures.^{1,2} However, ESDs generate surgical smoke or steam that can obstruct the laparoscopic view of the surgical field.^{3,4} Moreover, ESDs can also cause lateral thermal damage.⁵

Although Monopolar L-Hook is commercially available (Figure 1) and is commonly used in clinical practice, there is little or no documentation of the use of advanced (Gyrus-ACMI, Maple Grove, MA) PKS PlasmaSpatula cutting device (Figure 2) in the colpotomy step of total laparoscopic hysterectomy (TLH) with regard to thermal damage and surgical smoke.

The main objective of this study was to compare Monopolar L-Hook (VECTEC, Bioparc, Hauterive, France) and Bipolar Gyrus

® PKS PlasmaSpatula (Gyrus-ACMI, Maple Grove, MA) in the colpotomy step of TLH with regard to vaginal cuff thermal damage and surgical smoke. The primary outcomes were determined as vaginal cuff thermal damage (in millimeters), colpotomy duration (in minutes), intraoperative blood loss, effectiveness, safety, and amount of surgical smoke, while secondary outcomes were determined as cuff dehiscence, cuff cellulite, and postoperative pain assessment (Visual Analog Scale [VAS] scores).

Coronavirus disease 2019 (COVID-19) remains a serious health problem worldwide. There is no conclusive evidence that the aerosol produced by energy devices can transmit active severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus; however, the transmission is biologically plausible.⁶ The present study aimed to investigate the amount of surgical smoke produced by 2 different energy devices during laparoscopy. Our results may shed light on future studies regarding the transmissibility of COVID-19 via surgical smoke.

Methods

The present study was conducted at Alanya Alaaddin Keykubat University Obstetrics and Gynecology Department between September 2019 and March 2021. The study was approved by

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Figure 1. VECTEC Monopolar L-Hook cutting device.

the institutional ethics committee (Approval No: 25-23, Date: November 19, 2020).

A written informed consent was obtained from each patient. The study included women who were scheduled for laparoscopic hysterectomy due to benign or premalignant gynecological indications and consented to randomization for the present study. Exclusion criteria were as follows: uterine size exceeding 20 weeks gestation, desire for pregnancy, suspicious malignancy, contraindication for high intraabdominal pressure, conversion to laparotomy, and presence of deep endometriosis. Demographic characteristics, pre-, intra-, and postoperative values, and 3-month follow-up data were recorded for each patient.

The enrolled participants were randomized by sealed envelopes into 2 groups: (i) Monopolar L-Hook cutting group and (ii) Bipolar



Figure 2. Gyrus ® PKS PlasmaSpatula bipolar cutting device.

Gyrus ® PKS PlasmaSpatula group. The envelopes were selected randomly by each participant in the preoperative preparation room, and colpotomy was performed using the assigned ESD for each group. All patients were evaluated post-operatively on day 15 and at months 1 and 3 by the same physician.

The internationally standardized TLH procedure was performed in all patients. The patient was placed in the lithotomy position. Prior to general anesthesia, preoperative antibiotic prophylaxis was administered with 2 g cephazolin. Vaginal valve retractors were inserted and the cervix was held by a single-tooth tenaculum. A RUMI® II/KOH-Efficient™ (Cooper Surgical, Trumbull, CT, USA) Uterine Manipulator System (artUM) was inserted to assist the surgery. A 10-mm, 0-degree laparoscope was inserted into abdominal cavity by Verress needle or direct trocar method either through the umbilicus or Lee-huang point depending on the size of uterus. Advanced bipolar devices such as Ligasure (Covidien-Medtronic, Dublin, Ireland) were used during all the vessel- and tissue-sealing procedures.

Colpotomy was performed by a circumferential vaginal incision above the level of RUMI® II/KOH-Efficient™ manipulators. Monopolar L-Hook was adjusted to 35 w pure cut current for standardization. The uterus was extracted from the abdominal cavity via vagina in all patients. If the uterus was too big to be removed via vagina, the uterus was divided in half by using a morcellator knife during laparoscopy.⁷ The extracted uterus was immediately sent for pathological examination and all the specimens were examined macroscopically and microscopically by the same pathologist (C.G.). Since the study was designed as a blinded study, the pathologist did not know whether the specimen was in the Bipolar Gyrus ® PKS PlasmaSpatula cutting device group or Monopolar L-Hook group. During the pathological examination, the extent of lateral thermal damage was measured in width by using a light microscope from the point of instrument application to the margin of unchanged nearby tissue (Figures 3 and 4).

The vaginal cuff was closed using Vicryl 1.0 intracorporeal suture. Vaginal cuff suturing was initiated by a single Z-suture from the left attachment to the upper posterior vagina through the uterosacral ligament, and full thickness of posterior and anterior vaginal walls was also included. Serum hemoglobin (Hb) levels were measured 2 hours before and after the surgery.

After surgery, all the patients were instructed to avoid tub bath, sauna, spa, and sexual intercourse for 6 weeks. Patients were

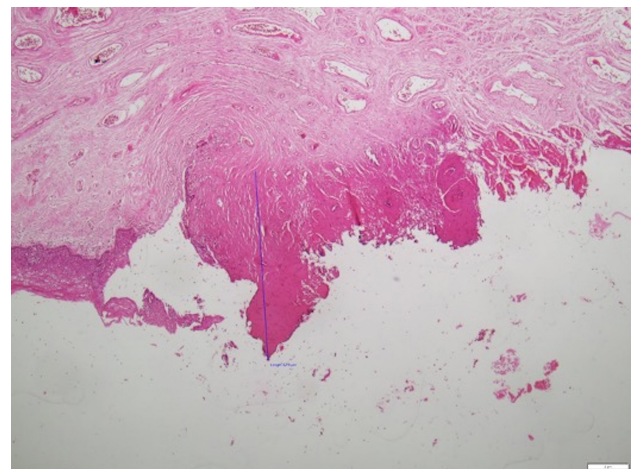


Figure 3. The depth of thermal injury measurement by VECTEC Monopolar L-Hook cutting device (H&E, x40). H&E, hematoxylin and eosin.

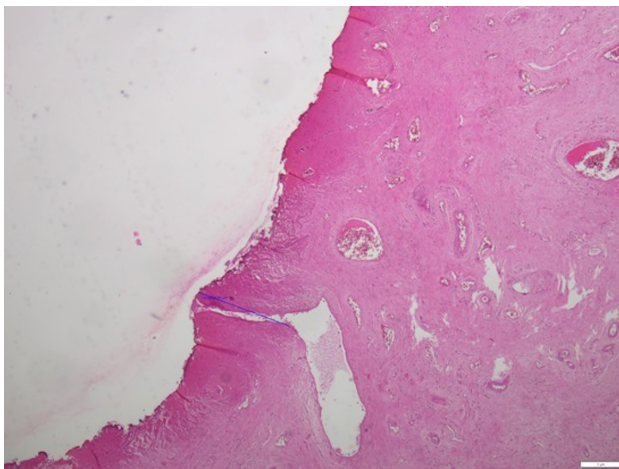


Figure 4. The depth of thermal injury measurement by Bipolar Gyrus ® PKS PlasmaSpatula cutting device (H&E, ×40). H&E, hematoxylin and eosin.

evaluated 3 times during the follow-up period (on day 15 and at month 1 and 3). Postoperative complications and complaints were recorded. Speculum examination and transvaginal ultrasonography was performed to detect hematomas, abscesses, or fluid-like urine discharging from the vaginal cuff.

Statistical analysis

Data were analyzed using Statistical Package for the Social Sciences for Windows version 20.0 (IBM SPSS Corp.; Armonk, NY, USA). Descriptives were expressed as frequencies (n) and percentages (%) for categorical variables and as median (interquartile range [IQR]) for continuous variables. Variables with non-normal distribution were compared using Mann–Whitney *U* test. A *P* value of <.05 was considered significant.

Results

The study was conducted on 59 women between September 2019 and March 2021. Two patients were excluded prior to the randomization process due to frozen pelvis caused by endometriosis. One patient withdrew from participation and another patient was lost to follow-up. Accordingly, the remaining 55 participants were randomly assigned to the Monopolar L-Hook group (*n* = 28) and Bipolar Gyrus ® PKS PlasmaSpatula cutting device group (*n* = 27).

Baseline characteristics of the patients: median age was 47.0 (range 42.0-52.0) years, mean body height was 160 (range,

156.0-167.0) cm, mean body weight was 75.0 (range, 66.0-84.0) kg, and mean BMI was 26.98 (range 25.3-32.6) kg/m².

Mean time from round ligament division to colpotomy was 14.0 (range 12.0-25.0) minutes, mean colpotomy time was 7.0 (range 4.0-11.0) minutes, and mean cuff closure time was 8.0 (range 6.0-13.0) minutes. Median surgery time was 46.0 (range 31.0-61.0) minutes, mean blood loss was 49.0 (range 34.0-65.0) cc, mean uterine weight was 212.0 (range 94.0-341.0) g, mean Hb decrease between post- and preoperative measurements was 1.1 (range, 0.4-1.8) g/dL, and there was no conversion to laparotomy in any patient.

No significant difference was found between the 2 groups with regard to demographic characteristics and intra- and postoperative values (*P* > .05 for both) (Tables 1 and 2). However, thermal damage was significantly greater in the Monopolar L-Hook group than in the Bipolar Gyrus ® PKS PlasmaSpatula cutting device group (8.1 mm [range 6.6-9.1 mm] (Figure 3) vs. 4.7 mm [range 4.1-5.6 mm], *P* = .000) (Figure 4). Additionally, the degree of surgical smoke or vapor obstructing the surgical field was subjectively higher in the Monopolar L-Hook group compared to the Bipolar Gyrus ® PKS PlasmaSpatula cutting device group.

During the postoperative follow-up period, only 1 complication (vaginal cuff infection) developed in 1 patient in the Monopolar L-Hook group, which was treated with 3 × 4.5 g Tazobactam for 14 days parenterally.

Discussion

Colpotomy is a part of the final surgical steps in TLH, following the ligation of the uterine arteries, skeletonizing of the cervix, and dissection of the bladder from the cervix. This step is relatively hazardous and time-consuming in the surgical procedure since it is in the anatomical area where most of the bleeding and ureter injuries occur.^{8,9} Ureter injuries may occur directly or due to thermal damage at the surgical margin. Also, thermal damage can change the stage of the cervical cancer due to the inability to evaluate the surgical margin microscopically as well.

Gyrus ® PKS PlasmaSpatula is a unique multifunctional device with the ability to electrosurgically cut and coagulate in the colpotomy step of TLH. Beside its sharp, smooth, precise cutting function, the tip of the instrument stays cool to minimize thermal spread. Moreover, its procedural effectiveness is enhanced by its angled tip and broad surface.

In our study, Bipolar Gyrus ® PKS PlasmaSpatula provided a relatively better surgical field as it did not produce excessive smoke and caused less thermal damage. However, the colpotomy time, cuff closure time, and total operative time were shorter in the Gyrus ® PKS PlasmaSpatula group, though no significant

Table 1. Comparison of Demographic Characteristics According to the Electrosurgical Device During Colpotomy Step

	Electrosurgery Device with Colpotomy				<i>P</i>
	Monopolar L-Hook (n = 28)		Bipolar Gyrus ® PKS PlasmaSpatula (n = 27)		
	Median	IQR	Median	IQR	
Age (years)	45.5	40.0-50.0	44.0	42.0-49.0	.732
Height (cm)	159.0	156.0-164.0	161.0	158.0-169.0	.822
Weight (kg)	73.8	67.0-87.0	77.0	65.0-82.0	.876
BMI	27.3	23.2-32.9	28.5	26.2-29.7	.957

*Mann–Whitney *U* test. BMI, body mass index; IQR, interquartile range (25th-75th percentile values).

Table 2. Comparison of Intra- and Postoperative Values According to the Electrosurgical Device During Colpotomy Step

	Electrosurgery Device During Colpotomy				<i>P</i>
	Monopolar L-Hook (n = 28)		Bipolar Gyrus ® PKS PlasmaSpatula (n = 27)		
	Median	IQR	Median	IQR	
Depth of thermal damage (mm)	8.1	6.6-9.1	4.7	4.1-5.6	.000
Time from round ligament division to colpotomy (minutes)	17.0	13.0-33.0	18.0	16.0-24.0	.342
Colpotomy time (minutes)	11.0	5.0-13.0	9.0	4.0-11.0	.382
Cuff closure time (minutes)	8.5	7.0-16.0	7.0	6.0-13.0	.927
Total operative time (minutes)	48.7	33.0-66.0	37.0	34.0-52.0	.305
Blood loss (cm³)	52.5	31.0-61.0	48.0	30.0-60.0	.987
Uterus weight (g)	210.0	92.0-320.0	213.0	128.0-340.0	.216
Hb decrease (g/dL)	1.1	0.2-1.7	1.0	0.4-1.7	.980
*Mann–Whitney <i>U</i> test. IQR, interquartile range (25th-75th percentile values).					

*Mann-Whitney U test. IQR, interquartile range (25th-75th percentile values).

difference was found between the 2 groups. Intraoperative blood loss was higher in the Gyrus® PKS PlasmaSpatula group, while no significant difference was found. Similarly, no significant difference was found between the 2 groups with regard to postoperative vital signs and VAS scores.

To date, numerous studies have assessed the safety and efficacy of instruments in gynecologic laparoscopy by comparing them with other electrosurgical devices.¹⁰⁻¹⁴ Teoh et al¹⁵ compared the results of 2 modes of colpotomy including the Valleylab V mode and the traditional monopolar cut/coagulate (cut/coag) mode in 110 subjects and reported that the use of V mode in the colpotomy step of TLH did not decrease the depth of thermal injury at the vaginal cuff compared to the traditional cut/coag mode.¹⁵ Uccella et al¹⁶ evaluated a large cohort of 12 398 patients and reported that the use of monopolar energy in the colpotomy step and reducing the power of monopolar energy from 60 watts to 50 watts did not alter the rate of cuff separations in TLH.¹⁶ Additionally, there are some animal studies comparing ultrasonic, monopolar, and bipolar energy during laparoscopic colpotomy.¹⁷

As far as we have researched in the literature in recent years, there are several studies comparing the clinical use of the Gyrus® PKS device during TLH. Misirlioglu et al¹⁸ demonstrated the clinical utility of the PKS OMNI electrosurgical device for gynecologic procedures, especially for TLH, and revealed that the PKS OMNI is a safe and practical device that can be used in TLH.¹⁸ Additionally, Urman et al¹⁹ demonstrated that PKS OMNI is a novel, underused energy modality that promotes quick recovery and acceptable operation time with minimal blood loss and excellent postoperative pain scores in their observational cohort study in 2015.¹⁹

To our knowledge, the present study is the first in vivo study to compare the Bipolar Gyrus® PKS PlasmaSpatula cutting device and the Monopolar L-Hook cutting device in the colpotomy step in TLH and to compare a bipolar cutting device with a monopolar device with regard to the thermal effect or the degree of surgical smoke.

In conclusion, Bipolar Gyrus® PKS PlasmaSpatula caused less thermal damage and surgical smoke compared to the Monopolar ESD. Moreover, Bipolar Gyrus® PKS PlasmaSpatula cutting device was found to be smoother, cleaner, and provided less thermal

damage and a non-smoked perfect surgical view. Further studies with larger patient series are needed on this subject.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Alaaddin Keykubat University (Date: November 19, 2020, No: 25-23).

Informed Consent: Written informed consent was obtained from all patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – M.T.Ç.; Design – M.T.Ç.; Supervision – M.S.Y., C.G.; Materials – M.T.Ç.; Data Collection and/or Processing – M.S.Y., C.G.; Analysis and/or Interpretation – M.S.Y.; Literature Search – M.T.Ç.; Writing Manuscript – M.T.Ç.; Critical Review – M.S.Y.

Declaration of Interests: The authors have no conflict of interest to declare.

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