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Characterization and mitigation of stray radiofrequency currents during monopolar resectoscopic electrosurgery

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KEYWORDS:
Resectoscope;
Monopolar;
Electrosurgery;
Hysteroscopy;
Endometrial ablation;
Active electrode monitoring

Abstract

STUDY OBJECTIVE: To determine patterns and range of stray radiofrequency (RF) currents flowing through the working element of monopolar resectoscopes during routine endometrial rollerball ablation or resection; and to determine whether straightforward modifications of the uterine resectoscope and the application of RF monitoring could provide a safe pathway for such currents.

DESIGN: Prospective in vivo measurements (Canadian Task Force classification II-1).

SETTING: University-affiliated teaching hospital.

PATIENTS: Twelve women undergoing resectoscopic surgery.

INTERVENTIONS: During routine resectoscopic surgery using 1.5% glycine irrigant solution, three modified 26F Storz resectoscope working elements (model 27070E) were adapted to be continuously monitored with an Encision AEM device for excessive capacitive coupling and other stray currents from insulation failure. Active electrodes used were 3 mm and 5 mm rollberballs and 8 mm–diameter cutting loops powered by ERBE or Valleylab generators at 120 W. Active and working element currents were monitored by Pearson current transformers followed by root-mean-squared detectors based on the Analog Devices AD-637 integrated circuit. Data were recorded using a Fluke 199C oscilloscope, then serially transferred to a notebook computer and analyzed using Flukeview, Excel, and Minitab software.

RESULTS: Typical values of working element currents ranged from 0.10 to 0.20 A. Active electrode currents were typically in the range of 0.50 to 1.10 A. Frequently, the working element current exceeded the typical values and ranged up to 0.60 A. These current surges produced a heat factor (I^2t) of 0.45 A^2.sec in a 10-second period.

CONCLUSIONS: During resectoscopic electrosurgery, baseline, most likely capacitive coupled, currents were always present. In addition, high values of working element currents occurred frequently, and they surged up to 0.60 A for significant periods of time. Without the modification of the resectoscopic device, these currents have the capability of flowing through the patient's genital tract and causing burns. Since monopolar electrosurgery remains an integral part of most hysteroscopic procedures, active electrode monitoring may offer a solution in protecting the patient and the surgeon from stray electrosurgical burns.

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In 1910, Edwin Beer reported on removal of neoplasms of the urinary bladder employing high-frequency electrical currents through a catheterizing cystoscope.[1] Since then, resectoscopic electrosurgery has been popularized by urologists for transurethral prostatectomy (TURP) and a variety of bladder lesions.

The urologic resectoscope was first used in gynecology in 1974 to excise submucous myomas hysteroscopically.[2] With the wide acceptance and popularization of resectoscopic electrosurgery to treat a variety of intrauterine lesions, including endometrial ablation, there has been an emergence of procedure-related complications, one of which is electrical injury to the vulva, vagina, and cervix. According to the U.S. Food and Drug Administration (FDA) database on Medical Device Reporting (MDR, (www.fda.gov/cdrmdrfile.html) and Manufacturer and User Facility Device Experience (MAUDE, www.fda.gov/cdrh/maude.html), vaginal burns associated with resectoscopic surgery were experienced as early as 1991. In the last decade, several reports on genital tract burns during rollerball endometrial ablation have been published.[3–5] The frequency of this complication has not been determined. According to the FDA database up to the beginning of 2003, there have been more than 50 vaginal burns associated with endometrial ablation, and most of the major manufacturers of resectoscopes used in gynecology have been implicated.

A study on laparoscopic-entry access injuries analyzed data provided by the Physician Insurers Association of America (PIAA) and the MDR and MAUDE FDA database. The study concluded that only 8% of laparoscopic-entry injuries were reported to the FDA.[6] If the same underreporting holds true for genital tract burns, then the number of genital tract burns would be in excess of 600 incidents. A significant number of burn injuries during hysteroscopy and laparoscopy have provoked medicolegal litigation.[4,7] Indeed, some of these litigated cases have not been identified in the FDA database.

The theory of stray electrical currents generated during resectoscopic electrosurgery causing genital tract burns was first proposed in 1997.[3,8] Following a series of in vitro experiments, it was proposed that capacitive-coupled currents induced by intact resectoscopes and electrodes may cause thermal injury to surrounding tissue during prolonged resectoscopic surgery. Furthermore, stray currents from defective insulation or insulation failure of the electrodes occurring during the procedure resulted in direct coupling of current to the telescope, working element, and sheath and caused extensive burns of surrounding tissues in contact with the sheath.[8] A series of in vitro experiments confirmed most of the previous findings. It was also proposed that in the presence of proximal electrode defects, high-voltage currents may contribute to thermal injury to the lower genital tract during radiofrequency (RF) resectoscopic surgery regardless of the uterine resectoscope model or the design of the electrosurgical generator.[9,10]

It is evident that resectoscopic surgery using RF currents results in a significant number of burns to the lower genital tract in women and possibly to the urethra in men. The objectives of our study were to determine patterns and range of stray currents flowing through the working element of monopolar resectoscopes during routine endometrial rollerball ablation or resection; and to determine whether straightforward modifications of the uterine monopolar resectoscope and the application of RF monitoring could provide a safe pathway for such currents.

Materials and methods

The study was approved by the local University of Western Ontario Health Sciences Research Ethics Board, and all patients signed informed consent. Twelve women were scheduled to undergo routine endometrial ablation for abnormal uterine bleeding from benign causes.

After appropriate analgesia/anesthesia and prepping and draping, the cervix was grasped with a tenaculum and dilated to 10 mm. We used 1.5% glycine solution to distend/irrigate the uterus, a Storz pump and fluid monitoring system, three Storz 26F (9-mm, model 26050 EG) gynecologic resectoscopes with 30-degree lens, and Storz electrodes (3-mm and 5-mm diameter rollerballs) and 8-mm diameter loops (Karl Storz, Tuttlingen, Germany). We used the ERBE ICC-350 (ERBE, Tubingen, Germany) and Valleylab Force FX electrosurgical generators (Valleylab, Boulder, CO) at a power of 120 W of coagulation or cut waveforms. The Valleylab FX was used in 4 of the 12 procedures, and the ERBE ICC-350 in 8. The endometrium was coagulated, resected, or both. The various procedures performed and electrodes and waveforms used in the 12 women are shown in Table 1.

Active and working element currents were monitored by Pearson (Pearson Electronics, Palo Alto, CA) current transformers followed by root-mean-squared (RMS) detectors based on the Analog Devices AD-637 integrated circuit (Analog Devices, Norwood, MA). Data were recorded using a Fluke 199C oscilloscope (Fluke Corp., Everett, WA), then serially transferred to a notebook computer and analyzed using Flukeview, Excel (Microsoft, Inc., Redmond, WA), and Minitab software (Minitab, Inc., State College, PA).

A shield-return current connection was run from the modified 26F Storz resectoscope working elements (model 27050E) through an Encision Active Electrode Monitoring (AEM) device (Encision, Inc., Boulder, CO) to the reference potential. The AEM is a shielding and monitoring technique commonly used in laparoscopic instruments. The purpose is to shunt stray currents caused by insulation failure and capacitive coupling, and to limit power if there are excessive currents detected. A diagram

Table 1 The various procedures performed and electrodes and waveforms used in 12 women

Number of patients	Procedure	Electrode	Waveform mode
6	Rollerball ablation	5-mm rollerball	Coagulation
2	Rollerball ablation	5-mm rollerball	Cut
2	Myomectomy	8-mm loop	Cut
1	Endometrial resection and myomectomy	8-mm loop	Cut
1	Rollerball ablation	3-mm rollerball	Coagulation

of the instrumentation and the circuits used during the procedures is shown in Figure 1. In addition, the metal external sheath of the resectoscope was replaced by a nonconductive sheath made of a paper-based material (Bakelite), previously approved by the FDA for use in urologic resectoscopes. The modified resectoscope with the active electrode and shield electrode attached to the working element and the outside sheath are shown in Figure 2.

Results

Baseline currents

Active electrode currents typically ranged between 0.50 to 1.10 A for both rollerball and loop electrodes (Figure 3). In all 12 procedures, shield-return currents were present in the working element of the resectoscope. Typical or baseline values of these shield-return currents ranged from 0.10 to 0.20 A during rollerball coagulation or resection with the cutting loop (Figure 3).

Surge currents

Frequently, the shield-return current exceeded the baseline value of 0.10 to 0.20 A and increased into the range of 0.30 to 0.60 A using either cut (Figure 4) or coagulation (Figure 5) waveforms. In 11 of the 12 procedures, there were such surges. In all, there were 118 surges of shield-return current above 0.30 A. The amplitude of the surges had a mean and SD of 0.38 A ± 0.065 A. The corresponding measures for the durations, mean, and SD were 0.38 sec ± 0.40 sec. Histograms of amplitudes and durations of these surges are shown in Figures 6 and 7, respectively.

The peak working element currents were approximately equal for the two generators used. The Valleylab FX generated a range of peak currents of 0.37 to 0.58 A in the eight procedures. There was not a clear statistical difference in the amplitudes of the procedure peak currents between the two generators.

Maximum heat factor

Heat factor is a quantity defined by Pearce that relates to the current-time exposure and the consequent ability to heat tissue.[11] Pearce defines heat factor as I^2t, the current-area density squared multiplied by time in seconds. Because the area of the working element current to tissue contact was not known, the present analysis used 1 cm^2 as an example contact area. Since the area is 1 cm^2, the quantity I^2t was used in place of J^2t, making calculations more straightforward. In the 12 procedures studied, and in the region of shield-return current surges,

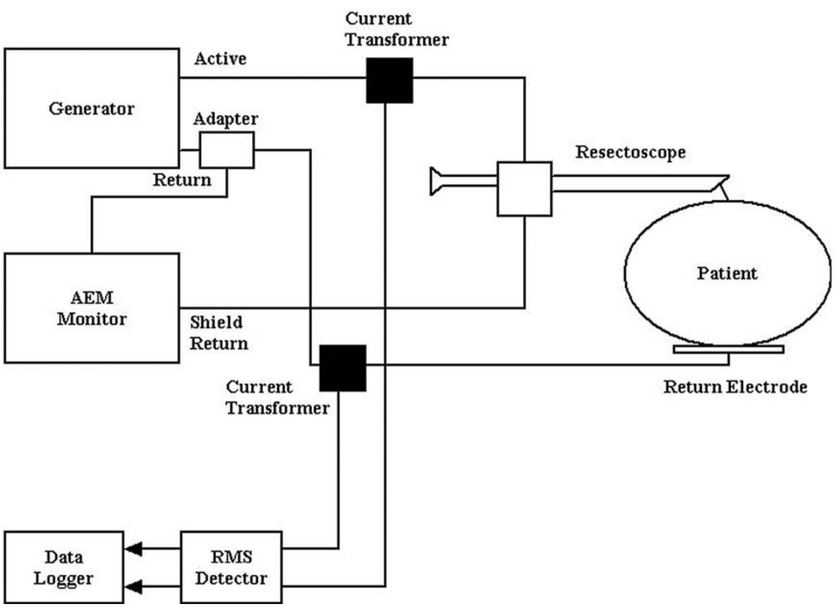

Figure 1 Diagrammatic representation of instruments and circuitry.

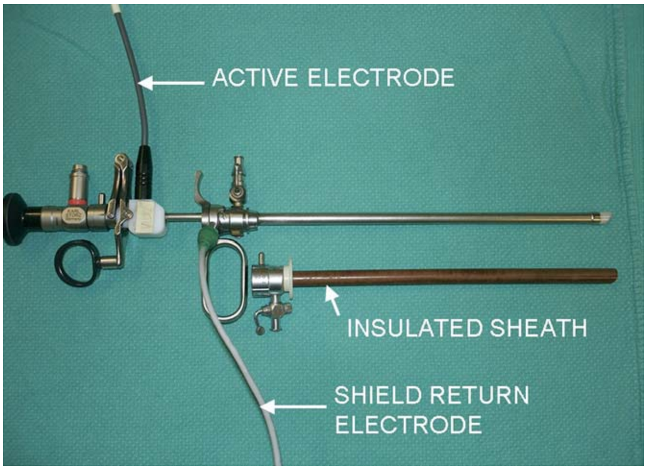

Figure 2 The internal conductive components of the working element are electrically connected to the Encision Active Electrode Monitoring protection circuitry. The outer sheath has been changed to a nonconductive material to eliminate the concern that the active currents could be collected via the outer conductive sheath to the electrosurgical unit (patents pending).

the worst-case heat factor (J^2t) was 0.45 A^2.sec in a 10-second period.

Extreme surges

In cases of extreme surges of working element current (above 0.63 A), the AEM would inhibit power from the generator. This occurred five times in 3 of the 12 procedures. This function is intended to minimize risk to the patient and surgeons. It also minimizes damage to the working element in the event of an insulation failure.

Durations of activations

A typical hysteroscopic endometrial ablation procedure lasting 8 minutes between first and last activation had 84 activations with a range of durations from 0.3 seconds to 13.9 seconds. The mean activation period was 3.2 seconds (Figure 8). In a typical procedure the, on-time of the foot switch of the electrosurgical generator was 58% of the operative procedure time, or approximately 4 minutes.

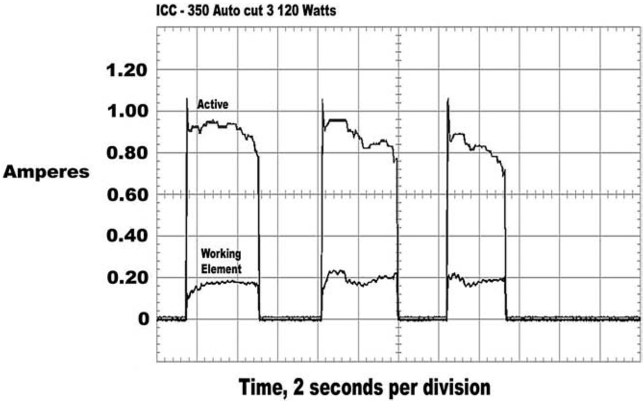

Figure 3 Baseline active and working element currents.

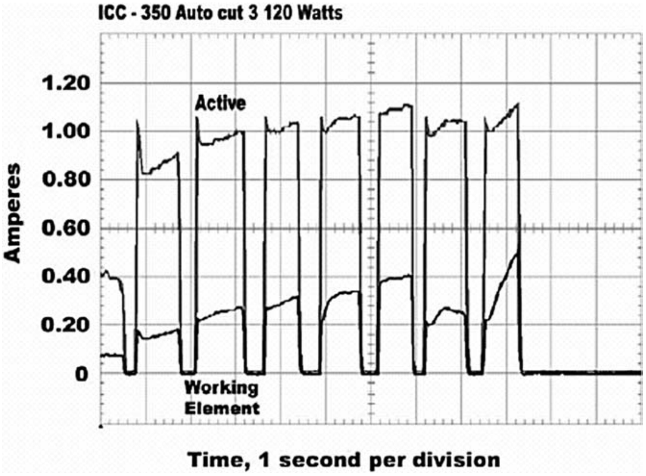

Figure 4 Surge active and working element currents with cut waveform.

Discussion

There are three aspects of this study that need to be emphasized. First, it is the first study known to the authors to measure electrical currents from the working element during routine monopolar resectoscopic surgery in women.

We measured baseline (typical) currents from the working element of three resectoscopes, using either the rollerball or the loop electrode, in the range of 0.10 to 0.20 A RMS (heating value). We also measured activation periods having a range of 0.3 to 13.9 seconds. The magnitude of these baseline currents is of the same range as the capacitive-coupling currents measured in open circuit previously.[8,10]

In a series of experiments on monitoring 3.8-cm^2 disposable silver ECG or 1-cm^2 Ferris Red Dot electrodes using four volunteers, Becker et al reported that 0.20 A for 30

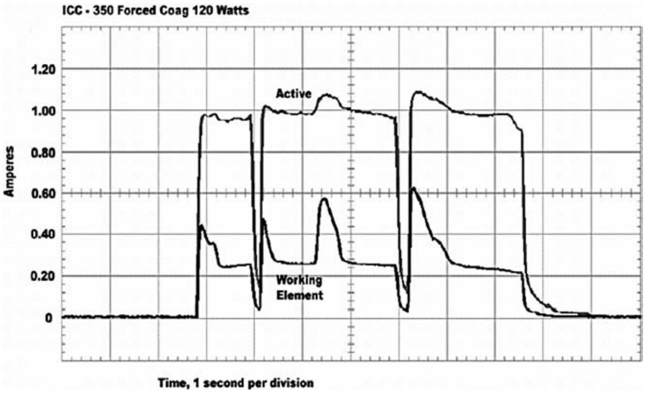

Figure 5 Surge active and working element current with coagulation waveform.

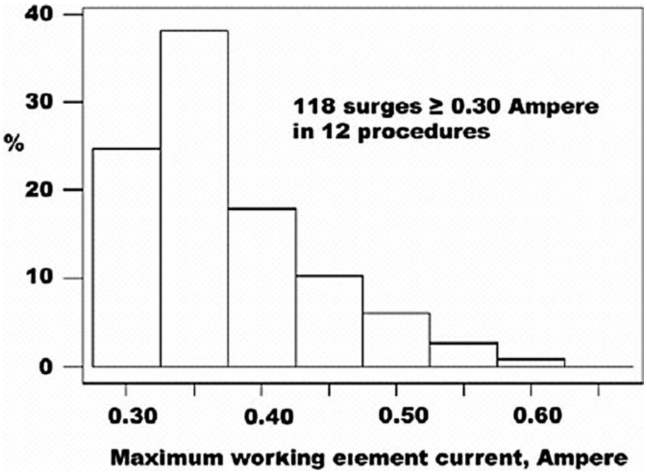

Figure 6 Histogram of the amplitude of the peak surge currents.

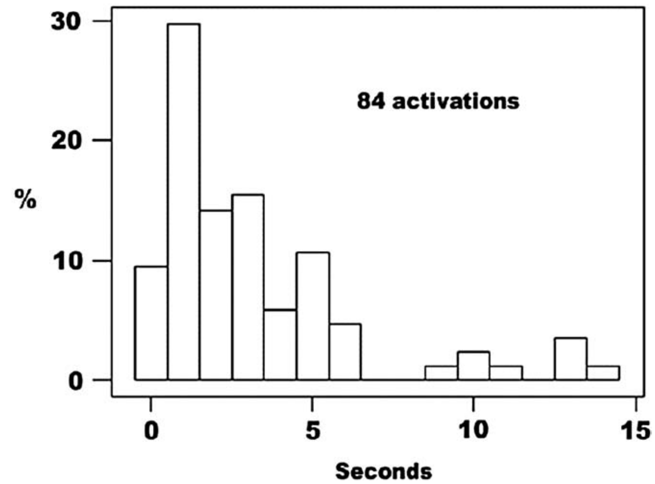

Figure 8 Histogram of activation durations during a typical endometrial ablation procedure.

seconds produced reddening of skin while 0.30 A for 20 seconds produced pain and blistering. Furthermore, 0.40 A for 10 seconds applied to a surface area of 3.8 cm^2 caused unbearable pain, while 0.40 A for 20 seconds to a 1-cm^2 area caused a second degree burn.[12] Work reported in 1986 indicates that 0.50 A applied through a small electrode to 1 cm^2 of tissue for 4 seconds would raise the temperature to a level likely to generate a burn.[11] Also, a study in 1992 reported that power densities of 7.5 W/cm^2 have the potential to burn.[13]

The 0.20 A baseline current flowing through a 200-Ohm contact resistance would produce 8.0 W of power; and 200 Ohms is certainly within the range of possible conditions for a 1-cm^2 contact area between a resectoscope sheath and wet vaginal epithelium.

Radiofrequency currents cause power dissipation when driven through contacts with tissue. Small contacts produce high impedances and high power densities. The relationship between the area and contact impedance of Becker's study monitoring electrodes and a potential small contact between a resectoscope and a patient's tissues is not known.[12] However, it is clear that the observed baseline currents might produce significant lesions given long activation periods and small contact areas.

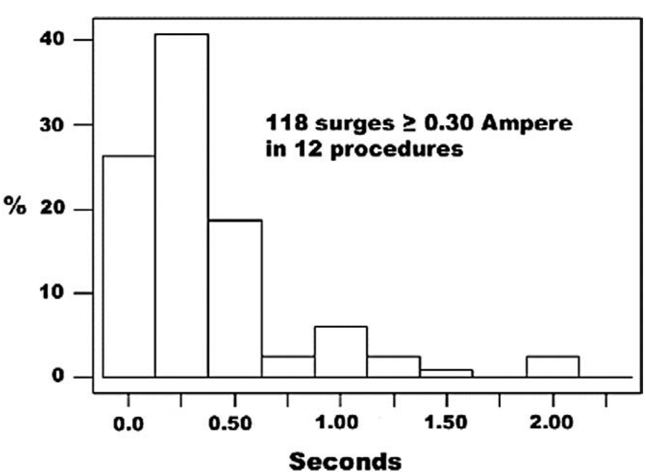

Figure 7 Histogram of the duration of the surge currents.

Second, the spontaneous, episodic surges of shield-return currents recorded on the working element of the resectoscope during this study may be of great significance. These surges occurred with first-time use, intact rollerball and loop electrodes in both coagulation and cut waveforms, and in both of the electrosurgical generators used. Surges of working element current having a value of 0.50 A and above occurred in 33% of the procedures. Higher values of current had lesser frequency of occurrence, and the worst-case current observed in the series of 12 procedures was 0.62 A.

Surges of 0.30 A were observed to last for up to 2.1 seconds. A 0.40 A surge lasting 0.8 seconds was occasionally encountered. It could be expected that longer durations would be encountered in a larger population of procedures given the activation times of more than 10 seconds commonly employed. A 0.40 A current has four times the capacity to heat tissue compared with the 0.20 A baseline current. Thus, even in the few procedures studied, the total heating potential of the working element current is uncomfortably close to the burn-generating exposures reported elsewhere.[11–13]

Conditions that might be expected to cause this level of current include:

1. Shorting of the electrode to the working element resulting from physical stress or insulation defects;
2. Increased local salinity around the active electrode by blood or clot;
3. Tissue chips present between the active electrode and the working element.

These processes were studied in 1977[14] and again in 1980.[15]

A substantial portion of the observed current surges, regardless of the underlying cause, would be available to flow to the patient's tissues absent any safe path provided.

These surges represent a clear safety hazard to the patient and the surgeon because the effects of stray energy are typically not in the view of the surgeon.

Solutions to avoid burns from stray currents have been explored during the last 30 years. In the 1970s, it was suspected that electrical currents on the external sheath of resectoscopes may be responsible for urethral strictures after TURP.[14] It was suggested that conductive lubricating jelly should be used with metal sheaths and nonconducting jelly be used with insulating sheaths of the resectoscope.[16] In January, 1980 patent # 4,184,492 was granted.[15] The patent describes the use of circuitry to prevent stray currents from harming the surgeon or the patient during radiofrequency electrosurgery. The authors are not aware of any such device being implemented in resectoscopic surgery.

The final aspect of this study is the introduction of active electrode monitoring as a mechanism to provide a safe path for stray currents produced during routine monopolar hysteroscopic electrosurgery. Furthermore, this mechanism detects and prevents excessive stray currents by continuously monitoring the resectoscope and deactivating the electrosurgical generator when excessive currents are detected.

Active electrode monitoring is a proven technology that has eliminated unintended stray electrosurgical burns due to capacitive coupling and insulation failure during laparoscopic procedures. Several hundred hospitals have adopted this technology within the past 10 years with no confirmed reported stray-current burns. The system consists of the coaxial shielding of the active electrode and a monitoring technique. When used in resectoscopic surgery, the monitor signals the electrosurgical unit to shut off power if excessive coupled currents are detected between the active electrode and the metal working element of the resectoscope.

The use of monopolar RF currents remains an integral part of resectoscopic surgery. Some devices have recently been introduced to address the concerns of stray monopolar energy. One such device includes a bipolar 2.5-mm-diameter cutting loop and a 4-mm wide × 4-mm diameter coagulating/vaporizing electrode (VersaPoint, Gynecare, a division of Ethicon, Somerville, NJ). However, the efficacy and safety of this bipolar resectoscope have not been reported. A recent study reported longer operating time and higher fluid absorption using the VersaPoint resectoscope (16 minutes compared with 10 minutes with the use of the monopolar resectoscope).[17] Although bipolar resectoscopes use normal saline to distend the uterus, serious adverse events from excessive fluid (liquid or gas) absorption have been reported.[18,19] Active fluid monitoring devices and strict adherence to fluid absorption guidelines may eliminate the consequences of excessive saline and other nonconductive fluids.

The cost to perform a monopolar hysteroscopic procedure may be significantly lower (fivefold) than with use of the bipolar alternative devices. Also, the availability of the 8 mm–diameter monopolar cutting loop and choice among a variety of power settings and waveforms facilitate the rapid debulking and removal of large amounts of intrauterine tissue.[17] However, in view of evidence indicating the presence of stray currents associated with monopolar RF, continued use of monopolar resectoscopic surgery in its present form will need to be reviewed.

Conclusions

This in vivo study indicates that significant working element currents can flow under apparently normal procedural conditions. In addition to baseline currents of 0.10 to 0.20 A, electrical surges occur and range in amplitude between 0.30 and 0.60 A. The measured baseline currents combined with the surges are able to produce a total heat loading that is capable of causing burns had the currents not been returned to a reference potential. This confirms the results of previous in vivo studies. It also indicates that a likely cause for reported vaginal burns are the commonly occurring stray currents. This study has also demonstrated that an adaptation of the AEM system may be effective in mitigating the hazards associated with the working element currents.

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