White Paper

J-Plasma, Monopolar Pencil, Argon Beam and CO2 Laser Electrosurgery: Comparative Evaluation of Thermal Spread in a Porcine Tissue Model

Jasmine Pedroso MD MPH*, Melissa Gutierrez MD, Warren Volker MD PhD

Las Vegas Minimally Invasive Surgery - Women's Pelvic Health Center, Well Health Women's Specialty Care, Las Vegas, Nevada

Abstract

Objective: To compare thermal spread of J-Plasma helium device to monopolar, argon beam and CO2 laser devices in a porcine tissue model.

Design: Prospective study comparing thermal spread of J-Plasma, Bovie monopolar pencil, Argon Beam Coagulator (ABC), and CO2 Laser devices on porcine peritoneum, bladder and small intestine tissue at clinically equivalent settings.

Methods: J-Plasma, monopolar Bovie, ABC, and CO2 Laser devices were applied to porcine small intestine, bladder and peritoneal tissues at equivalent settings of 15% power 4 L/min gas flow, 30W cut, 70W 4 L/min, and super pulse 12W, respectively. Lateral and depth of thermal spread in each tissue type was then evaluated histologically.

Results: Lateral and depth of thermal spread varied depending on device and tissue type. J-Plasma showed comparable if not lower lateral and depth of thermal spread compared to Bovie, ABC, and CO2 Laser devices in all tissues, with maximum depth of 0.334mm in small intestine, and maximum lateral spread of 2.63mm on peritoneum. Greatest depth of spread was achieved by the ABC at 1.8mm in small intestine. CO2 Laser had the greatest lateral thermal spread on peritoneum at 2.99mm. ABC had the greatest lateral thermal spread in bladder, 3.51mm, and 3.57mm on small intestine.

Conclusions: Compared to the monopolar, argon beam and laser devices tested, the J-Plasma helium device achieved comparable if not lower lateral and depth of thermal spread in a variety of tissues when applied at clinically equivalent settings, however further studies are required to compare thermal effect of each device in the clinical setting.

Keywords: Laparoscopy; Surgical Energy; Laser; Argon; J-Plasma; Histology; Electrosurgery, Thermal Spread

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Corresponding author: Jasmine Pedroso, MD MPH, Las Vegas Minimally Invasive Surgery - Women's Pelvic Health Center 9260 W. Sunset Road Suite 100 Las Vegas, NV 89148 E-mail: jasmine.pedroso@gmail.com

INTRODUCTION

The J-Plasma surgical energy device is a new FDA-approved multi-modal electrosurgical alternative to traditional monopolar, bipolar, or laser devices, that allows surgeons to cut, coagulate, fulgurate and dissect with use of a single instrument in both open and laparoscopic surgery. The purpose of this study is to understand how J-Plasma surgical energy compares to a monopolar, argon beam and CO2 laser device in terms of depth of thermal spread in a porcine tissue model.

Pedroso et al.

BACKGROUND

J-Plasma Technology

The J-Plasma electrosurgical device works by passing inert helium gas through an electrically-charged retractable surgical blade to create cold plasma. Helium gas is present in air (.000524%) and is colorless, odorless, tasteless, non-toxic, inert, and monatomic. The helium plasma stream that is created, in tandem with the surgical blade, allows the surgeon to cut, coagulate, fulgurate and dissect with use of a single easy-to-use surgical instrument.

Traditionally the surgeon must choose between different devices be it; a monopolar pencil, a bipolar coagulator, a laser or argon beam, depending on whether he/she wishes to cut, coagulate or fulgurate tissue and how large or small the depth and breadth of surgical energy effect is desired for treatment. J-Plasma's retractable surgical blade and simple, multi-modality design allows a surgeon to fluently and intuitively transition between cutting, coagulating and fulgurating with only one instrument. Moreover, a surgeon's control of the flow of gas through the instrument, independent of power settings, produces a multitude of additional target tissue effects, such as cooling for delicate areas or pushing blood or debris aside to reach and treat underlying tissues.

Pulsing the J-Plasma energy gives a surgeon additional treatment options similar to argon or laser. This changing of the pulse rates of J-Plasma allows the tissue to a cooling phase to improve surgical outcomes even more.

Changing electrosurgical devices during surgery also often means changing generators, changing power settings, connecting grounding pads, and placing foot pedals, all of which can increase OR time. During more critical times, when the surgeon is trying to achieve hemostasis for example, changing devices can take the attention of the surgeon away from the patient and lead to more blood loss or other complications.

Like the monopolar pencil and bipolar coagulator, the effect of J-Plasma is governed by the frequency and intensity of current flowing through the instrument, which can be controlled on the generator. However, only with the J-Plasma can a surgeon again intuitively transition from cutting to coagulation during the same activation (single button push) - no grounding pads or foot pedals necessary. Furthermore, unlike with usage of laser devices, the J-Plasma does not require eye protection, wetting of surgical drapes, or the worry about over shooting or "pass through" during its use.

When dealing with surgical energy, the J-Plasma device may result in reduced complication rate, blood loss, and operating time due to its multiple functions simple functionality, minimal collateral tissue damage, and smaller smoke plumes, compared to other surgical energy devices.

Comparative Tissue Effects

With J-Plasma, as with all surgical energy devices, the lateral thermal spread of the instrument depends on multiple factors: the power settings, contact versus non-contact application, how long the device's energy is applied to tissue, and the characteristics of the target tissue. With typical (default settings) use, the J-Plasma energy has a maximum depth of spread of about 2mm, a maximum lateral spread of about 4mm, and a maximum plasma stream of only 15mm. This is when the device is applied for about 5 seconds and from 5mm away from a surgical site. The most distal part of the blade under these default

settings reaches a maximum temperature of over 100° Celsius at the tip, but that temp falls rapidly after activation ceases to room temperature (~25°C) due in part to the helium gas's constant temperature.

Multiple device comparative studies design methodologies to evaluate surgical energy, their devices that deliver them and their effects. Sutton et al. 8 and Govekar et al. 9 emphasized that that permanent tissue damage starts occurs at temperatures above 42° Celsius, especially when the instrument is applied for a prolonged period of time. The monopolar pencil however has a mean depth of thermal damage of 4.75mm, with mean width of spread of 8.5mm, at 20W/10W pure coagulation. The Bipolar Malis has a thermal depth of 0.86mm and width of 3.21mm. 8 The Harmonic scalpel has a thermal depth of 6.00mm, and width of 5.50mm at a level 3 setting, and the CO² laser has a thermal depth of 0.88 and width of 0.89mm at 11W, 100msec. 10

Wang et al. compared monopolar, bipolar and ultrasonic energy modalities in multiple categories illustrating differences in standard power settings, degree of typical thermal spreads at those settings, and maximum temperatures. Traditional monopolar devices such as the Bovie pencil, at a setting of 50-80W had a maximum temperature of over 100° Celsius and a thermal spread that was not well assessed in literature. Traditional bipolar instruments, such as the Kleppenger, at a setting of 30-50W, can reach a maximum temperature of over 100° Celsius and a thermal spread between 2-6mm. Advanced bipolar instruments, including the Ligasure and Gyrus PK devices, had a range of thermal spread from 1-4mm. Ultrasonic instruments, including the Harmonic scalpel, at a frequency of 55,000 Hz, reached a maximum temperature of less than 80 ° Celsius and had a lateral thermal spread of 1-4mm.

Furthermore, monopolar and bipolar instruments remain hot even after their activation. The test methodology of Sutton et al. demonstrated that even after only 5 seconds of application at a low power setting (20 Watts), the monopolar device can take as long as 15 seconds before it returns to a safe temperature of less than 42° Celsius. Because the J-Plasma, does not conduct heat after its application, the surgeon can safely and immediately transition from coagulating or fulgurating tissue to cutting and dissecting, resulting in decreased inadvertent damage to the tissue compared to other modalities. Additionally smaller smoke plumes and less char lead to improved visualization for the surgeon.

At a distance of between 5-10mm from uterine tissue and when applied for 5 seconds at 20% power, the PlasmaJet had a lateral thermal spread of 4.66 ± 0.91 mm. ¹² Another study by Nezhat et al. explained previous animal studies demonstrated a thermal spread of 0.5-2mm and had applied PlasmaJet to tissue at 100% power, about 5mm from target tissue but without energy application time for successful laparoscopic treatment of endometriosis ⁶ At a power setting of 4 W and a distance of 5 mm, the Helica (HTC) had a lateral spread of 7.67 ± 1.21 mm on uterine tissue. ⁶ Deb et al. also showed that there was no significant difference in the mean depth of tissue damage seen between PlasmaJet and HTC in the uterus, ovary and fallopian tube, however there was significantly less lateral spread of tissue damage seen with PlasmaJet compared to the HTC in all three tissue types. ¹²

Compared to other plasma devices, the J-Plasma has a smaller depth of penetration and lower thermal spread. Additionally, many of the cited articles use a low setting of 20 Watts as a quantifiable point to get thermal data metrics. J-Plasma at 50% power is equivalent to 20 Watts. Thus at a default setting of 10% power, J-Plasma is emitting about 4 Watts of power.

In this study we compare thermal spread of the J-Plasma Helium device, Bovie monopolar pencil, Argon Beam Coagulator (ABC), and CO2 Laser devices on porcine peritoneum, bladder and small intestine tissue at clinically equivalent settings.

Pedroso et al. 4

METHODS

Porcine small intestine, bladder and peritoneal tissues were exposed to clinically J-Plasma at 15% power, 4 L/min gas flow, Bovie monopolar pencil at cut setting of 30W, Argon Beam Coagulator (ABC) at 70W, 4 L/min, and CO2 Laser super pulse at 12W. These tissues were then evaluated histologically to compare the depth of thermal spread in each tissue at the above clinically equivalent settings.

RESULTS

The histological effects of monopolar (coag), argon beam (ABC), and CO₂ laser and J-Plasma electrosurgical devices on the peritoneum, bladder and small intestine are illustrated in figures 10 through 12, respectively.

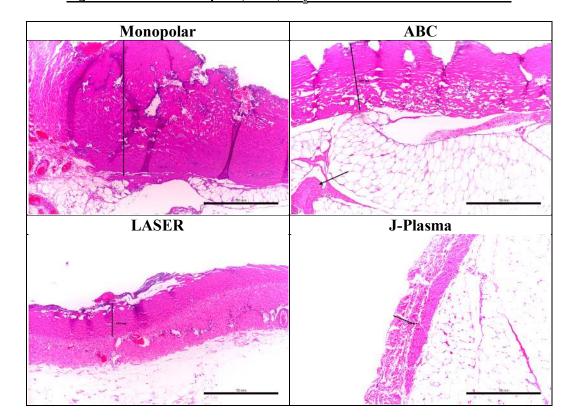


Figure 1 - Effect of Monopolar, ABC, CO₂ Laser and J-Plasma on Peritoneum

Figure 2 - Comparing tissue effects of equivalent power Monopolar, ABC, CO₂ Laser and J-Plasma on Bladder

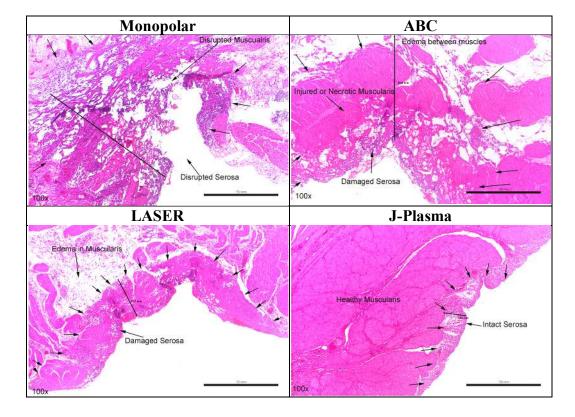
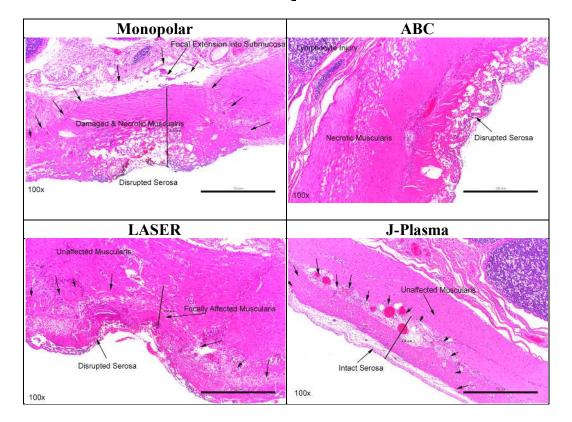
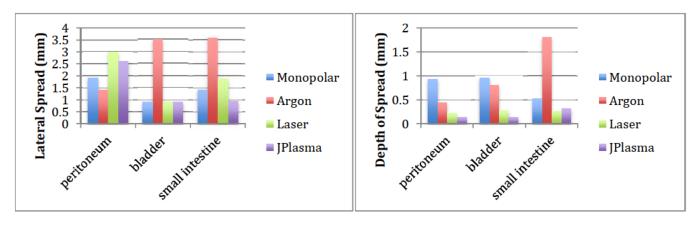


Figure 3 – Effect of Monopolar, ABC, CO₂ Laser and J-Plasma on Small Intestine



Pedroso et al. 6

<u>Figure 4 - Comparing Lateral Spread (left) and Depth of Thermal Spread (right) of Monopolar, Argon, Laser and J-Plasma on Peritoneum, Bladder and Small Intestine</u>



Lateral and depth of thermal spread varied depending on device and tissue type. J-Plasma showed comparable if not lower lateral and depth of thermal spread compared to Bovie, ABC, and CO2 Laser devices in all tissues, with maximum depth of 0.334mm in small intestine, and maximum lateral spread of 2.63mm on peritoneum. Greatest depth of spread was achieved by the ABC at 1.8mm in small intestine. CO2 Laser had the greatest lateral thermal spread on peritoneum at 2.99mm. ABC had the greatest lateral thermal spread in bladder, 3.51mm, and 3.57mm on small intestine.

DISCUSSION

The J-Plasma electrosurgical device is a multi-modal electrosurgical alternative to traditional monopolar, bipolar, laser or other plasma devices that allow surgeons to cut, coagulate, fulgurate and dissect with use of a single instrument. This study demonstrates that compared to the monopolar, argon beam and laser devices tested, the J-Plasma helium device may achieve comparable if not lower lateral and depth of thermal spread in a variety of tissues when applied at clinically equivalent settings, however further studies are required to compare thermal effect of each device in the clinical setting. These advances can be applied to a multitude of procedures in the operating room.

In our Minimally Invasive Gynecologic Surgery practice in Las Vegas, Nevada, the J-Plasma device has been used successfully for cutting, coagulating, dissection and fulguration in laparoscopic hysterectomies, ovarian cystectomies, myomectomies, adhesiolysis and ablation of endometriotic lesions, uterosacral nerve transection, presacral neuretomies, ablation of vulvar condyloma, and even for cesarean sections. We have observed in all the above cases that use of the J-Plasma has the potential to save operating time due to its multi-functionality and ease of use, especially when one can switch from sharp dissection to fulguration with the push of a button. Additionally, use of the device may lead to faster healing times, decreased complications, and decreased post-op pain due to minimal lateral and depth of thermal spread while performing delicate dissection around the bladder, ureter, tubes and ovaries.

Future studies comparing similar electrosurgical devices in terms of surgical outcome, patient satisfaction and cost are likely next steps in evaluating the potential benefits of the J-Plasma device.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. For listing of indications for use, precautions and warnings please refer to the instructions for use for all J-Plasma® products and accessories.

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