



OB - STATS INC.

Research • Editing • Statistics

J PLASMA - Final

Thermal effect of J-Plasma energy in a porcine tissue model: Implications for Minimally Invasive Surgery

Jasmine D. Pedroso MD

Las Vegas Minimally Invasive Surgery/Women's Pelvic Health Center

Assistant FMIGS Program Director, Minimally Invasive Gynecologic Surgery

9260 Sunset Rd. Suite 100

Las Vegas, NV 89148

Phone: 702-304-5800

Fax: 702-795-1065

Melissa M. Gutierrez MD

Las Vegas Minimally Invasive Surgery/Women's Pelvic Health Center

Assistant FMIGS Program Director, Minimally Invasive Gynecologic Surgery

9260 Sunset Rd. Suite 100

Las Vegas, NV 89148

Phone: 702-304-5800

Fax: 702-795-1065

K. Warren Volker MD, PhD

Las Vegas Minimally Invasive Surgery/Women's Pelvic Health Center

FMIGS Program Director, Minimally Invasive Gynecologic Surgery

9260 Sunset Rd. Suite 100

Las Vegas, NV 89148

Phone: 702-304-5800

Fax: 702-795-1065

David L Howard MD, PhD

Las Vegas Minimally Invasive Surgery/Women's Pelvic Health Center

Research Director, Minimally Invasive Gynecologic Surgery

9260 Sunset Rd. Suite 100

Las Vegas, NV 89148

Phone: 702-304-5800

Fax: 702-795-1065

ABSTRACT

Objective: To evaluate tissue effect of J-Plasma® (Bovie Medical Corporation, Clearwater, FL, USA) in porcine liver, kidney, muscle, ovarian, and uterine tissue blocks.

Design: Prospective study utilizing porcine tissue blocks to evaluate the thermal spread of J-Plasma device on liver, kidney, muscle, ovarian, and uterine tissue at various power settings, gas flow, and exposure times.

Methods: J-Plasma helium was used in porcine liver, kidney, and muscle tissue at 20%, 50%, and 100% power and 1 L/min, 3 L/min, and 5 L/min gas flow at 1, 5, and 10-second intervals. J-Plasma was then used in ovarian and uterine tissue at maximum power and gas flow settings in intervals of 1, 5, 10, and 30 seconds. Histologic evaluation of each tissue was then performed to measure thermal spread.

Results: Regardless of tissue type, increased power setting, gas flow rate, and exposure time correlated with greater depth of thermal spread in liver, kidney, and muscle tissue. J-Plasma did not exceed 2mm thermal spread on liver, kidney, muscle, ovarian, and uterine tissue, even at a maximum setting of 100% power and 5 L/min gas flow after 5 seconds. Prolonged exposure to J-Plasma of up to 30 seconds resulted in increased length and width of thermal spread of up to 12mm, but did not result in significantly increased depth at 2.84mm.

Conclusions: The J-Plasma helium device has minimal lateral and depth of thermal spread in a variety of tissue types and can likely be used for a multitude of gynecologic surgical procedures. However, further studies are needed to demonstrate device safety in a clinical setting.

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

INTRODUCTION

The J-Plasma® (Bovie Medical Corporation, Clearwater, FL, USA) 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 surgery¹.

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.

Plasma devices use a partially ionized gas containing free electrons and charged ions that can carry an electric current. Unlike a laser, which transfers energy in the form of a beam of light, plasma devices transmit energy through a stream of ionized inert gas (gas plasma), allowing for minimal electrical flow through its stream to the intended surgical site.

The purpose of this study was to evaluate the thermal effect of J-Plasma energy on liver, kidney, muscle, ovarian, and uterine tissue at various power and gas flow settings and at different exposure intervals, utilizing porcine tissue models.

METHODS

The J-Plasma device (open or laparoscopic) has a hand-held, 5mm diameter surgical probe that has a single push button hand activator (or foot pedal optional) and a retractable scalpel-like blade connected to a Bovie ICON GS Generator™ (Bovie Medical Corporation, Clearwater, FL, USA) (Fig. 1)¹.

On the J-Plasma generator, the surgeon can independently control the flow rate of gas and amount of electrical energy put into the plasma stream. An increase in the power setting corresponds to an increase in the amount of heat energy applied to the plasma stream. An increase in the gas flow rate on the other hand has a cooling effect. The device, under standard settings (10% power and 4 L/min), creates just enough tip temperature to initiate a working cold plasma, but that temperature falls immediately to room temperature after activation ceases (approximately 25° Celsius).

Surgeons have the option to retract or extend the surgical blade during operation at precise increments, providing multiple cut levels in a single instrument. While extended, the blade can be used like a standard scalpel for incisions, biopsies, and delicate dissection. Additionally, when the blade is extended and electrically charged, the device creates helium plasma concentrated at the tip of the blade, which can be used for cutting tissue or coagulating with distinct pinpoint accuracy. When the blade is retracted and the device activated, the plasma can be used to coagulate and fulgurate, or “paint”, the surface of larger surgical areas.

Porcine tissue models were utilized in this study to evaluate the histologic thermal effect of J-Plasma technology on liver, kidney, muscle, ovarian, and uterine tissue when exposed to various power and gas flow settings and at different time intervals. Two interventions were used to evaluate this effect.

In the first intervention, porcine liver, kidney, and muscle tissue was exposed to J-Plasma energy at powers settings of 20%, 50%, and 100%; at gas flow settings of 1 L/min, 3 L/min, and 5 L/min; and time intervals of 1, 5, and 10 seconds. These tissues were then evaluated histologically to compare the depth of thermal spread in each tissue at the above power and gas flow settings.

The second intervention was a more in-depth histologic study of the thermal effect of J-Plasma on ovarian and uterine tissue at maximum power, gas flow settings, and exposure times. The length, width, and depth of thermal spread of J-Plasma energy was measured on ovarian and uterine tissue when applied at 1, 5, 10, and 30-second

intervals at the device's max power setting of 100% power and 5L/min gas flow.

We hypothesized that, like other plasma devices, the thermal depth of spread will increase linearly with increased power setting, gas flow rate, and exposure time, and, furthermore, that this effect will vary with tissue type.

RESULTS

Histologic depth of thermal spread of J-Plasma energy on porcine liver, kidney, and muscle tissue at 1, 5, and 10-second intervals; at power settings of 20%, 50%, and 100%; and at gas flow settings of 1 L/min, 3 L/min, and 5 L/min, respectively, is shown in Table 1. For each type of tissue there was linear increase in the depth of thermal spread with increasing duration of activation and increasing power settings.

Figures 2 through 4 show the effect of J-Plasma on thermal depth in porcine liver, kidney, and muscle tissue at approximately 5mm away from tissue at 20%, 50%, and 100% power; at 1, 5, and 10-second application times; and at constant gas flow settings of 5 L/min.

Histologic evaluation of porcine liver, kidney, and muscle tissue shows that the depth of thermal spread of J-Plasma increases linearly with exposure time at a given gas flow rate and power setting. Furthermore, when comparing liver, kidney, and muscle tissue, this linear relationship did not significantly vary by tissue type. At a maximum setting of 100% power and 5 L/min gas flow, the depth of thermal spread of J-Plasma did not exceed 2mm on liver, kidney, and muscle tissue, even if applied for 5 seconds.

The above finding was confirmed on histologic evaluation of ovarian and uterine tissue when J-Plasma was applied at various time intervals at the device's maximum power setting of 100% power and 5L/min gas flow. Figures 5 through 8 show H&E stains demonstrating the histological effect of application time on thermal depth, length, and width of spread of J-Plasma on porcine, ovarian, and uterine tissue at time intervals of 1, 5, 10, and 30 seconds and at maximum settings.

Histological studies to evaluate the effect of J-Plasma on normal porcine tissue show that the use of the J-Plasma device at 1, 5, 10, and 30-second intervals provides consistent, superficial coagulative necrosis with no associated inflammation.

In Table 2 we quantitatively show the characteristics of thermal spread observed when J-Plasma is applied to uterine and ovarian tissue at increasing time intervals at maximum settings. Even at 30 seconds of application at maximum settings, the depth of spread was less than 3mm, while the length and width was between 10 and 12mm in both uterine and ovarian porcine tissue.

DISCUSSION

The principal finding from this porcine tissue study is that even at settings that greatly exceed the manufacturer's recommendation, the depth of thermal spread associated with the J-Plasma device was less than 3mm regardless of the type of tissue (ovarian, liver, muscle, or uterine).

It is important to compare the J-Plasma device with comparable products. The Argon Beam Coagulator® (ABC®) (Conmed, Utica, NY, USA)², is an electrosurgical device utilizing plasma technology in open and laparoscopic surgery. The ABC achieves non-contact coagulation of tissue by a combination of heating and arcing. High-frequency monopolar current passes through ionized argon gas at an adjustable rate between 0.5

L/min to 7 L/min via a rigid electrode. The monopolar current flows through the electrode at 5,000 to 9,000 volts and, thus, requires placement of a grounding pad. The depth and spread of coagulation is a function of current density, flow rate of gas, duration of application, and distance of the probe tip to the target tissue. The typical thermal spread (diameter) from typical application of the ABC is 4 to 10mm. Bristow and colleagues found the Argon Beam Coagulator to have utility in achieving complete cytoreduction in women undergoing surgical management of advanced stage ovarian cancer.³ Other studies have also found this device to have utility in terms of rapidly stopping presacral bleeding.⁴

The PlasmaJet (Plasma Surgical, Roswell, GA, USA) emits an electrically neutral argon plasma stream through bipolar electrodes within an insulated handpiece⁵. Like the ABC, coagulation and fulguration is achieved without direct contact with tissue. However, unlike the ABC, the PlasmaJet emits a non-energized argon plasma stream of less than 0.4 L/min, at lower voltage of 30 to 60 volts, and with a smaller thermal spread of 0.5 to 2mm, depending on duration of application to the tissue. Additionally, unlike the ABC, gas passes through bipolar electrodes and, thus, a grounding pad is not necessary.

Tanner et al⁶ conducted a porcine study directly comparing the rate of bowel perforation, depth of thermal injury, and extent of inflammatory response with ABC compared to the PlasmaJet device. Use of the PlasmaJet device resulted in a more predictable tissue effect with less inflammatory response, especially when used at low power settings. Treatment with ABC resulted in greater tissue coagulation and desiccation, as well as increased rates of mucosal necrosis, especially at higher settings.

The Helica Thermal Coagulator® (HTC)⁵ (Helica Instruments Limited, Edinburgh, UK) is another plasma device used for coagulation and fulguration of tissue. Instead of argon gas, the HTC utilizes electrically charged helium (He) plasma at low-power levels ranging from 2 to 35W, reaching a temperature of about 800° Celsius.

Deb et al⁵ conducted an in-vivo human study directly comparing the HTC to ABC in terms of the effect on uterine

tissue, ovarian tissue, and the fallopian tubes. One key finding was that the lateral spread (width of tissue damage) was lesser with PlasmaJet than with HTC.

J-Plasma utilizes light, kinetic, thermal, and mechanical energy for surgical treatment. Light energy emitted from the tip of the probe is used to illuminate the target tissue and reveals the direction of plasma flow, such that the surgeon can apply energy with more precision to surgical target areas. Kinetic energy from the flow of gas is used to clear fluid or debris from the surface of tissue, allowing for adequate treatment of the underlying target tissues. Thermal energy in the form of heated helium plasma concentrated at the tip of the retractable blade can be used for coagulation and fulguration. Most notably, unlike the PlasmaJet or Helica device (HTC), the J-Plasma uses mechanical energy via the retractable blade that not only allows for more precise dissection/debridement and cold-cutting of tissue, but also provides tactile feedback as it directly contacts tissue.

There is currently only one published report of the J-Plasma device in humans. This report was an abstract of a video presentation in which the surgeon, Dr. Parsa, demonstrated retroperitoneal dissection of an ovarian endometrioma lying close to the colon. The surgeon, in his abstract, reported that the extreme precision achieved with the J-Plasma, along with the very small lateral thermal spread (when used at recommended settings), were critical in allowing him to use energy so close to a vital organ (the colon).⁷

The main limitation of our study was that it was conducted on porcine tissue, and, therefore, the results may not necessarily extrapolate to human tissue. Further human studies are needed to completely evaluate the utility of J-Plasma in the clinical setting.

CONCLUSIONS

J-Plasma is a newly FDA-approved device for open and laparoscopic surgery with predictable thermal spread in a variety of tissue types. Thermal depth of spread increased linearly with increased power setting, gas flow rate,

and exposure time. Even at settings that greatly exceed the manufacturer's recommendation, the depth of thermal spread associated with the J-Plasma device was less than 3mm (regardless of the type of tissue), and the diameter of lateral spread was 12mm or less. Based on the tissue types tested, J-Plasma can be used for a multitude of gynecologic surgical procedures. Additional studies are needed to demonstrate utility of the device in a clinical setting.

REFERENCES

1. Bovie Medical Corporation. icon GS User's Guide. Clearwater: Bovie Medical Corporation;2013. 60 pg.
2. Sutton C. Power sources in endoscopic surgery. *Curr Opin Obstet Gyn* 1995;7(4):248-256.
3. Bristow RE, Montz FJ. Complete surgical cytoreduction of advanced ovarian carcinoma using the argon beam coagulator. *Gynecologic oncology* 2001;83(1):39-48.
4. Saurabh S, Strobos EH, Patankar S, Zinkin L, Kassir A, Snyder M. The argon beam coagulator: a more effective and expeditious way to address presacral bleeding. *Tech Coloproctol* 2014;18(1):73-76.
5. Deb S, Sahu B, Deen S, Newman C, Powell M. Comparison of tissue effects quantified histologically between PlasmaJet coagulator and Helica thermal coagulator. *Arch Gynecol Obstet* 2012;286(2):399-402.
6. Tanner EJ, Dun E, Sonoda Y, Olawaiye AB, Chi DS. A Comparison of Thermal Plasma Energy Versus Argon Beam Coagulator-Induced Intestinal Injury After Vaporization in a Porcine Model. *Int J Gynecol Cancer* 2017;27(1):177-182.
7. Parsa M. Retroperitoneal Dissection of Ovarian Endometrioma Using J-Plasma Technology. *Journal of minimally invasive gynecology* 2015;22(6S):S140.