White Paper

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

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Abstract

Objective: To evaluate tissue effect of J-Plasma 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 tissues at 20%, 50% and 100% power, 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*

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

BACKGROUND

Plasma Technology in Surgery

The surgical effects of coagulation and fulguration have been achieved with plasma technology since its inception. Plasma devices use a partially ionized gas containing free electrons and charged ions that can carry an electric current. Unlike the laser, which transfers energy in the form of a beam of light, plasma devices transmits energy through a stream of ionized inert gas (gas plasma), allowing for minimal electricity flow through that stream to the intended surgical site.

The Argon Beam Coagulator (ABC, Conmed), also very similar the Argon Plasma Coagulator (APC, ERBE), is an electrosurgical device utilizing such 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.[5] The monopolar current flows through the electrode at 5000-9000 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 4-10mm.[6]

The PlasmaJet (PlasmaSurgical) emits an electrically neutral argon plasma stream through bipolar electrodes within an insulated handpiece. Similar to the Argon Beam Coagulator, 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 30-60 volts, and with a smaller thermal spread of 0.5 – 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.[6]

The Helica thermal coagulator (HTC) 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 2–35 W, reaching a temperature of about 800° Celsius.

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.

Figure 1 - J-Plasma Handpiece and Generator

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

Surgeons have the option to retract or extend the surgical blade at precise increments providing multiple cut levels during operation 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. Unlike other forms of electrosurgery the device's energy output level is so low and the energy's current is directed not into the body (non-conductive) but into the probe, the need for a return/neutral pad is removed.

Figure 2 - J-Plasma Stream from Tip

Set apart from other surgical device energies, 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 thus 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.

On the J-Plasma generator, the surgeon is able to control the flow rate of gas and amount of electrical energy put into the plasma stream, independently. 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 tip temperatures just enough needed to initiate a working cold plasma, but that temp falls immediately after activation ceases to room temperature to around 25° Celsius after activation.

This study utilizes porcine tissue models 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 times. We hypothesize 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.

METHODS

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 tissues 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 tissues were exposed to J-Plasma energy at powers settings of 20, 50 and 100 percent, and 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 is a more in-depth histologic study of the thermal effect of J-Plasma on ovarian and uterine tissue at maximum power and gas flow settings, and maximum exposure times. The length, width and depth of thermal spread of J-Plasma energy 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.

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 powers settings of 20, 50 and 100 percent, and at gas flow settings of 1 L/min, 3 L/min, and 5 L/min is shown in table 1.

Table 1 - Effect of Power, Gas Flow and Exposure Time on Thermal Spread in Liver, Kidney and Muscle Tissue

Thermal Depth		Liver (mm)	Kidney (mm)	Muscle (mm)
Gas Flow Rate (1 L/min)				
20 % Power	1 sec	0.40	0.40	0.54
	5 sec	1.10	0.62	0.85
	10 sec	1.51	1.25	1.26
50 % Power	1 sec	0.56	0.47	0.58
	5 sec	1.40	0.96	1.07
	10 sec	1.72	1.62	1.09
100 % Power	1 sec	0.54	0.75	0.47
	5 sec	1.72	1.39	1.18
	10 sec	-N/A-	-N/A-	-N/A-
Gas Flow Rate (3 L/min)				
20 % Power	1 sec	0.81	0.47	0.72
	5 sec	1.23	0.93	1.28
	10 sec	1.36	1.48	1.44
50 % Power	1 sec	0.50	0.45	0.82
	5 sec	1.43	1.10	1.29
	10 sec	1.95	1.70	2.20
100 % Power	1 sec	0.64	0.68	1.10
	5 sec	1.45	1.35	1.81
	10 sec	-N/A-	-N/A-	-N/A-
Gas Flow Rate (5 L/min)				
20 % Power	1 sec	0.73	0.61	0.67
	5 sec	0.87	0.97	1.03
	10 sec	1.21	1.33	1.32
50 % Power	1 sec	0.63	0.61	0.83
	5 sec	1.53	1.31	1.68
	10 sec	2.24	1.88	1.95
100 % Power	1 sec	0.42	0.80	0.71
	5 sec	1.73	1.85	1.85
	10 sec	-N/A-	-N/A-	-N/A-

Figures 3 through 5 shows 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 and at 1, 5 and 10 second application times, and at constant gas flow settings of 5 L/min.

Figure 3 - Effect of Power and Application Time on Thermal Depth in Liver tissue at 5 L/min Gas Flow

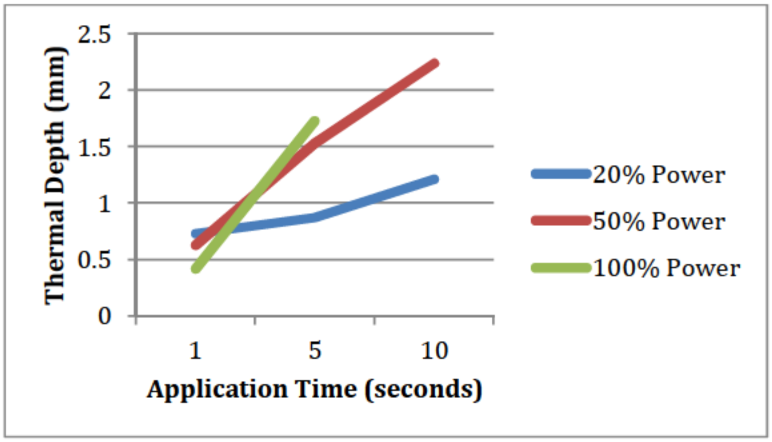


Figure 4 - Effect of Power and Application Time on Thermal Depth in Kidney tissue at 5 L/min Gas Flow

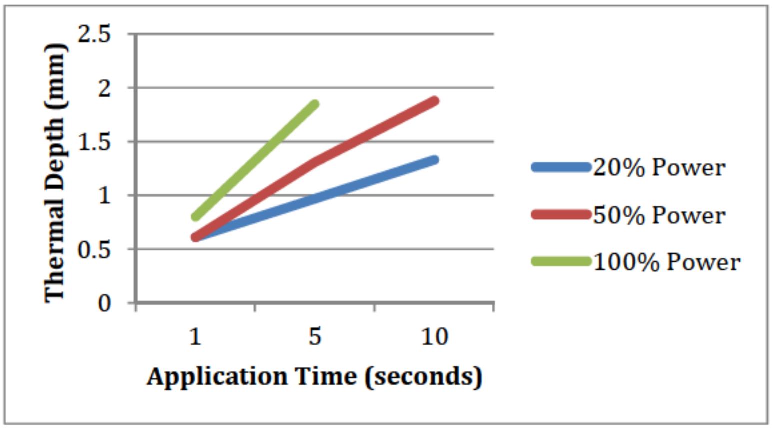
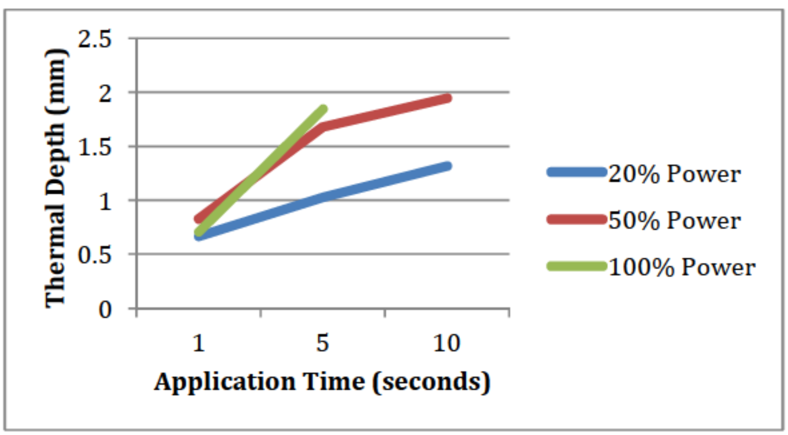


Figure 5 - Effect of Power and Application Time on Thermal Depth in Muscle tissue at 5 L/min: Gas Flow

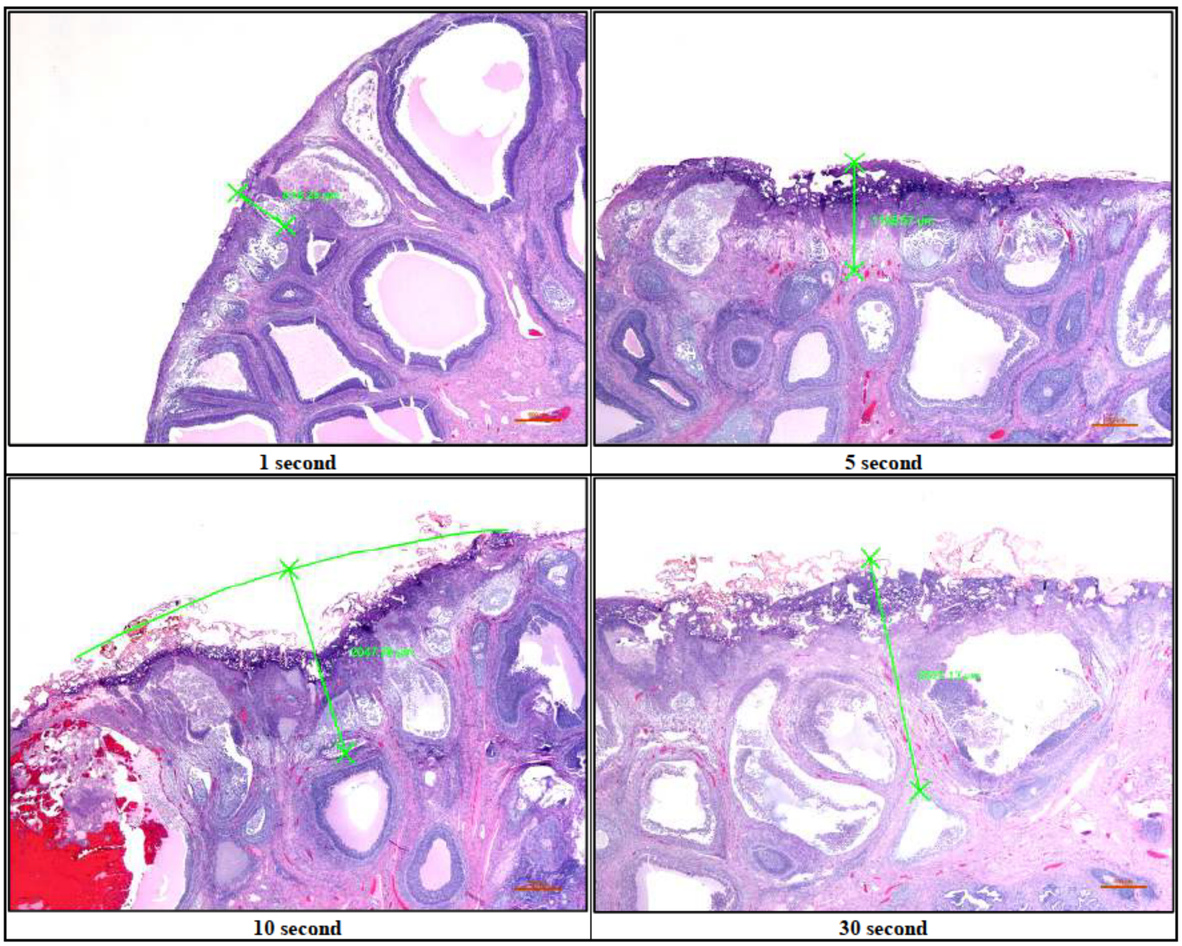


Histologic evaluation of porcine liver, kidney and muscle tissues shows that the depth of thermal spread of J-Plasma increases linearly with increasing power, gas flow and exposure time. Furthermore, when comparing liver, kidney, and muscle tissues, this linear relationship does not significantly vary by tissue type. At a maximum setting of 100% power and 5 L/min gas flow, the depth of thermal spread of J-Plasma does not exceed 2mm on liver, kidney and muscle tissue, even if applied for 5 seconds. The greatest depth of thermal spread was only 2.24mm when J-Plasma was applied for 10 seconds at maximum power and gas flow settings on liver tissue.

This 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 6 thru 9 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, at maximum settings.

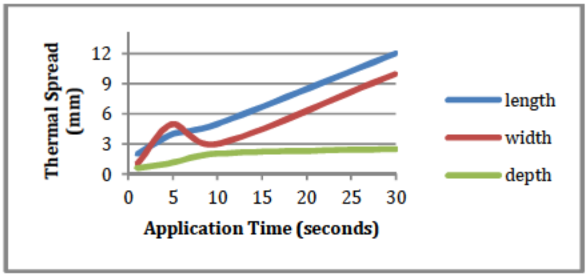
Histological studies to evaluate the effect of J-Plasma on normal porcine tissue show that the use of the J-Plasma device at 1, 5, 10 and 30 second intervals provides consistent, superficial coagulative necrosis with no associated inflammation. (Data on file. (JP-001))

Figure 6 - Effect of J-Plasma on ovarian tissue after 1, 5, 10 and 30 second applications, at max settings.



1 second | 5 second | 10 second | 30 second

Figure 6 - Effect of Application Time on Thermal Spread in Ovarian Tissue at 100% power, 5 L/min gas flow



When the device is applied for 1 second on ovarian tissue, the depth of spread is only 0.62mm, with a length of 2mm and width of 1mm. When the device is applied for 5 seconds on ovarian tissue, the depth of spread is only 1.15mm, with a length of 4mm and width of 5mm. When the device is applied for 10 seconds on ovarian tissue, the depth of spread is only 2.05mm, with a length of 5mm and width of 3mm. When the device is applied for 30 seconds on ovarian tissue, the depth of spread is only 2.53mm, with a length of 12mm and width of 10mm.

Figure 8 – Effect of J-Plasma on uterine tissue after 1, 5, 10 and 30 second applications, at max settings.

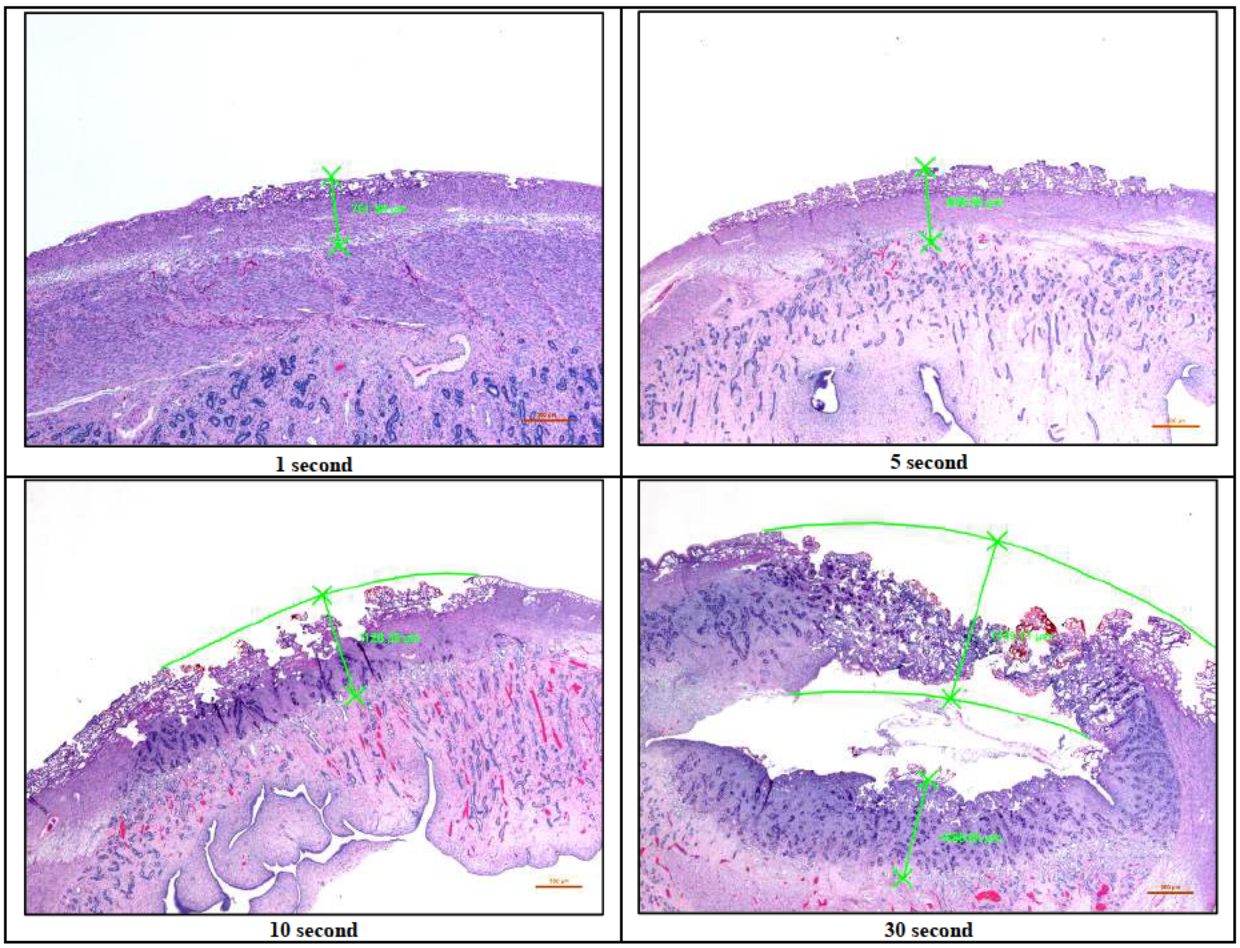
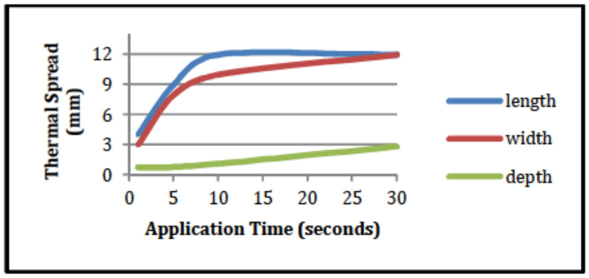


Figure 9 - Effect of Application Time on Thermal Spread in Uterine Tissue at 100% power, 5 L/min gas flow



When the device is applied for 1 second on uterine tissue, the depth of spread is only 0.75mm, with a length of 4mm and width of 3mm. When the device is applied for 5 seconds on uterine tissue, the depth of spread is only 0.81, with a length of 9mm and width of 8mm. When the device is applied for 10 seconds on uterine tissue, the depth of spread is only 1.13mm, with a length of 12mm and width of 10mm. When the device is applied for 30 seconds on uterine tissue, the depth of spread is only 2.84mm, with a length of 12mm and width of 12mm.

Interestingly, while prolonged exposure to J-Plasma energy did result in increased length and width of thermal spread as high as 12mm, especially in ovarian tissue, prolonged exposure did not result in significantly increased depth of thermal spread over 3mm, even when applied at the highest power and gas flow settings for as long as 30 seconds. (Take into account this was user spread and variability, the surgeon was not in the best position to accurately measure results and spread, additionally and more importantly, the instructions for use clearly state that activations of J-Plasma should not be longer than 10 seconds) (Bovie Medical Corporation, 2013).

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, and this effect varied with tissue type. The depth of tissue effect with J-Plasma ranges from no visible effect to about 2.0mm, with lateral spread ranging between 1.0mm and 4.0mm total diameter with typical use. 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.

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