

TREATING ENDOMETRIOSIS AND CHRONIC PELVIC PAIN WITH J-PLASMA®

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The Challengeⁱ

Risk-free Treatment of Endometriosis and Chronic Pelvic Pain

Endometriosis affects 6% to 10% of reproductive aged women.¹ Effective treatment of endometriosis is often hindered by risk of injury to female patients' reproductive organs, resulting in chronic issues and a high recurrence rate. It has been estimated that the annual health care burden in the United States for endometriosis exceeds \$20 billion.²

Today, laparoscopy is the gold standard for diagnosing and surgically treating endometriosis. However, it is limited by its ability to fully visualize the extent of disease in many cases. Separate papers by Balaschi and Murphy found that random biopsy samples of grossly normal peritoneum endometriosis patients revealed disease in 11% to 25% of the biopsies.^{3,4} Demco and associates found when performing wide local excisions for deeply infiltrating endometriosis that non-visualized disease in normal appearing peritoneum may be up to 27mm from the lesion.⁵

The high recurrence rate for female patients is largely due to the inability to visualize occult endometrial implants in up to one in four cases. The recurrence rate has been reported as high as 30% to 43% at four and eight years, respectively.⁶ The need exists to safely treat both visible and occult endometrial lesions in a manner that eliminates the disease without causing significant inflammation, scarring, and collateral thermal injury.

The Solution

Advanced, Highly Localized Cold Plasma Electrosurgical Device

J-Plasma® from Bovie Medical Corporation represents a patented approach to electrosurgery whereby a helium gas plasma, fueled by electrosurgical energy, flows into the application site for only a brief interval then disperses out leaving very precise, predictable effects. There is no net flow of electricity around the body, so no return electrode is required. The cold plasma effect is highly localized, minimizing collateral damage to surrounding healthy tissue and having no grounding pad, both aspects of which differentiates J-Plasma® from standard electrosurgical devices.

What is plasma? In its simplest state, plasma is the result of energizing a gas to a level that produces a mixture of neutral atoms, molecules, ions and electrons. Plasma has the unique ability to exist and function at a cold state (room temperature) or extreme temperature (>800°F). Researchers have found that this unique spectrum of temperatures opens itself to enormous therapeutic possibilities.

J-Plasma® uses nonconductive currents and limits direct injury with its reduced tissue spread, minimizing the risk of direct and capacitive coupling. Additionally, J-Plasma® allows for excision or ablation of endometrial implants with controlled precision and reduced fear of injury to adjacent vital structures. Two trials comparing excision

ⁱ Surgical treatment of endometriosis is either conservative or definitive. This paper will focus on conservative surgery. Conservative surgery involves excision or ablation of endometriotic lesions with the intent of preserving the uterus and as much ovarian tissue as possible. [Practice Committee of American Society for Reproductive Medicine. Treatment of pelvic pain associated with endometriosis. Fertil Steril 2008; 90:S260]

with ablation (monopolar electrosurgery in both trials: excision trial-CUT and COAG, and ablation trial-COAG only) found no difference in pain scores at 6 to 12 months.^{7,8}

A recent prospective study compared the depth and thermal spread of J-Plasma on porcine liver, kidney, muscle, ovarian, and uterine tissue at maximum power settings of 100% and 5 L/min gas flow for 5 seconds. At this setting, the thermal spread did not exceed 2mm. When the exposure interval was increased to 30 seconds, the maximum depth of was 2.84mm.⁹

Table 1.0 provides a comparison of existing surgical energy modalities available to gynecologists. The following identifies variable differences in the devices and their use in surgery.

Modality	Tissue Manipulation (Not Energized)	Energy Control	Safety
J-Plasma®	Sharp Dissection Blunt Dissection	Continuous or Pulsed	No neutral grounding pad required. Tissue cooling effect post activation.
Electrosurgical Monopolar Pencil	Blunt Dissection	Continuous	Requires neutral grounding.
Ultrasonic/Harmonic Energy	Blunt Dissection	Continuous	No neutral grounding pad required.
CO₂ Laser	Blunt Dissection	Continuous or Pulsed	Safety precautions required for some laser devices; i.e. glasses, wet drapes.
Argon Beam Coagulator	Blunt Dissection	Continuous	Requires neutral grounding.

Table 1.0 - Surgical Energy Modality Comparison

The Result

J-Plasma offers surgeons a safe, viable, and risk-free alternative in the treatment of endometriosis and chronic pelvic pain. A case series of 10 patients treated with J-Plasma® was conducted from August 2013 to April 2014. Patients were interviewed at their two-week follow-up appointment and received a call from a designated office interviewer at three months. All contacted patients reported that they were pain-free and happy with the results. No adverse events were reported. (Patients will continue to be enrolled in this protocol and followed for 6, 12, and 18 months.)

Reported benefits of using J-Plasma® in treating endometriosis and chronic pelvic pain include:

- Minimized lateral and depth of thermal spread
- Reduced healing times
- Decreased complications and procedure time
- Improved patient outcomes: decreased post-op pain
- Reduced risk vital structures like the bladder, ureter, fallopian tubes and ovaries
- Improved visualization for surgeon from smaller smoke plumes and less char
- Effective across multiple tissue types

“My experience in treating endometriosis in the past was often times one of frustration. Due to concerns for uncontrolled lateral spread of the currently available energy sources, I would often abort procedures knowing that I had not adequately ablated or resected involved disease. The high frequency of recurrence of symptoms also left me more than dissatisfied. My introduction to J-Plasma® generated significant excitement. I became convinced that I could more to adequately treat a patient’s disease because I could operate in and around vital structures without the fear of causing injury.

It is my practice to ablate any grossly apparent superficial endometrial implants seen laparoscopically. As a prophylactic measure, the uterosacral ligaments and cul-de-sac peritoneum are coated with low energy plasma. My hypothesis is that by employing this technique, occult lesions should be eliminated and thereby extending the disease-free interval with an improved clinical outcome.”

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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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