White Paper

NOVEL SURGICAL APPROACH TARGETING CHRONIC PELVIC PAIN WITH J-PLASMA®

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Introduction

Chronic pelvic pain affects 15-20% of reproductive aged women.[1] In a large series, the type and frequency of laparoscopic findings in women with chronic pelvic pain identified no visualized pathology 35% and the existence of endometriosis 33%, adhesions 24%, chronic pelvic inflammatory disease 5%, and ovarian cysts 3%.[2] The large non-visualized pathology group could be partially explained by separate papers presented by Balaschi and Murphy who found that random biopsy samples of grossly normal peritoneum endometriosis patients detected disease in 11% to 25% of biopsies.[3,4] Standard medical and surgical therapies targeting endometriosis lesions are not consistently effective and pain frequently recurs even without visible disease at repeat laparoscopy.[5-7] One explanation of the high recurrence rate of endometriosis is the presence of occult disease.

The Challenge[i]

Existing Surgical Options Lack Effectiveness for Occult Endometriosis Sufferers

Several surgical interventions popularized for chronic pelvic pain sufferers with endometriosis include:

Apparent Lesion Removal: This intervention targets removing visible endometriosis lesions and scar tissue using one of many laparoscopic surgical tools. However, this common surgical approach often misses occult lesions, which limits the success of eradicating chronic pelvic pain. Furthermore, the success rate for this intervention is dependent on the extent of the disease and the surgeon's skill,[8] as well as the surgical tool employed for limited collateral tissue damage and/or resultant adhesions.

Complete Peritoneum Removal: One surgical intervention proposed with deep pelvic endometriosis is based on the removal of the greatest possible amount of compromised pelvic peritoneum tissue.[9] Additionally, considering disruption of the peritoneum is a known cause of adhesion formation[12] and pelvic adhesions are also a known cause of pelvic pain, surgeons must carefully weigh the risks. Even surgical barrier products available today for surgeons offer limited at best adhesion prevention.

Nerve Pathways Removal: Another surgical approach popularized in the 1990s is the sectioning of sympathetic and parasympathetic nerves in the presacral or uterosacral/uterine junction. The theory behind these treatments hinges on afferent pain fibers traveling in these autonomic nerves in the pelvic; if they are interrupted, pain should be eliminated or reduced. One such procedure is Laparoscopic Uterosacral Nerve Ablation (LUNA), which consists of cutting the uterosacral nerve pathways as it enters the uterus. This intervention is difficult for surgeons and involves significant risk of urinary and digestive side effects secondary to nerve damage.[10,11] Additionally, a randomized controlled trial in 2009 found that among women with chronic pelvic pain, LUNA did not result in improvements in pain, dysmenorrhea, dyspareunia, or quality of life compared with laparoscopy without pelvic denervation.[13]

[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 endomtriosis. Fertil Steril 2008; 90:S260]

Another such procedure is the surgical removal of the nerve tissues to the uterus, or Presacral Neurectomy (PSN). Interrupting the autonomic nerves in the presacral area has found to help with midline pelvic pain and primary uterine dysmenorrhea. However, studies vary whether the improvements in symptoms noted with PSN are significantly beneficial and outweigh the risks to be performed routinely.

With the LUNA and PSN procedures, transection at either location only treats a small proportion of the afferent nerve fibers that are likely involved in the pain cycle associated with chronic pelvic pain and endometriosis. Injury to these nerves is known to lead to urinary retention, constipations, and pelvic support and sexual functions issues.[14] Additionally, both procedures have been met with limited success and risk considerable side effects on the gastrointestinal and urinary tract.

Existing Surgical Instruments Lack Versatile Control Near Vital Organs

Existing surgical instrumentation prevent surgeons from negotiating around vital internal structures confidently. One main concern with traditional electrocautery is controlling the energy spread. When treating diseased tissue close to vital structures such as the bowel, bladder, ureter or vessels, the current conservative surgical approach reduces the risk of significant side effects, injury, or delayed morbidity. The tradeoff has been less than favorable outcomes for chronic pelvic pain and endometrioses patients.

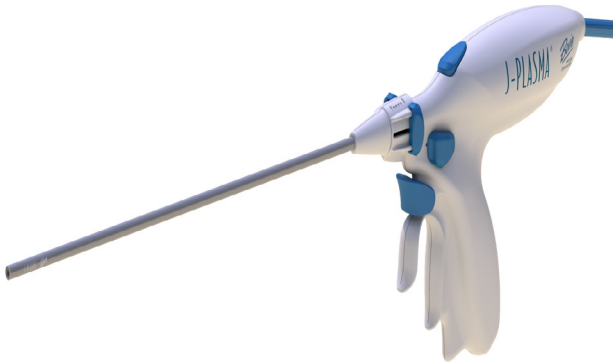
The need exists for a new, versatile surgical approach and instrumentation with precise thermal control that safely and effectively treats both apparent and occult diseased uterine tissue located along known pelvic nerve pathways.

The Solution

J-Plasma® from Bovie Medical Corporation is a new FDA-approved electrosurgical device harnessing the power of helium gas plasma for precise and controlled cutting, coagulation, fulguration, and dissection of diseased tissue. With virtually no thermal flow or collateral tissue damage, surgeons are afforded a new, innovative surgical tool for tackling chronic pelvic pain.

Craig E. McCoy, DO FACOG FPMRS of the Women's Wellness Center in Columbia, Missouri has perfected a broader, gradated surgical approach with J-Plasma targeting apparent, deep, and occult diseased tissue along the pelvic lining and ligaments.

1. Treat All Apparent Diseased Uterine Tissue



Visible endometriosis lesions are either ablated or excised with the J-Plasma system based on their character, location, and suspected depth of penetration. The J-Plasma electrosurgical generator is set at a power of 20% with 4 liters of flow and a pulse of 20/20. The handheld surgical device works by passing inert helium gas through the electrically charged surgical probe with retractable blade energizing the gas to a plasma stream. This helium plasma stream concentrates at the tip of the device, and this highly focused energy allows the surgeon to cut, fulgurate, coagulate, and dissect tissue. The pulse mode setting allows for control in reducing the amount of thermalized plasma energy allowed to come into contact with the tissue.

Ablation is accomplished with the J-Plasma by slowly moving the 5 mm diameter surgical device with the blade retracted over the lesion in a steady uniform motion until superficial tissue denaturation occurs. Depth of penetration is not more than 200 microns. Unlike electrosurgical and laser devices that remain hot after deactivation, the J-Plasma blade does not conduct heat immediately after deactivated. Additionally, the J-Plasma offers improved surgical visualization because it creates minimal smoke plume and less char.

Once the tissue becomes denatured, minimal pressure with the blunt tip of the J-Plasma is necessary to remove the desiccated tissue.

To remove deep lesions, the J-Plasma blade is extended to the desired length. This device will cut to the length of the blade, so like a scalpel, care is essential to control cutting depth. The use of a grasper helps in elevating the lesion for the depth of the excision. I recommend applying a shallow approach to excising deep lesions initially until one becomes familiar with dissecting and separating the tissue layers using the J-Plasma.

2. Treat Uterosacral Ligament Occult Diseased Tissue

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.[15] Occult diseased tissue is present in up to 25% of patients with endometriosis. Among the possible locations for endometriosis, the uterosacral ligament is the most common topography affected.[16] The uterosacral ligament nerves are part of the convergent neural pathways within the uterus and play a significant role in pelvic pain. I hypothesize treating any superficial disease that causes stimulation to afferent nerves traveling to or from the uterosacral ligament/nerve effectively eliminates any underlying disease and thereby reduces associated pelvic pain.

Part two of my surgical approach for endometriosis employs low power heated plasma to desiccate occult disease located on the area over the uterosacral ligament without stripping the peritoneum. This avoids potential urinary and gastrointestinal side effects and significant pelvic adhesions. To begin, I superficially ablate the ligament and peritoneum medial to the ligament with the J-Plasma generator set at a power of 20% with 4 liters of flow and a pulse of 20/20. The area medial to the ligament up to 1 centimeter is treated, as well as the area between the ligaments at the base of the uterus.

To treat a larger area in a more efficient manner, the heated flow of plasma is reduced from 4 liters to 2 liters. This increases the lateral thermal spread pattern without significantly changing its depth of penetration. J-Plasma desiccates tissue on a much smaller scale as compared with current electrosurgical devices. My experience suggests that a depth to 1mm at the uterosacral nerves is more than sufficient for addressing the peritoneum medially and interrupting any of the afferrent nerves as they approach the uterosacral nerve. By painting the uterosacral ligaments with low energized heated plasma, there is little inflammation to the peritoneum and reduced potential for scar formation.

The Result

J-Plasma offers Surgeons Controlled, Safe Tissue Layer Removal

Bovie Medical Corporation's new J-Plasma increases a surgeon's ability to target endometriosis and chronic pelvic pain. The high precision, low thermal spread of J-Plasma allows for versatile treatment of visual and hidden lesions on vital uterine organs and nerve pathways. I have adapted and integrated medical and surgical interventions with the J-Plasma innovative technology to successfully excise diseased tissue – layer by layer. The result has been less inflammation, accelerated healing (as compared to electrocautery), reduced adhesion formation, and improved outcomes in patients with chronic pelvic pain and endometriosis.

In a recent nine-question surgical satisfaction questionnaire of 26 chronic pelvic pain and endometriosis patients treated with J-Plasma, 21 reported decreased post-op pain within 12 months. In fact, 85% respondents were satisfied/very satisfied with how their pain was controlled immediately after the surgery, both in the hospital and at home.

A chief benefit of the J-Plasma is the ability for providers to effectively localize removal of diseased tissue with minimal impact to surrounding healthy tissue. Survey results indicate this precision decreases complications and reduces healing time, which patient experience as overall low 'downtime.' A vast majority of the women (92%) surveyed were satisfied with the amount of time it took to return to work or their normal exercise routine and 88% were satisfied with how long it took to return to their daily activities in and outside the home.

This new surgical option in the battle to treat, at the source, endometriosis and chronic pelvic pain improves patient outcome. Most patients (77%) were satisfied with the surgical results with 96% recommending this surgery to someone else and 88% indicating they would do the surgery again. No complications were reported in the group.

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-operative 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

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