

Revolutionizing Hysteroscopic Tissue Removal Using the MyoSure® System

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Introduction

Abnormal uterine bleeding affects approximately 30% of women and has been associated with endometrial polyps, fibroids, particularly submucosal, retained products of conception (RPOC), endometritis, atrophic endometrium, endometrial carcinoma and various entities of endometrial hyperplasia.¹⁻³ Assessment of the endometrium could include endometrial biopsy, ultrasound, saline infused sonography, CT scan and MRI. Ultimately, direct visualization via hysteroscopy is known to provide a minimally invasive approach to visualize the endometrial cavity and enable subsequent removal of structural uterine lesions using electrosurgical loop or hysteroscopic morcellation. Hysteroscopic morcellation offers the advantage of simultaneous visualization and minimally invasive resection and/or sampling of uterine lesions without the use of energy, thereby improving procedure efficiency and outcomes. Three morcellation devices—the TRUCLEAR™ Hysteroscopic Morcellator, Symphion™ Tissue Removal System and the MyoSure® Hysteroscopic Tissue Removal System (Myosure Tissue Removal System)—are currently available.⁴ This supplement will review the technology, data and clinical experiences using the MyoSure Tissue Removal System.

Resection of Polyps and Fibroids

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Endometrial polyps are a common intrauterine condition and are associated with abnormal uterine bleeding, subfertility, and premalignant and malignant tissue changes.⁵ Similarly, submucosal leiomyomas or fibroids are also associated with abnormal uterine bleeding, and subfertility and are rarely confused with malignant

masses or sarcomas.⁶ Most recent guidelines therefore recommend polypectomy and myomectomy followed by histopathological examination to exclude the possibility of endometrial cancer.^{7,8} Electrosurgical resection with monopolar or bipolar current has been traditionally used to remove large polyps and fibroids. However, this has been associated with cervical dilatation to 10 mm and rare risk of hyponatremia related to non-saline distension media utilized with the monopolar resectoscope. Other

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risks include: complications associated with excess absorption of some distension media, risk of thermal damage to healthy endometrium leading to synechiae, risk of perforation and visual field limitation from intrauterine chips.^{9,10} Hysteroscopic morcellation involves the use of a blade and a suction tube to simultaneously excise and remove tissue as well as clear a bloody field, thereby improving visibility and reducing the risk of perforations. In addition, hysteroscopic morcellation requires less cervical dilation and less anesthesia which improves patient satisfaction and reduces procedure time.¹¹ A recent meta-analysis of four randomized clinical trials and three retrospective observational studies compared hysteroscopic morcellation with electrosurgical resection for the removal of intracavitary lesions. The authors concluded that patients undergoing intrauterine morcellation with either of the available devices had a smaller fluid deficit as opposed to those treated with electrosurgical resection. In addition, hysteroscopic morcellation of polyps and fibroids with either of the available devices is associated with a shorter procedure duration and lower odds of incomplete lesion removal, respectively. This meta-analysis thus demonstrated the advantages of hysteroscopic morcellation over electrosurgical resection in the removal of structural endometrial lesions 3 cm or less in size.⁴ Another systematic review and meta-analysis comparing hysteroscopic morcellation with resectoscopy similarly concluded that hysteroscopic morcellation is associated with a higher success rate and a shorter operative time among patients with endometrial polyps and submucous myomas.¹²

A prospective US multicenter registry determined the feasibility of the MyoSure Tissue Removal System in surgical as well as office-based facilities and among patients treated for abnormal uterine bleeding or infertility. Mean percentage of fibroids removed with the MyoSure system was 95.4%, with the mean fibroid diameter of 2.2 cm and mean polyp diameter of 1.3 cm. While this study provides a representative depiction of hysteroscopic morcellation used in routine practice in the US, it also reports a high level of physician satisfaction with the MyoSure system.¹³ In 2015, Rubino and Lukes published a randomized, prospective, comparative trial incorporating nine ob/gyn practices and hospitals in the United States.¹⁴ The authors evaluated 12-month outcomes for patients undergoing MyoSure hysteroscopic morcellation of uterine polyps and myomas. Symptom severity as measured by the UFS-QOL (Uterine Fibroid Symptom-Quality of Life) scale improved significantly ($P < .01$) between baseline (mean score of 67.5 ± 15.4) and 12 months post-procedure (mean score of 22.3 ± 22.6). The HRQOL (The Health-Related Quality of Life) scale also improved significantly ($P < .01$).¹⁴

Another prospective cohort study investigated the effectiveness of the MyoSure system for the removal of intrauterine pathology by trainees (61% of cases) and senior clinicians. Results from this report indicated that regardless of clinician experience, polypectomy with the MyoSure system was associated with 92% complete resection including polyps up to 7 cm MyoSure was

also effective in removing Type 0, I, and II submucosal fibroids.¹⁵ Additionally, no patients experienced intraoperative complications consistent with previously reported less than <0.1% incidence with hysteroscopic morcellation.¹⁶ This is a 10-fold decrease from the complication rate reported with electrosurgical loop.¹⁷ More recently, a retrospective case series from two US fertility clinics assessed fertility outcomes among subfertile women after treatment of intrauterine lesions with the MyoSure system. As observed in Table 1, use of the MyoSure system for the removal of intrauterine leiomyomas and polyps supports subsequent conception and live birth rates among subfertile women undergoing fertility treatment.¹⁸

TABLE 1: Fertility Outcomes after Hysteroscopic Morcellation of Intrauterine Leiomyomas and Polyps. Modified from Bhalani et al.¹⁸

Fertility Outcomes	Total (n=62)
Pregnancy, no. (% of women)	44 (71)
Time to pregnancy, months, mean \pm SD	8.4 \pm 7.0
Live birth, living child (% of pregnancies)	39 (78)

Taken together, these recent studies highlight the usefulness of the MyoSure system in the removal of polyps and fibroids for both clinicians and patients. As an infertility specialist and surgical innovator, hysteroscopic morcellation has been part of my surgical armamentarium for the management of endometrial polyps, uterine fibroids and retained products of conception for over the past decade. In my experience, as no energy is utilized, the ability to perform hysteroscopic morcellation provides a safe and efficient alternative, which minimizes the risk of tissue necrosis and subsequent intrauterine adhesions. Furthermore, normalizing the uterine cavity with the MyoSure system supports my patients' ability to achieve successful pregnancies.

Endometrial Tissue Sampling for Pathology

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Traditionally, blind endometrial biopsy and dilation & curettage (D&C) have been the mainstay of endometrial tissue sampling for pathological evaluation.¹ However, several studies have indicated the limitations of curettage and blind biopsy in obtaining adequate samples and diagnosing focal intrauterine lesions. For instance, one study from 1993 demonstrated that the percentage of endometrial surface area sampled by the Pipelle device was only 4.2%.¹⁹ Similarly in 1975, Stock and Kanbour showed that approximately 60% of curettage specimens sampled less than half of the uterine cavity.²⁰ A prospective study from 2001 compared the adequacy of D&C vs hysteroscopy with endometrial resection in obtaining a representative endometrial sample in women with postmenopausal bleeding and endometrium

≥5 mm. This study demonstrated that compared to hysteroscopy, D&C missed 58% of polyps, 50% of hyperplasias, 60% of complex atypical hyperplasias, and 11% of endometrial cancers, thereby indicating that hysteroscopy with visual biopsy is superior to D&C for obtaining a representative endometrial sample.²¹

Another prospective trial described the low sensitivity and accuracy of blind biopsy with Novak's curette in the diagnosis of benign focal intracavitary lesions. This study concluded that hysteroscopy enables accurate biopsy and direct visualization of the uterine cavity, which can aid in overcoming the false-negative results of blind biopsy.²² A retrospective cohort study corroborated that random endometrial sampling with Novak's curette alone is ineffective in the diagnosis of intrauterine focal lesions and needs to be combined with diagnostic hysteroscopy.²³ To that end, visually directed removal of pathology, with either graspers or the electrical loop, has now become routine.²⁴ Resectoscopy with monopolar or bipolar current, however, is associated with the risk of trauma to adjacent endometrial tissue, which can lead to the development of intrauterine adhesions as well as the distortion of tissue morphology from thermal artifact.¹⁰ Given that recommendations from the Society for Gynecologic Oncology consider devices yielding crushed, cauterized, or very small samples as "unacceptable" for diagnosis of endometrial carcinoma, there has been a need to improve endometrial sample collection.²⁵ It is widely recognized that endometrial cancer is frequently identified after a biopsy sample of complex atypical hyperplasia (CAH). Indeed, up to 40% of cases of CAH on pre-hysterectomy endometrial curetting will have cancer and on occasion will have significant myometrial invasion.²⁶ Investigators have suggested that greater tissue volume at biopsy provided for pathologic diagnosing could reduce these discrepant results.²⁷

Since the MyoSure Tissue Removal System enables concurrent resection and aspiration of endometrial tissue without electrocautery, it eliminates thermal artifact in tissue samples submitted for histologic evaluation. In my opinion, the MyoSure system also allows for a thorough sampling of the endometrial cavity while constant visualization reduces the risk of perforation compared to blind D&C. A recent analysis used extirpated uteri from postmenopausal women to compare endometrial sampling with the MyoSure system and blind curettage.²⁸ This study demonstrated that use of the MyoSure system for endometrial sampling yielded more tissue for histopathological investigation versus sharp curettage. Further studies are warranted to determine if the extensive sampling capability of the MyoSure system is equivalent to outcomes associated with endometrial resection by loop.

MyoSure Curettage

In my personal practice, I recently encountered a 44-year-old healthy G0 who presented with menorrhagia and was unable to tolerate an office endometrial biopsy or saline ultrasound and was taken to the operating room

(OR) for hysteroscopy and MyoSure curettage, as well as sharp curette. Use of the MyoSure system enabled easy visualization and removal of multiple polyps. Additional tissue from all quadrants was also removed without difficulty using the MyoSure system. Pathology from the MyoSure sampling demonstrated a minute foci of endometrial adenocarcinoma, with staining concerning for Lynch syndrome. The routine curettage, by comparison, showed no overt abnormal pathology. The patient subsequently tested positive for Lynch syndrome and underwent LAVH, BSO and staging, with grade 1 endometrial adenocarcinoma confirmed in the uterine corpus as well. This case demonstrates for me the benefits of MyoSure Curettage for endometrial sampling compared to blind sharp curette.

In-office Use of the MyoSure System

Charles E. Miller, MD, FACOG

For many gynecologists, diagnostic hysteroscopy in the office setting has become routine for the evaluation of abnormal uterine bleeding. Endometrial sampling or resection of visually identified intrauterine pathology, on the other hand, is primarily deferred to the operating room and completed under general anesthesia. Recent studies have demonstrated that including endometrial sampling and removing endometrial polyps during hysteroscopy can be safely performed in the office with high patient tolerance and satisfaction.²⁹⁻³¹ The literature is replete in regards to use of hysteroscopic morcellation for the management of endometrial polyps in an outpatient setting.³⁰⁻³² A randomized prospective comparative trial comparing office and ambulatory surgical center use of the MyoSure system for removal of polyps and fibroids concluded that the MyoSure system proves to be efficacious in both settings.¹⁴ Similarly, a randomized controlled trial comparing two types of paracervical or intracervical block was associated with low pain scores during operative procedures with the MyoSure system.³³

A subsequent prospective study on the use of MyoSure hysteroscopic morcellation to manage endometrial polyps in an office-based (outpatient) setting by McIlwaine and McElhinney was published in 2015.³² While this study was performed in a public hospital, evacuation of endometrial polyps was performed under local anesthesia. The mean polyp size was 13 mm and the mean resection time was 39.4 seconds. Complete resection was achieved in 95.2% of the cases. The median visual analogue score (VAS) was 2.7. In general, women were very satisfied; over 97% would recommend the procedure to a friend and over 95% were happy to consider a repeat procedure in the future if required. The complication rate was 4.8% and all were minor in nature.³² The authors determined that in-office polypectomy can also save critical healthcare resources.

In the past, reimbursement rates may have led to some resistance to adoption. However, based on the Centers for Medicare and Medicaid Services (CMS) 2017 Physician Schedule, the physician fee was significantly

increased to \$1,382.07 for hysteroscopy and biopsy (CPT Code 58558) performed in the office setting.³⁴ This is not only encouraging to physicians in their efforts to perform polypectomy in-office, but is more cost-effective for the patient, physician, and overall health system. This also allows the physician to be more efficient and the patient to be in a more comfortable environment.

The MyoSure system is of small enough diameter to allow for use with minimal cervical dilation which can typically be performed using local anesthesia in the form of paracervical block. In addition, the MyoSure system uses no electrical energy and is associated with minimal discomfort to patients during polypectomy under local anesthesia. Furthermore, there are versatile MyoSure devices available that are designed to access hard-to-reach pathology, resect smaller and softer tissue, and remove a range of tissue types and sizes.³⁵

Removal of RPOC

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RPOC are known to occur after miscarriage, vaginal or cesarean delivery, and medical or surgical pregnancy termination.³⁶ While bleeding and infections are the RPOC-associated short-term complications, formation of intrauterine adhesions has been described as the long-term complication of RPOC. Indeed, intrauterine adhesions are known to significantly affect future reproductive outcomes due to infertility, miscarriages, and pregnancy complications such as placenta accreta.³⁷ D&C represents the traditional surgical treatment of RPOC which has been reported to increase the endometrial trauma from the RPOC.³⁸ Currently, hysteroscopy to identify the areas with the suspected RPOC followed by removal of the RPOC using the loop as curettage with gentle motions without application of current is recommended.³⁹ A recent meta-analysis reported that hysteroscopic removal of RPOC led to low complication rates, low rates of intrauterine adhesions and high rates of subsequent pregnancies as compared with blind curettage.⁴⁰ A retrospective case series evaluated the effectiveness of hysteroscopic morcellation in removing RPOC among women with histologic confirmation of placental remnants after miscarriage, termination of pregnancy or delivery. Data from this analysis reported that hysteroscopic morcellation led to successful removal of placental remnants as the first approach in 94.3% of cases, among which 85.7% of cases were associated with no adverse events. This

study supported the expanded utility of hysteroscopic morcellation devices in the removal of RPOC.⁴¹ A 2014 case presentation reported the utility of the MyoSure system in the successful and expeditious removal of RPOC in a 33-year-old patient with a loss at 10 weeks' gestation.⁴² Similarly, the MyoSure system was useful in resecting RPOC in a 24-year-old woman with recurrent miscarriages and intrauterine adhesions following treatment of non-progressive pregnancies. Use of the MyoSure system in this case was not only associated with successful removal of RPOC, but also prevention of adhesion formation and a subsequent ongoing viable pregnancy.⁴³ Another case report demonstrated the utility of the MyoSure system in the management of a cornual ectopic pregnancy that had failed medical therapy.⁴⁴ A prospective cohort study that used the MyoSure system to resect RPOC in 16 cases reported that this device was useful in the removal of smaller volumes of residual tissue (up to 10 mL).¹⁵ Although the experience at present is limited, in our institution the use of the Myosure system for RPOC is actually seen as the best indication for the device—providing excellent removal of the retained tissue without damaging the uterine wall. The technique seems to be especially promising for the prevention of adhesion formation when compared with our experience with traditional D&C.^{45,46} Hysteroscopic removal, specifically with the MyoSure system, seems to improve these results but it remains to be proven.

In light of all these results, removal of RPOC with hysteroscopic morcellation devices appears to be safe and effective.

Conclusions

Several clinical studies confirm the effectiveness of the MyoSure Tissue Removal System in the resection of polyps and fibroids in the hospital and office setting.^{4,13,15} In order to treat a wide range of intrauterine pathology and a full spectrum of intrauterine procedures, the MyoSure Tissue Removal System offers multiple device types: MyoSure LITE, REACH and XL. In previously subfertile women, normalizing the uterine cavity by treating intrauterine pathology with the MyoSure system supports subsequent conception and live birth rates.¹⁸ In addition, MyoSure has shown to obtain adequate and sufficient endometrial samples for histopathological assessment.²⁸ The utility of the MyoSure system has now been expanded to the removal of retained products of conception.⁴²

Important Safety Information for the MyoSure® Hysteroscopic Tissue Removal System

Indications for Use: The MyoSure Tissue Removal System is intended for hysteroscopic intrauterine procedures by trained gynecologists to resect and remove tissue including submucous myomas and endometrial polyps.

Contraindications: The MyoSure Tissue Removal System should not be used with pregnant patients or patients exhibiting pelvic infection, cervical malignancies, or previously diagnosed endometrial cancer.

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D&C ENDOMETRIAL POLYP SUBMUCOUS MYOMA ADHESIOLYSIS
 POLYPS ≤ 3 CM POLYPECTOMY MYOMECTOMY ALL POLYPS
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IMPORTANT SAFETY INFORMATION

The MyoSure® tissue removal system is intended for hysteroscopic intrauterine procedures by trained gynecologists to resect and remove tissue including submucous myomas, endometrial polyps, and retained products of conception. It is not appropriate for patients who are or may be pregnant, or are exhibiting pelvic infection, cervical malignancies, or previously diagnosed endometrial cancer.

REFERENCE: 1. Satisfaction. For you and your patients. MyoSure Tissue Removal System. <http://myosure.com/sites/myosure/files/MyoSure-Tissue-Removal-Procedure-Physician-Brochure.pdf>. Accessed October 5, 2016.

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