

Clinical Evaluation of a New Hysteroscopic Morcellator—Retrospective Case Review

Charles Miller, MD;¹ Larry Glazerman, MD;² Kelly Roy, MD;³ Andrea Lukes, MD⁴

From ¹Edward Hospital, Naperville, Illinois; ²University of South Florida, Tampa, Florida; ³Phoenix Gynecology Consultants, Phoenix, Arizona; ⁴Carolina Women's Research and Wellness Center, Durham, North Carolina

Address correspondence to: Charles Miller, MD
Edward Hospital
120 Osler Drive (Edward Hospital Campus)
Naperville, IL 60540
Phone: 630-428-2229 Fax: 630-428-0336
Email: chucks1011@aol.com

Abstract

Objective: The objective of this study was to clinically assess the cutting efficiency and safety of a new hysteroscopic morcellator. **Methods:** A retrospective review of medical records for 11 premenopausal women who had been treated with the new hysteroscopic morcellator was conducted at 4 hospital or ambulatory surgical center sites. Four physicians performed hysteroscopic operative procedures to remove intrauterine polyps and type 0 (completely within the uterine cavity), type I (mostly within the cavity), and type II (< 40% within the cavity) submucous myomas. Percent pathology removed, total morcellation time, total fluid used, fluid deficit, and treatment-related adverse events were assessed. **Results:** In all cases involving polyps and type 0 and type I submucous myomas, 100% of target pathology was removed by the morcellator device. The morcellator removed 50% of target pathology (100% of the intrauterine portion) in the single case involving a type II submucous myoma. For all cases, mean morcellation time was 3 minutes 3 seconds (range 14 seconds for polyps \leq 1 cm to 22 minutes 38 seconds for a 4 cm submucous myoma). Fluid deficits for the reported cases ranged from 30 mL to 1,900 mL based on the size of the pathology and associated duration of the procedure. None of the study subjects experienced an adverse event. **Conclusions:** Early data suggest that this new hysteroscopic morcellator may be a safe and efficient treatment option for the removal of intracavity myomas and polyps.

Key Words: Morcellator, hysteroscope, myomectomy, polypectomy, uterine fibroids

Disclosure: Interlace Medical, Inc. sponsored this study. Dr. Miller has received grant/research support from Ferring Pharmaceuticals, Duramed Research, Inc., Baxter Healthcare Corporation, Covidien, and Genzyme. He is a consultant to Ferring Pharmaceuticals, Ethicon Endo Surgery, Ethicon Women's Health and Urology, Boston Scientific, V. Mueller/Cardinal Health Medical Products, and Interlace Medical. He is a member of the speakers' bureaus for Ferring Pharmaceuticals, Ethicon Endo Surgery, and Ethicon Women's Health and Urology. Dr. Roy is a consultant to Interlace Medical and Smith & Nephew and owns stock in Interlace Medical. Dr. Lukes is a consultant to Interlace Medical. Dr. Glazerman has disclosed no relevant conflicts of interest.

Introduction

Operative hysteroscopy is a well established treatment method for intrauterine fibroids and polyps. Current treatment options for polyps and submucous fibroids have several restrictions that have limited their widespread adoption by obstetrics/gynecology practitioners. Currently, the most popular tools for removing polyps and submucous fibroids are monopolar or bipolar hysteroscopic loop resection devices or other radiofrequency (RF) ablation devices that employ high-frequency electrical current. Although these devices provide good clinical results,¹ they are associated with a risk of excessive intravasation of distention fluid, which may pose a threat to life.² In addition, such devices present a risk of misdirected RF energy and associated perforation or uncontrolled monopolar leakage cur-

rent and related burns.^{3,4} Loop resection devices and RF ablation devices require extensive training⁵ and skill by users. Because the visual field is frequently obscured by debris during resection, repeated removal and reinsertion of instruments is required to remove resected tissue, which prolongs procedure times thereby adding to the risk of intravasation. The repeated removal and reinsertion of instruments also increases the risk of perforation and cervical laceration.

Current hysteroscopic morcellator technology (Operative Hysteroscopy System, Smith & Nephew, Andover, Massachusetts) has been commercially available since 2006. The morcellation technique used with the Operative Hysteroscopy System is more convenient than loop resection



Figure 1. Hysteroscopic Morcellator System (Interlace Medical, Inc., Framingham, Massachusetts).



Figure 2. Side-facing cutting window and inner cutter blade.

techniques because it is effective at resecting small submucous myomas and polyps while simultaneously extracting resected tissue from the uterine cavity.⁶ Also, the size of the hysteroscope (9 mm OD) requires extensive cervical dilation, which is usually done in conjunction with anesthesia protocols that are administered in an ambulatory surgical center (ASC) or hospital setting.⁶ Given the limitations of current treatment options and equipment, the authors believe that there is a continuing need for a device that can be used to treat polyps and intrauterine submucous myomas in a less invasive and more efficient manner than is presently available. Such a device should be fast acting, easy to operate, and safe to use in the removal of all polyps and non-type II submucous fibroids; dimensionally compatible with an oral sedation/paracervical block protocol; and capable of immediately removing resected tissue from the uterine cavity to preserve visualization of the operative field.

The authors report on the initial clinical use of a new, slim profile (3 mm OD) hysteroscopic morcellator device. The new device's design and operational capabilities make it a minimally invasive,

easy-to-use, and efficient treatment option for polyps and intrauterine submucous myomas.

Materials and Methods

A retrospective review of medical records for an unselected series of 11 premenopausal women who had been treated with the new hysteroscopic morcellator was conducted at 4 hospital or ASC sites. The morcellator evaluated in this study was used to treat subjects who had been scheduled for hysteroscopic resection of intrauterine pathology during a 4-month timeframe (September 2008 through January 2009). The morcellator was cleared by the US Food and Drug Administration (K073690) at the time of the treatment procedures, so subject agreement based on routine institutional practice was obtained prior to treatment administration. Because the treating physician or a medical staff member at each site retrospectively reviewed medical records associated with the hysteroscopic myomectomy or polypectomy performed on each subject, the requirement for study-related subject consent was waived by the institutional review boards responsible for overseeing the study.

The new hysteroscopic morcellator described in this study (Interlace Medical, Inc., Framingham, Massachusetts) consists of an electrical control box, a foot pedal, and a morcellator handpiece (Figure 1) that features a rotating/reciprocating 2 mm OD cutter blade encased in a 3 mm OD outer tube. The cutter is connected to a vacuum source that aspirates resected tissue through a side-facing cutting window in the morcellator's outer tube (Figure 2). Resected tissue is captured in a standard vacuum canister tissue trap and is available for pathological examination.

Ultrasound and/or hysteroscopic examination of the uterine cavity was performed to confirm the size (diameter) and location of targeted intrauterine pathology prior to treatment initiation in all cases. No pretreatment of fibroids was performed prior to their attempted removal with the new hysteroscopic morcellator. All cases were conducted in a hospital outpatient or ASC setting. During procedures with the new hysteroscopic morcellator, each subject was prepped, draped, and given general anesthesia or intravenous sedation in accordance with standard institutional practice.

The morcellator handpiece was connected to a vacuum canister, which was connected to a regulated wall vacuum. The morcellator was then introduced transvaginally through the straight working channel of a commercial continuous flow hysteroscope (9 mm OD) or dedicated introducer sheath (5.5 mm OD) whose inflow was connected to a peristaltic fluid management device that permitted adjustment of distension fluid flow rate (500 mL/min) and uterine distension pressure (60 mmHg–100 mmHg) for the reported cases.

Depending on duration of the treatment procedure, one or more 3,000 cc bags of normal saline solution were used to achieve uterine distension and irrigation. Spent distension fluid from the

Table 1
Operative Hysteroscopy Outcome Measures

Pathology Type	Polyps	Myomas (Type 0)	Myomas (Type I)	Myomas (Type II)
No. of abnormalities	14 (70%)	2 (10%)	3 (15%)	1 (5%)
Size of intrauterine abnormality, diameter (mm)	9.6 (5–30; 5)	22.5 (15–30; 22.5)	31.7 (20–40; 35)	50.0
No. of treatment sessions per subject	1	1	1	1
% tissue removed	100%	100%	100%	50%
Weight of removed tissue (g)	1.9 (0.5–4.3; 1.8)	9.6 (4.3–14.9; 9.6)	20.8 (4.5–45.3; 12.5)	11.7
Morcellation time (min:sec)	0:37 (0:14–0:58; 0:40)	2:19 (0:38–4:00; 2:19)	9:10 (0:14–22:38; 4:39)	11:49
Total distension fluid (mL)	2,382.5 (600–6,730; 1,000)	3,400 (1,500–5,300; 3,400)	11,153.3 (4,670–24,000; 4,790)	1,700
Fluid deficit (mL)	190.8 (30–460; 150)	205.0 (200–210; 205)	1,300 (500–1,900; 1,500)	Not recorded

Values are given in mean (range; median) or number (%)

hysteroscope and collection drape (gravity outflow) and the morcellator (vacuum outflow) was collected into vacuum canisters. Measured volumes of collected distension media from all sources were subtracted from the measured inflow volume to determine the fluid deficit.

Once uterine distension was achieved and targeted pathology was visualized, treatment commenced. Treatment was terminated when all pathology had been resected and removed from the uterus or when the treating physician determined that no further use of the morcellator was warranted. An automatic timer on the front panel of the hysteroscopic morcellator's motor control box indicated morcellation time. Percent of targeted pathology removed by the morcellator was determined via the treating physician's post-treatment hysteroscopic examination of the uterine cavity. All resected tissue was collected in a standard tissue trap that was weighed before and after treatment so that the weight of resected tissue could be determined. All resected tissue was subsequently submitted for pathology review.

Study data was subjected to routine statistical analysis using Microsoft Excel with mean, median, and range computed for study endpoints.

Results

In this 11-subject case series, medical records pertaining to treatment with the new morcellator and associated post-treatment follow-up were reviewed 3 to 10 months post-procedure. The median subject age was 41 years (range 29–58 years), and subjects' preoperative diagnoses were abnormal uterine bleeding (AUB) or infertility secondary to intrauterine pathology.

Pretreatment hysteroscopic or ultrasound examination of the target pathology revealed that the 11 subjects presented with 14 endometrial polyps and 6 submucous myomas (2 type 0, 3 type I, and 1 type II). Five subjects experienced multiple intrauterine pathologies, 5 subjects presented with a single intrauterine myoma, and 1 subject presented with a single polyp. Mean polyp size was 9.6 mm (range 5 mm–30 mm). Mean submucous myoma size was 31.7 mm (range 15 mm–50 mm).

Table 1 presents the study outcome measures. The mean morcellation time for complete resection of target pathology for each type of case was as follows: polypectomies, 37 seconds; type 0 myomas, 2 minutes 19 seconds; and type I myomas, 9 minutes 10 seconds. Target pathology was 50% resected (100% of the intrauterine portion was removed) in the single type II myomectomy case with a

morcellation time of 11 minutes 49 seconds. Tissue remaining within the uterine wall was removed via laparoscopic surgery.

Total fluid volumes and fluid deficit varied depending on the type of pathology and duration of the procedure. Total fluid volumes and fluid deficits ranged from 600 mL and 30 mL, respectively, for the treatment of polyps (42 second morcellation time) to 24,000 mL and 1,500 mL for the treatment of a 4 cm type I fibroid with a significant intramural component (22 minute 38 second morcellation time). No subject treated with the new device experienced either an acute or a delayed onset adverse event based on a review of medical records at 3 to 10 months post-procedure.

Discussion

Despite the small cohort size and retrospective nature of this study, results from this case series demonstrate that the new hysteroscopic morcellator is a safe, effective, and efficient treatment option for the removal of submucous myomas and polyps from the uterine cavity. All users felt that the new morcellator device was efficient at cutting all types of polyps and type 0 and type I submucous fibroids and extremely effective at removing resected tissue from the uterine cavity to preserve visualization of the operative field. All subjects had their intrauterine pathology removed in a single treatment session. While the device was most efficient at removing polyps and type 0 and type I submucous fibroids, it also effectively removed the intracavity portion of the single type II myoma. In type II myoma cases, the morcellator also may be effective at removing the intramural fibroid tissue if a technique is employed that enables the portion of fibroid embedded in the uterine wall to be avulsed into the uterine cavity where it can be morcellated and removed.⁷ Specifically, decreasing uterine pressure by draining the uterine cavity of distension fluid for a 3-minute interval enables fibroid tissue remaining in the uterine wall to be expelled into the uterine cavity. It is then possible to resect the avulsed tissue without resecting below the level of the endometrium. This technique maximizes effectiveness of the new morcellator's side-facing cutting window, which by nature of its design limits the device's ability to directly access the intramural portion of the fibroid while at the same time potentially decreases the risk of uterine wall perforation.

The new morcellator's design features and performance capabilities address several limitations of current submucous fibroid and polyp treatment options. Specifically, the morcellator's cutting efficiency resulted in relatively short morcellation times thereby potentially mitigating the amount of fluid intravasated in all cases. The new morcellator's compatibility with physiologic distension media (eg, saline, Ringers lactate) also may mitigate the risks of fluid intravasation in that the American Association of Gynecologic Laparoscopists fluid management guidelines indicate that more saline can be intravasated than anionic solution.⁸ The new morcellator does not employ RF energy, and its side-facing window design limits the depth of tissue resection,

thus theoretically decreasing the chance of perforation. The lack of RF energy as a cutting source eliminates the potential for tissue burns and enables pathology examination of resected tissue specimen margins. The morcellator's ability to immediately remove tissue fragments from the uterine cavity facilitates visualization of the operative field and minimizes the need for device removal and re-insertion, thereby reducing procedure time and associated risk of intravasation, cervical trauma, and perforation. As risk of air embolism increases with trauma to the cervical vessels, hysteroscopic morcellation provides a safe alternative to loop resectoscopy methods.⁹

The new morcellator is compatible with commercially available fluid management systems (eg, those manufactured by Stryker, Storz, Smith & Nephew, ACMI, Davol) and hysteroscopes that have a straight working channel ≥ 3 mm/9 Fr. Because the new device incorporates a low profile design (3 mm OD) that is compatible with an appropriately sized (eg, ≤ 6 mm/18 Fr OD) introducer sheath or hysteroscope, the new morcellator has potential to be used in a physician's office in conjunction with an oral sedation/paracervical block protocol. While the new morcellator is an attractive current treatment alternative for hospital or ASC-based myomectomy and polypectomy procedures, additional studies and improvements in device design are recommended prior to office-based use of the device. ■

References

1. Emanuel MH, Wamsteker K, Hart AA, Metz G, Lammes FB. Long-term results of hysteroscopic myomectomy for abnormal uterine bleeding. *Obstet Gynecol.* 1999;93(5 Pt 1):743-748.
2. Vulgaropoulos SP, Haley LC, Hulka JF. Intrauterine pressure and fluid absorption during continuous flow hysteroscopy. *Am J Obstet Gynecol.* 1992;167(2):386-390.
3. Sutton CJG, McDonald R. Endometrial resection. In: Lewis BV, Magos AL, eds. *Endometrial Ablation*. Edinburgh: Churchill Livingstone; 1993:131-140.
4. Odell R. Electrosurgery. In: Sutton CJG, Diamond MP, eds. *Endoscopic Surgery for Gynaecologists*. London: WB Saunders; 1993:51-59.
5. Emanuel MH, Wamsteker K. The Intra Uterine Morcellator: a new hysteroscopic operating technique to remove intrauterine polyps and myomas. *J Minim Invasive Gynecol.* 2005;12(1):62-66.
6. van Dongen H, Emanuel MH, Wolterbeek R, Trimbos JB, Jansen FW. Hysteroscopic morcellator for removal of intrauterine polyps and myomas: a randomized controlled pilot study among residents in training. *J Minim Invasive Gynecol.* 2008;15(4):466-471.
7. Loffer FD. Removal of large symptomatic intrauterine growths by the hysteroscopic resectoscope. *Obstet Gynecol.* 1990;76(5 Pt 1):836-840.
8. Loffer FD, Bradley LD, Brill AI, Brooks PG, Cooper JM. Hysteroscopic Fluid Monitoring Guidelines. *J Am Assoc Gynecol Laparosc.* 2000;7(3):438.
9. Miller C. Hysteroscopic morcellation. In: O'Donovan P, Miller C, eds. *Modern Management of Abnormal Uterine Bleeding*. London: Informa Healthcare; 2008:215-219.

Reprinted with permission from the *Journal of Medicine*. Copyright © 2009 Sequence Medical.