

# CLINICAL EVALUATION OF A 1<sup>ST</sup> GENERATION INTERLACE MEDICAL HYSTEROSCOPIC TISSUE REMOVAL SYSTEM

C. Miller, M.D., J. Greenberg, M.D., J. Petrozza, M.D., K. Roy, M.D.,  
J. Garza-Leal, M.D., I. Hernandez, M.D., K. Finkelstein, D.O., A. Cholkeri-Singh, M.D.,  
J. Miner, M.D., Y. Groszman, M.D., D. Fylstra, M.D., A. Lukes, M.D.

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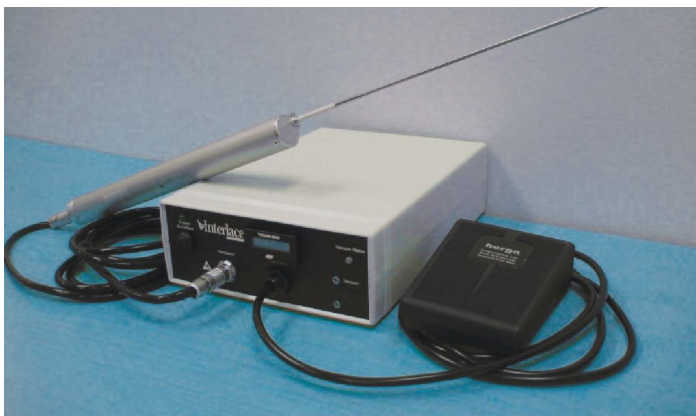
## OBJECTIVE

A new hysteroscopic tissue removal device was placed at ten (10) sites and used by fourteen (14) interventional OB/GYN practitioners to remove intrauterine fibroids and polyps from women suffering from AUB or infertility. The treating physicians assessed cutting efficiency, tissue removal capability and safety of the new device.

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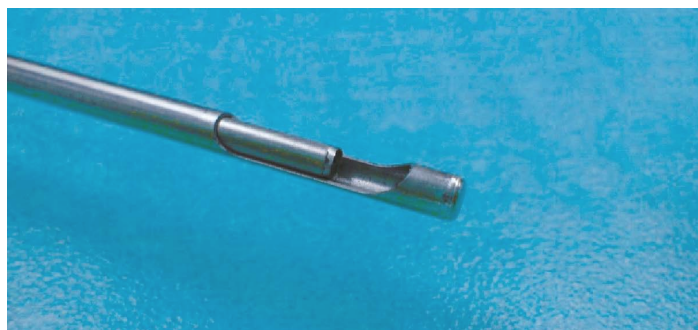
## MATERIALS AND METHODS

The new hysteroscopic tissue removal device described in this paper was developed by Interlace Medical Inc. as a minimally invasive treatment option to remove 3 cm intra-cavity fibroids and 5 cm polyps in 10 minutes or less. The 1st generation device consists of a control box, a foot pedal, and a tissue removal device (**Figure 1**).



*Figure 1. Interlace Medical Hysteroscopic Tissue Removal System*

The tissue removal device features a 2 mm cutter blade encased in a 3 mm outer tube. The cutter blade is powered by an electro-mechanical drive system which enables simultaneous rotation and reciprocation of the cutter. The cutter is also connected to a vacuum source which continuously aspirates resected tissue through a side-facing cutting window in the outer tube (**Figure 2**).



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

The tissue removal device's side-facing cutting window dimensions limit the depth of tissue resection to minimize perforation risk. When the device is not cutting, the cutting window automatically closes to prevent a loss of uterine distension, thereby reducing the potential for uterine perforation and making rapid resection procedures possible. Resected tissue is captured in a vacuum canister tissue trap and is available for pathologic examination. Because the cutter does not utilize RF energy, the specimen margins remain intact.

The tissue removal device evaluated in this study is FDA cleared and was used on an unselected series of forty-eight (48) patients who had been scheduled for hysteroscopic resection of intrauterine pathology from August, 2008 through June, 2009. Patient agreement based on routine institutional practice was obtained prior to treatment administration.

Procedurally, each patient was prepped, anesthetized and cervically dilated in accordance with standard institutional practice. Ultrasound and/or hysteroscopic examination of the uterine cavity confirmed the size (diameter) and location of targeted intrauterine pathology prior to treatment initiation in all cases. The tissue removal device was connected to a vacuum canister which was itself connected to regulated wall vacuum. The device was then introduced transvaginally through the straight working channel of a continuous flow hysteroscope or dedicated introducer sheath whose inflow was connected to a peristaltic fluid management device which permitted adjustment of distension fluid flow rate (500 ml/min) and uterine distension pressure (60-100 mmHg) for the reported cases.

Depending on the duration of the treatment procedure, one or more 3 liter bags of normal saline solution were used to achieve uterine distension and irrigation. Spent distension fluid from the hysteroscope and collection drape (gravity outflow) and the tissue removal device (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.

When 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 tissue removal device was warranted. Treatment (tissue removal) time was indicated by an automatic timer on the front panel of the hysteroscopic tissue removal device's control box. Percent of targeted pathology removed by the device 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 which was weighed pre and post 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 and median values, ranges and standard deviation being computed for study endpoints.

## RESULTS

Pre-treatment hysteroscopic or ultrasound examination of the target pathology revealed that 21 patients presented with 43 endometrial polyps and 29 patients presented with 31 submucosal myomas (N = 12 type 0, N = 11 type I, N = 8 type II). Thirteen patients experienced multiple intrauterine pathologies, 26 patients presented with a single intrauterine myoma and 9 patients presented with a single polyp. Mean polyp size was 1.2 cm (range .3 cm - 3.0 cm). Mean submucous myoma size was 3.1 cm (range .7 cm - 15.0 cm).

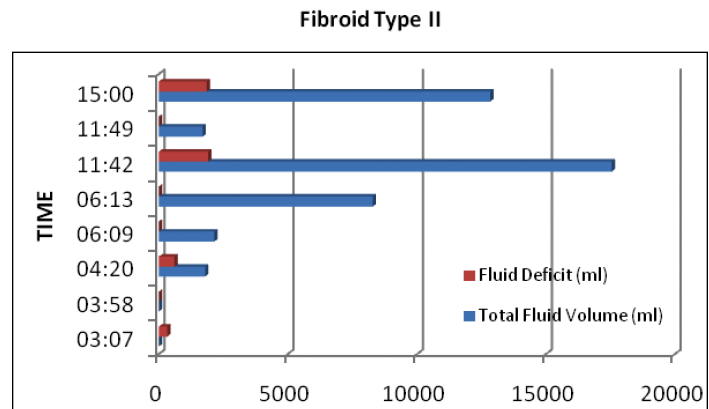
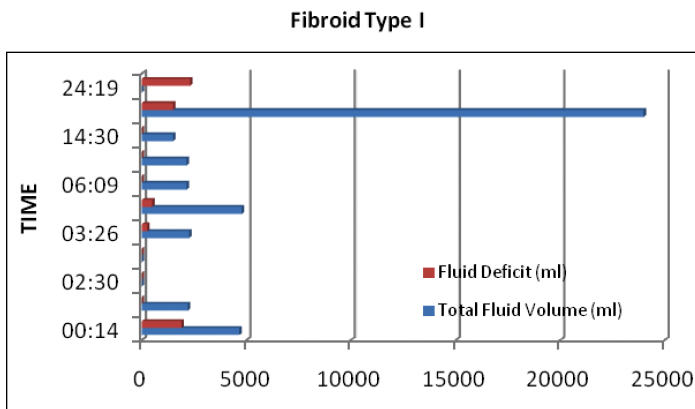
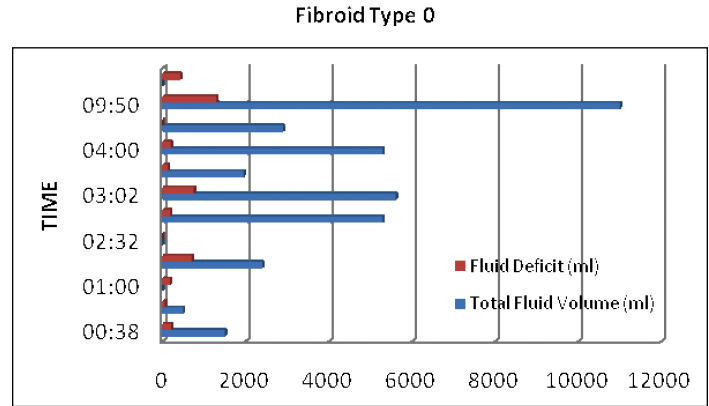
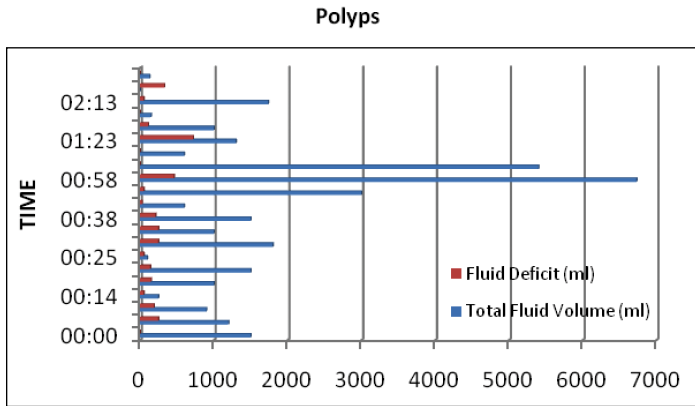
Treatment outcome measures are presented in Table 1. The mean treatment time for resection of target pathology for each type of case was as follows: polypectomies (54 seconds), type 0 myomas (4 minutes 19 seconds), type I myomas (8 minutes 11 seconds) and type II myomas (7 minutes 47 seconds). For the type II myomectomy cases, 50-90% of the target pathology was resected (100% of the intrauterine portion was removed).

Total fluid volumes and fluid deficit varied depending on the type of pathology and duration of the procedure as presented in the following charts. The fluid deficit ranged from 30 ml for a polyp (0:42 sec resection time) to 600 ml for a 4 cm Type II fibroid (11:42 min:sec resection time). The equivalent total fluid volumes for these procedures was 1.9L and 17.5L, respectively.

TABLE 1 – TREATMENT OUTCOMES VS. PATHOLOGY TYPE & SIZE

Pathology Type	Size (cm) [Mean; range]	Treatment Time (min:sec) [Mean; range]	% Tissue Removed	Wt. Tissue Removed (g) [Mean; range]
Polyps	1.2; .3 – 3.0	00:54; 00:03 – 03:07	100%	2.0; 0.2 – 6.0
Type 0 Myomas	2.2; 1.0 – 3.0	04:19; 00:38 – 13:10	99%	7.6; 1.4 – 18.9
Type I Myomas	2.9; .7 – 5.0	08:11; 00:14 – 24:19	96%	20.5; 1.8 – 59.5
Type II Myomas	4.9; 1.0 – 15.0	07:47; 03:07 – 15:00	66%	12.5; 1.8 – 43.7

## FLUID VOLUMES & FLUID DEFICIT VS. PATHOLOGY TYPE & TREATMENT TIME



No patient treated with the new device experienced an acute-onset adverse event either intra-operatively or during post-procedure recovery.

### DISCUSSION

Monopolar or bipolar hysteroscopic loop resection devices or other RF ablation devices which employ high-frequency electrical current are the most commonly used tools for removing submucosal fibroids and polyps. While providing good clinical results,<sup>1</sup> these devices have also been associated with the following risks:

- excessive intravasation of distention fluid which may pose a threat to life<sup>2</sup>
- misdirected RF energy and associated perforation risk
- uncontrolled monopolar leakage current and related burns<sup>3-4</sup>
- obscured visual field due to debris during resection
- perforation and cervical laceration due to repeated removal and reinsertion of instruments to remove resected tissue

Loop resection devices and RF ablation devices also require extensive training<sup>5</sup> and skill by users.

Hysteroscopic morcellator technology (Smith & Nephew) has been commercially available since 2006. The S&N morcellation technique is easier to learn and use than loop resection techniques,<sup>6</sup> is effective at resecting small submucosal myomas and polyps.<sup>6</sup> However, the S&N system has the disadvantage of requiring a dedicated fluid pump and hysteroscope. Also, the S&N hysteroscope's 9 mm OD size requires extensive cervical dilation such that it must be used in conjunction with anesthesia protocols which are administered in an ASC or hospital setting.<sup>6</sup>

Given the limitations of current treatment options, there is a continued need on the part of OBGYN interventionalists and their patients for a device that is fast, easy to learn, safe to use and capable of immediately removing resected fibroid and polyp tissue from the uterine cavity to preserve visualization of the operative field. Ideally, such a device would be low profile in nature and thus compatible with an oral sedation/paracervical block protocol, thereby enabling the removal of

all polyps and moderately sized ( $\leq 3$  cm) non-type II submucous fibroids in an office setting.

This study demonstrated that the Interlace Medical hysteroscopic tissue removal device is a safe, effective and efficient treatment option for the removal of submucous myomas and polyps from the uterine cavity. Physicians felt that the new device efficiently cut submucous fibroids and polyps and was extremely effective at removing resected tissue from the uterine cavity to preserve visualization of the operative field. All patients had their intrauterine pathology removed in a single treatment session. While the device was most efficient at removing polyps, type 0 and type I submucosal fibroids, it also effectively removed the intracavity portion of type II myomas. In type II myoma cases, the Interlace Medical tissue removal device 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 resected and removed.<sup>7</sup> 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 with minimal disruption of the myometrium. This technique maximizes effectiveness of the new device'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 decreasing the risk of uterine wall perforation.

The new tissue removal device's design features address several limitations of current submucous fibroid and polyp treatment options. Specifically, the device's cutting efficiency resulted in relatively short procedure times thereby mitigating the risk of fluid extravasation. The risks of fluid extravasation were further reduced by the device's compatibility with physiologic distension media (e.g. saline, lactated Ringer's solution). The new tissue removal device's side-facing window design limits the depth of tissue resection thus minimizing the chance of perforation events. 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 device'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 extravasation and perforation.

The Interlace Medical tissue removal device is compatible with commercially available fluid management systems (e.g. Stryker, Storz, Smith & Nephew, ACMI, Davol) and hysteroscopes which have a straight working channel  $\geq 3$  mm. Because the new device incorporates a low, 3 mm OD profile design which is compatible with an appropriately sized (e.g.  $\leq 6$  mm OD) introducer sheath or hysteroscope, the new tissue removal device may be usable in a physician's office setting in conjunction with an oral sedation/paracervical block protocol. The new device is an attractive current treatment alternative for hospital or ASC-based myomectomy and polypectomy procedures, with additional studies recommended prior to office-based use of the device.

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135 Newbury Street  
Framingham, MA 01701  
Tel: 508.875.1343  
Fax: 508.370.8026  
[www.interlacemedical.com](http://www.interlacemedical.com)  
[www.myosure.com](http://www.myosure.com)