Hysteroscopic Morcellation in the UK: Published data and audit data from the Queen Alexandra Hospital, Portsmouth.

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Background
Treatment of submucosal fibroids has evolved since the early introduction of transcervical techniques first described in 1976 by Neuwirth and Amin using the urologic resectoscope.1 Although some physicians may continue to employ blind techniques such as sharp curettage or polypectomy forceps, most clinicians have become proficient in the use of hysteroscopic resectoscopy using electrosurgery. Recognizing the limitations of hysteroscopic resectoscopy with electrothermal energy, the hysteroscopic morcellator was introduced in 2006 and has proven to be an effective and safe procedure for the transcervical removal of uterine fibroids.2

Review of the data
There is abundant literature on the use of hysteroscopic resectoscopy demonstrating both clinical efficacy and safety.3 Nonetheless, there are reports of serious adverse events (rate 0.13%) related to distension fluid overload, infection, uterine perforation, death, and thermal injury from electrosurgical technique.4 Gas embolism has also been identified as a risk due to vapours derived from radiofrequency electrical current within the uterine cavity. Repetitive insertion of the device, commonly required to remove resected tissue fragments, puts the patient at risk for an air embolism.5 Furthermore, the risk of complications including infection, uterine perforation, and excess fluid absorption increases with operative time.6

By decreasing the time of procedure and eliminating the use of electrothermal energy, many of the risks associated with hysteroscopic resectoscopy might be reduced with the use of hysteroscopic morcellation. Hysteroscopic morcellation relies on mechanical energy to resect and remove intrauterine tissue pathology under direct visualisation.7 The MyoSure® tissue removal system, the second device for hysteroscopic morcellation, was commercially available in 20108 in the United States, and in September 2011 in Europe. Recognising the benefits of hysteroscopic morcellation over traditional electrosurgical resection, there has been wide spread adoption of the technology in the United States and in Europe. Hologic closely tracks reportable adverse events associated with the use of the MyoSure device through Hologic Quality Assurance and the MAUDE database. Based on the number of devices shipped, Hologic estimates that over 80,000 procedures for removal of intrauterine pathology have been performed to date using the MyoSure device with a calculated rate of serious adverse events that is approximately 0.06%.9

Published clinical studies have also demonstrated the safe use and clinical efficacy of hysteroscopic morcellation. In a randomised control study of 60 women comparing hysteroscopic morcellation to conventional resectoscopy, there was significant reduction in operative time and total volume of distension media. The number of hysteroscope reinsertions to remove chips was 7 (range 3-50) when using the resecting loop compared to 1 (range 1-2) when the morcellator was used. There was no difference in fluid deficit and there were no complications in either group.10 A retrospective analysis of 311 patients comparing patients who underwent hysteroscopic removal of endometrial polyps with either intrauterine morcellation or resection found no significant differences in recurrence of bleeding symptoms. Compared with hysteroscopic resection, intrauterine morcellation was associated with fewer recurrences of endometrial polyps. Of note, intrauterine morcellation did not seem to affect the histopathologic evaluation of removed samples.11

In a study comparing hysteroscopic morcellation of fibroids and polyps using the MyoSure system performed in the operating theatre versus the office setting, 41 patients (100%) had successful procedures with no serious adverse events.12 Subsequently, an additional 35 patients (100%) were included in the study with no serious adverse events reported.13 The MyoSure tissue removal system was also evaluated in a study, comparing two different local anaesthetic regimens; there were no adverse events in either group.14
MyoSure

There are currently three device options for the MyoSure tissue removal device (TRD) depending upon the pathology identified within the uterine cavity. The MyoSure TRD can be used for all polyps and is recommended for use in fibroids up to 3 cms in diameter. The fibroid tissue removal rate with the MyoSure TRD is 1.5 gms/min. The MyoSure LITE is recommended for the removal of polyps up to 3 cms in size. Both the MyoSure and MyoSure LITE TRDs are introduced into the uterus through a 6.25 mm hysteroscope. The MyoSure XL TRD has a larger window length and depth resulting in an increased tissue removal rate of 4.3 gms/min. The MyoSure XL TRD is recommended for use with all intrauterine pathology including large fibroids and is placed through a 7.25 mm hysteroscope.

Experience at Queen Alexandra Hospital Portsmouth

Since adoption of the MyoSure hysteroscopic TRD at Queen Alexandra Hospital, Portsmouth, over 85 cases have been performed and outcomes audited. The first 4 patients were treated under general anaesthesia using the MyoSure system during the initial evaluation of the device. Thereafter the standard has become to treat patients in the ambulatory setting, fully awake, without sedation, facilitated by oral analgesia and local anaesthesia.

<table>
<thead>
<tr>
<th></th>
<th>MyoSure LITE</th>
<th>MyoSure</th>
<th>MyoSure XL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tissue recommended</td>
<td>Polyps ≤ 3 cm</td>
<td>All polyps</td>
<td>All intrauterine pathology including large fibroids (any fibroid where you want to experience cutting efficiency)</td>
</tr>
<tr>
<td>Scope compatibility</td>
<td>MyoSure, MyoSure XL</td>
<td>MyoSure, MyoSure XL</td>
<td>MyoSure XL</td>
</tr>
<tr>
<td>Blade material</td>
<td>Stainless steel</td>
<td>Coated stainless steel with ultra hardness and high wear resistance</td>
<td>Coated stainless steel with ultra hardness and high wear resistance</td>
</tr>
<tr>
<td>Performance specifications</td>
<td>3 cm polyp ≤2 minutes</td>
<td>3 cm fibroid ≤10 minutes</td>
<td>5 cm fibroid ≤15 minutes</td>
</tr>
<tr>
<td>Tissue removal rate</td>
<td>7.0 g/min (polyp tissue)</td>
<td>1.5 g/min (fibroid tissue)</td>
<td>4.3 g/min (fibroid tissue)</td>
</tr>
<tr>
<td>Window size</td>
<td>31 mm³</td>
<td>54 mm³</td>
<td>98 mm³</td>
</tr>
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The MyoSure LITE TRD has to date been utilised in 43 patients for removal of polyps up to 6 cms long. The product information recommends treatment of polyps up to 3 cm. However, the device efficiently treated larger polyps without any evidence of blunting. Resection time varied from 2 seconds to just over 2 minutes.

The MyoSure TRD was employed for resecting large polyps and fibroids up to 3 cms in diameter. The range of resection time was 16 seconds to approximately 19.5 minutes. Nearly all cases were treated in less than 10 minutes with the majority less than 5 minutes. The one case which took 19.5 minutes was during the initial evaluation where a treatment was attempted without the Aquilex® fluid control system.

Larger pathology was managed with the MyoSure XL TRD, including a patient with a 6 cm fibroid, that was resected in 12 minutes 20 seconds and another patient with a 3 cm fibroid and 2 cm polyp, with a total cutting time of 2 minutes 18 seconds.

Overall patient satisfaction ranged from 7-10 out of a highest score of 10. No adverse events occurred in these patients.
The audit data from this series of patients supported by anecdotal reports from other units indicate the benefits of the MyoSure system for removal of polyps and fibroids include:

- Fast resection times with short duration of surgery.
- Ability to use the device in awake patients with local anaesthesia.
- Potential cost-efficacy by performing operative hysteroscopy in the ambulatory clinic.
- Potential cost-efficacy of offering a “see and treat” clinic.
- Potential to reduce risk of uterine perforation due to reduction in uterine manipulations as resected tissue is extracted through the device during the resection and the procedure is performed with direct visualisation.
- Potential of improved safety due to utilisation of normal saline, rather than glycine, which is associated with less complications for the patient.
- Potential to optimally, or completely, resect more lesions than traditional techniques.

Hysteroscopic removal of fibroids and polyps is being performed safely and effectively in the outpatient setting without the use of general anaesthesia, providing patients with excellent patient outcomes. With the adoption of smaller diameter hysteroscopic devices for removing these lesions, patients can avoid the risks of inpatient general anaesthesia, which is especially important in those women with medical co-morbidity, including obesity.

Hysteroscopic resection in the ambulatory setting provides improved convenience, increased patient safety, especially in patients at high risk of general anaesthesia and cost-savings to the Hospital by moving these treatments out the very expensive operating theatre environment.

Hologic’s Aquilex® fluid control system allows accurate measurement of fluid balance, with an integral warning system to identify when large fluid deficits are being reached. The use of this device facilitates optimisation of the visual field during resection and optimisation of resection efficiency. The use of such a fluid management system for all operative hysteroscopy procedures should be considered to optimise patient safety, to reduce treatment time and optimise patient experience in the ambulatory setting.

Conclusion

Hysteroscopic resection of submucosal fibroids and polyps has been demonstrated to improve the outcomes in women suffering with abnormal uterine bleeding or infertility.\textsuperscript{17,18,19} Traditional techniques for management of these lesions include blind curettage or forceps and electrosurgery. The introduction of hysteroscopic tissue resection devices to remove polyps and fibroids, under direct visualisation using mechanical energy, overcomes many of the difficulties and limitations encountered with traditional modalities, providing shorter treatment time, improved safety, particularly with lower risk of perforation, thermal or electrical injury and reduced need for general anaesthesia.\textsuperscript{16,19} Hysteroscopic tissue resection devices should be considered the treatment of choice for the majority of such lesions.

Figure 1. Type 1 submucous fibroid approximately 2.5 cms.

Figure 2. Complete removal of fibroid with the MyoSure device.

Time of removal 4 minutes 57 seconds.