

## GYNECOLOGY

# Power morcellators: a review of current practice and assessment of risk

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Power morcellation has come under scrutiny because of a highly publicized case of disseminated leiomyosarcoma following a laparoscopic hysterectomy. A recent Federal and Drug Administration safety communication discouraging use of power morcellators on presumed uterine leiomyoma further highlights the need for reexamination of uterine tissue extraction. This clinical opinion aims to summarize current approaches to uterine/fibroid tissue extraction including the associated immediate and long-term potential risks of open power morcellation. The known data about risk of uterine sarcoma is reviewed followed by a discussion of acceptable risk and informed consent in the context of shared-decision making.

**Key words:** hysterectomy, leiomyoma, morcellation, myomectomy, uterine malignancy

Recent popular media attention around surgical management of presumed uterine leiomyoma has created an opportunity to properly define a patient-centered research agenda and clinical management strategy. A highly publicized case of disseminated leiomyosarcoma following a laparoscopic hysterectomy, has led to the recent Food and Drug Administration (FDA) safety communication discouraging use of power morcellators for leiomyoma extraction.<sup>1,2</sup> Balancing gains in quality of life vs unanticipated dissemination of cancer must qualify advances in minimally invasive surgery (MIS).<sup>3,4</sup> The goal of this clinical

opinion is to summarize current approaches to uterine/fibroid tissue extraction, the known data about risk of unanticipated uterine sarcoma, and potential applications to this problem from shared decision-making studies.

The term morcellation refers to reduction of a solid tissue specimen into smaller pieces to permit extraction through smaller incisions. This has been the preferred method of removing larger masses laparoscopically through a widened trocar site.<sup>5</sup> Initially, this was done manually whereby a scalpel was introduced directly through a skin incision, and later manually operated cutting devices.<sup>6</sup> Both of these methods appear inefficient, as one small case series suggested a mean 53 minute time savings for myoma removal using an electro-mechanical morcellator model vs a manually operated morcellator, as well as an anecdotal case of operator elbow injury from overuse of the mechanical morcellator.<sup>7</sup>

The advantages of minimally invasive hysterectomy have been well documented and include less blood loss, fewer wound complications, less post-operative pain, shorter hospital stay, and quicker return to activity when compared with abdominal hysterectomies.<sup>8</sup> Total laparoscopic hysterectomy permits removal of smaller uteri

intact transvaginally perhaps up to 280 g using the analogous cutoff suggested for vaginal hysterectomy.<sup>9</sup> Intact vaginal removal is not an option with markedly large uteri or after a supracervical hysterectomy. Successful vaginal removal of larger specimens has been described in case series using colpotomy and/or morcellation techniques.<sup>10,11</sup> Power morcellators were first described in 1993<sup>12</sup> and permit rapid division of large pelvic masses, when suspected to be of low risk of malignancy, into fragments retrievable through small port site incisions. Gynecologists have heavily used this extraction technology, because of the high prevalence of symptomatic leiomyoma (40-60%) in reproductive age women who are not prepared to have complete hysterectomy. However, other specialties have applied this to laparoscopic removal of splenic and renal tissues.<sup>13,14</sup>

## Morcellator risks

Power morcellators pose well recognized inherent risks of iatrogenic sharp tool injury. The high-speed spinning blade must be vigilantly kept away from the adjacent abdominal viscera and vasculature. A recent review of the direct (intraoperative) morcellator risks voluntarily reported via MedSun and the FDA device database (MAUDE) identified a total of 55 injuries from 1993-2013.<sup>15</sup> The authors caution underreporting likely underestimates the true prevalence. Injuries have been described to vasculature, small and large bowel, bladder, ureter, fallopian tubes, and omentum during laparoscopic myomectomy and hysterectomy. No single morcellator was implicated in all types of injury, which were attributed to a lack of training/control/experience, poor visualization, and instrument malfunction. Although this database cannot generate precise epidemiologic estimates, this suggests a

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Received May 2, 2014; revised July 14, 2014; accepted July 24, 2014.

S.S. and J.F.M. report no conflict of interest. F.F.T. has conducted sponsored research for AbbVie and also served on an advisory board for the company.

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0002-9378/free

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<http://dx.doi.org/10.1016/j.ajog.2014.07.046>

crude 0.02–0.007% complication rate, assuming between 25,000–70,000 morcellation cases are performed annually.<sup>16</sup>

### Dissemination risk of power morcellated tissues

The most serious long-term concerns of open power morcellation include intraperitoneal spillage of benign and malignant tissues. Division of unprotected uterine tissue with a morcellator's rotary blade may disperse fragments in multiple directions, necessitating meticulous retrieval of small pieces after primary extraction. Despite optimizing exposure through careful irrigation of the abdominal cavity and patient repositioning, some residual fragments could theoretically elude detection.<sup>15</sup> This can cause peritoneal dissemination of a previously contained cancer, as recently publicized.

Iatrogenic peritoneal leiomyomatosis appears to be the most common complication following power morcellation with a reported incidence of 0.5–1.2%.<sup>17,18</sup> Although cases are often asymptomatic, symptoms of abdominal pain or bloating, with or without a palpable mass, may not appear until 1 to 2 decades later.<sup>17,19</sup> Implantation of myomas at the trocar site of power morcellation has also been reported.<sup>20</sup> The recurrence rate for this condition and type of follow-up required are unknown as there are reports of multiple recurrences.<sup>21</sup>

Despite standard preoperative evaluation for malignancy, occult uterine cancers such as endometrial adenocarcinoma (EC), leiomyosarcoma (LMS), and endometrial stromal sarcomas (ESS) are occasionally unexpectedly encountered (3/1332 in a large historical cohort of presumed leiomyoma).<sup>22</sup> Sarcomas in particular are problematic because they have nonspecific presenting symptoms resembling those from leiomyoma. The overall 5-year survival rate is 65.7%, with a high rate of recurrence even in early stage disease.<sup>23</sup> A substantial proportion of these are encountered incidentally, with Perri and colleagues<sup>24</sup> reporting 43% (16/37) of Stage I cases had undergone a partial surgical procedure preceding primary

surgical treatment. As Goff has concisely stated, the challenge in gynecology has been balancing the serious prognosis of sarcoma against its low incidence to reduce skin incision size and morbidity (including bowel obstruction from adhesions) when managing presumed uterine leiomyoma.<sup>25</sup>

A key question is the extent to which exposure or division in situ of a uterine malignancy will adversely impact survival and/or require additional surgery. A compounding problem is the difficulty of surgical staging<sup>26</sup> and assessment of tumor grading, sizing, and depth of invasion in morcellated uterine malignancies because of the specimen being extracted in piecemeal, limiting estimation of size and margins.<sup>27</sup> Small series including heterogeneous collections of different morcellation techniques (including via hysteroscopy)<sup>24</sup> and routes of tumor injury collectively suggest any form of tumor division may incur a higher risk of recurrence and shortened survival (hazard ratio, 2.85 risk of death; 95% confidence interval, 1.05–7.5). However, many of these retrospective studies fail to explicitly describe how the morcellation was performed (route or exact method)—these were not all power morcellated cases. Additional major confounding factors unmeasured include consequences of incidental tumor injury because of use of graspers or tenaculum during laparoscopic or open surgeries, which is impossible to extract retrospectively from operative reports.

Morcellation of occult EC and uterine sarcomas has been previously reported.<sup>26,28–30</sup> In one series of laparoscopic hysterectomy with morcellation, 10/1115 patients (0.9%) were identified as having either EC (50%), or sarcoma (50%).<sup>26</sup> In follow-up between 7–59 months, 1 patient developed a recurrence and 1 patient was upstaged at reoperation. Rapid dissemination of morcellated EC has also been reported.<sup>31</sup>

In a case series of 1584 patients undergoing laparoscopic hysterectomy with morcellation (both electromechanical and by hand) and preoperatively screened for uterine and cervical malignancies, 4 (0.25%) patients were

found to have EC (50%) or LMS (50%).<sup>29</sup> In a short follow-up (28–52 months), no recurrences were noted. A retrospective review of Brigham and Women's Hospital experience with 1091 patients undergoing power morcellation found 1.2% of the patients had an unexpected sarcoma or other pathologic variants of leiomyomas, including atypical, cellular, or smooth muscle tumors of uncertain malignant potential changes.<sup>28</sup>

The findings of LMS in presumed nonmorcellated hysterectomy specimens has been reported at 0.23–0.49%.<sup>32,33</sup> A retrospective review of patients with initially presumed Stage I LMS revealed an improved 5-year survival in patients undergoing an abdominal hysterectomy (62.5%) vs those undergoing morcellation at myomectomy or laparoscopic supracervical hysterectomy including reexploration (37.5%) ( $P = .03$ ).<sup>24</sup> A similar survival advantage with nonmorcellated compared with morcellated tissue has been described by Park and colleagues. Their study notably included largely laparoscopically assisted vaginal hysterectomies (18/25 of morcellated cases), and also included women with higher stages of LMS (including with restaging).<sup>34</sup> Rapid intraperitoneal dissemination of LMS has been reported in patients with morcellated LMS.<sup>31,35</sup> The potential value of reoperation after morcellated LMS or smooth muscle tumors of uncertain malignant potential was demonstrated at reexploration with 4/12 asymptomatic patients harboring malignancy (50% survival in that group with 23.4 month median follow-up).<sup>36</sup>

Although ESS behaves in a less biologically aggressive fashion, Park and colleagues<sup>37</sup> retrospective review of patients with ESS undergoing morcellation vs intact removal also found improved disease-free survival among those with intact removal, although overall 5-year survival was high in both groups (83% intact removal, 92% morcellation, nonsignificant  $P$  value). As with the Park and colleagues<sup>37</sup> LMS study, most did not undergo subsequent staging. Specific case reports following ESS power morcellation have shown that

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