# The Morcellator Controversy

*By Nancy L. Pennie*

Power morcellation is a minimally-invasive laparoscopic procedure. It may be used to remove the uterus (hysterectomy), or uterine growths that are generally assumed to be benign (myomectomy). The device used during the procedure, a power morcellator, is a tubular device with a high-speed, rotating cutting blade, which fragments tissue and allows for its removal through the small incision. To prevent excised tissue from potentially contaminating healthy tissue, a specimen bag for encapsulating the fragmented tissue may be used. This tissue may be aspirated from the bag, or the bag itself may be removed with its contents, for pathologic examination.

The power morcellator for gynecologic use was approved by the U.S. Food and Drug Administration (FDA) in the 1990s, with stated benefits that, usually, included smaller incisions, quicker patient recovery, and less pain than open surgery. Although the FDA understood that morcellators may spread cancerous cells, the magnitude of the risk, it now says, was underestimated at the oft-quoted rate of 1 in 10,000.

The power morcellator came to market by virtue of the FDA's 510(k) regulatory scheme, which 'grandfathered' the device without human clinical trials. Under the 510(k) approval process for new devices, a product which is substantially similar to a device already approved by the agency, may be approved. The 510(k) process does not typically require human clinical trials to prove safety and effectiveness, and is attractive because it is therefore expedited. This regulatory scheme, however, may require tightened follow-up reporting for adverse events, as the quid pro quo for a relatively streamlined approval process.

On April 17, 2014, the FDA issued a Safety Communication, discouraging doctors from using the power morcellator during laparoscopic hysterectomy and laparoscopic myomectomy for treatment of uterine fibroids, because of the risk that the device could promote the spread of undetected uterine sarcomas and other cancers. These cancers may be difficult to detect prior to surgery, and the dissemination of tumor cells during uterine morcellation can accelerate the spread of the cancer, significantly decreasing a woman's chance of long-term survival. Data analysis by the FDA led it to conclude that the risk of a patient having an unsuspected uterine sarcoma was 1 in 350, among those who were undergoing hysterectomy or myomectomy for treatment of fibroids. If power morcellation is done in these women, there is a risk that the procedure will spread the cancerous tissue throughout the abdomen and pelvis. In the face of the ability of the power morcellator to spread cancerous tissue, the risk that such cancerous tissue may be unsuspected preoperatively, and the fact that there is no reliable way to predict whether a woman with fibroids may have a uterine sarcoma, the FDA discouraged use of laparoscopic power morcellation during hysterectomy and myomectomy, for uterine fibroids.

The FDA encouraged clinicians and patients to discuss other options, including traditional vaginal or abdominal hysterectomy, myomectomy, laparoscopic hysterectomy and myomectomy without morcellation, laparotomy through a smaller incision (mini-laparotomy), uterine artery embolization, drug therapy, and high-intensity focused ultrasound. The FDA recommended that the laparoscopic uterine power morcellator not be used in women who had suspected or known uterine cancer. It further recommended that patients be informed of the potential for spread of cancer and a worse prognosis, in the event that a power morcellator was used. Finally, the FDA noted that some hospitals and clinicians advocated use of a specimen bag during morcellation, to decrease the risk of cancerous tissue coming into contact with healthy tissue. The agency instructed manufacturers of the device to review their product labels for accuracy regarding risk.

The FDA warning came on the heels of a report that an occult uterine leiomyosarcoma had been disseminated in a patient with uterine fibroids, who had undergone power morcellation, and an announcement by the American Association of Gynecologic Laparoscopists (AAGL) that it was forming a task force to examine ways to reduce and/or eliminate potential risks associated with tissue extraction. The American College of Obstetricians and Gynecologists (ACOG) had already reaffirmed, in 2011, its 2009 statement that vaginal hysterectomy was the approach of choice when feasible, based on lower complication rates and cost-effectiveness; laparoscopic and abdominal hysterectomy were identified as possible alternatives when vaginal hysterectomy was not an option.

On April 30, 2014, Johnson & Johnson, among the biggest makers of the device, announced that it was suspending worldwide distribution of power morcellators manufactured by its Ethicon division. On July 31, 2014, it voluntarily recalled its power morcellators worldwide. Johnson & Johnson stated that the morcellators were removed from the market while the role of morcellation for patients with symptomatic fibroid disease is redefined by the FDA and the medical community. The devices were withdrawn from the market until further medical guidelines for use were developed, and/or new technologies were developed which may mitigate the risk. Johnson & Johnson noted that instructions for its morcellation devices have always included cautions about possible spread of malignant tissue.

The FDA convened a meeting of its Medical Device Advisory Committee in July 2014, to discuss the clinical role of laparoscopic power morcellation in treating uterine fibroids, whether specimen bags enhanced the safety of power morcellators, and the advisability of a "boxed warning" relating to the cancer risk for these devices. The panel deemed it critical that doctors discuss the risks and benefits of all options with their patients.

Four months later, on November 24, 2014, the FDA issued a Safety Communication, updating its April 2014 Safety Communication. Using strong language, the FDA did not merely "discourage" the use of laparoscopic power morcellation, it warned against using laparoscopic power

morcellators in the majority of women undergoing myomectomy or hysterectomy for treatment of fibroids. The FDA emphasized that the extent of the risk is not known with certainty, and that the FDA believes that the risk of cancer spread from use of the power morcellator is higher than previously understood. Stopping short of banning the device altogether, the FDA issued guidance to manufacturers of morcellators, and further, issued recommendations to health care providers and women. Safety information was published on its website, to publicize and to help people understand the risks associated with laparoscopic power morcellators.

Manufacturers of new and existing laparoscopic power morcellators were asked to update their product labels by including two new contraindications for use, and a new boxed warning that contained forceful language. The FDA strongly urged these manufacturers to include on their product labels a warning that uterine tissue may contain unsuspected cancer, patient selection for morcellator use should be limited, and that physicians should share this information directly with patients. In a rare use of its powers, the FDA ordered that its safety guidance had immediate effect, to help address what the FDA considered a significant public health issue.

Health care providers were advised to be aware of the two new contraindications for laparoscopic power morcellator use, which were identified by the FDA: peri- or post-menopausal women with suspected fibroids, or patients who are candidates for en bloc tissue removal, such as through mini-laparotomy incisions – groups which comprise the majority of women with fibroids who undergo hysterectomy and myomectomy; and patients in whom the tissue to be morcellated is known or suspected to contain malignancy. Health care providers were advised to be aware, as well, of the new boxed warning which the FDA recommended: uterine tissue may contain unsuspected cancer, which may be spread during fibroid surgery and decrease long-term survival; this information should be shared with patients when considering power morcellator surgery; all available treatment options for women with uterine fibroids should be carefully considered; and the risks and benefits of all treatments should be thoroughly discussed, being certain to inform the small group of patients for whom morcellator use "may" be acceptable that their fibroid(s) may contain unexpected cancerous tissue and that this cancer may be spread by the power morcellator, significantly worsening their prognosis. The FDA refrained from identifying any acceptable use, noting that the population "might include" "some" younger women who wish to retain their fertility, or who are not yet peri-menopausal but desire to keep their uterus after being informed of the risks.

As the FDA had done in April 2014, recommendations were issued to women, to thoroughly discuss with their health care provider all options available to treat their condition, and to be aware of the associated risks and benefits of medical devices and procedures; to ask, if laparoscopic hysterectomy or myomectomy is recommended, whether power morcellation will be done, and if so, why the physician believes it to be appropriate in the patient's particular situation; to follow-up on a routine basis with a physician if the patient has already had a hysterectomy or myomectomy for fibroids, and has been told that the tissue was not cancerous, if the patient is asymptomatic, or has persistent symptoms or questions.

The FDA continues to evaluate the risks associated with the power morcellator, through review of reported adverse events, peer-reviewed scientific literature, and information provided by patients, health care providers, professional societies, and medical device manufacturers. The spread of unsuspected cancer through laparoscopic power morcellation, to treat uterine fibroids, is reportable as a serious injury. If necessary, further action may be taken by the agency in the future.

Some hospitals have banned the device, or strictly limited its use. Insurers have announced that they may no longer cover uterine power morcellation surgery, or otherwise seek to curtail its use; and have questioned the FDA process by which medical devices come to market and are monitored for adverse events, once they are on the market. Some physicians cite to the influence of device manufacturers' marketing in their decision-making to use the 'latest and greatest' hi-tech device, and question whether physician education of alternative surgical techniques needs to be re-examined and strengthened. Still, the power morcellator remains available and some gynecologists continue to use the device. They argue that surgeon experience confers protection during power morcellator surgery; that the minimally invasive device has benefits; that alternative procedures carry risks too; that the device does not cause the cancer which may be lurking; and that patients, not insurers, should make decisions about whether to undergo power morcellation surgery. At least one device manufacturer has threatened legal action to combat what it deems to be unfounded and unproven claims.

**About the Author**

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## AHRMNY WEBINAR SUMMARY

On September 17, 2015 AHRMNY hosted a webinar entitled: "Understanding the Parallels Between Risk Management and Patient Experience Initiatives" presented by Alice Vautour, Vice President of Product Development and Legal Teams at MRM Group and Shannon Grad, Director of Patient and Family Experience at Connecticut Children's Medical Center.

Patient experience scores are becoming an increasingly important metric in outcome-based reimbursements, yet the implications of these survey results are still evolving. This flux leaves many providers, risk managers, patient experience leaders, and other healthcare professionals struggling to understand how the metrics will affect their daily practice, as well as their organization's revenue cycle and overall cost of risk. These individuals are also charged with the task of educating providers about the impact of the patient experience metrics and ways to impact the patients' experience at their institutions. The goal of the webinar is to help those individuals responsible for patient experience initiatives understand the parallels between risk management and the patient experience and empower them with strategies to have a positive impact on each.