

# Will open power morcellation of uterine tissue remain an option during hysterectomy and myomectomy?

Q&A with Ray A. Wertheim, MD, and Harry Reich, MD

↻ An upcoming FDA hearing on the use of this technology has cast a cloud over its future. Here, two members of the AAGL Tissue Extraction Task Force discuss the evidence and emphasize the importance of preserving minimally invasive options in women's health.

The use of power morcellation to remove the uterus or uterine tumors during hysterectomy and myomectomy has been in the limelight in 2014—particularly morcellation performed in an “open” fashion (without use of a protective bag). Concerns about the dispersion of tissue throughout the peritoneal cavity—including the risk of disseminating tissue from leiomyosarcoma, a rare but deadly cancer—have drawn statements from the American College of Obstetricians and Gynecologists (ACOG),

the AAGL, the US Food and Drug Administration (FDA), and others, cautioning against the use of open power morcellation in women with a known or suspected malignancy.

In February 2014, Robert L. Barbieri, MD, chair of obstetrics and gynecology at Brigham and Women's Hospital, wrote about this concern for OBG MANAGEMENT in his capacity as editor in chief of the journal.

“When used to treat tumors presumed to be fibroids, open power morcellation is associated with an increased risk of dispersing benign myoma tissue and occult malignant leiomyosarcoma tissue throughout the abdominal cavity,” he wrote.<sup>1</sup> “Dispersion of benign myoma tissue may result in the growth of fibroids on the peritoneal surface, omentum, and bowel, causing abdominal and pelvic pain and necessitating reoperation. Dispersion of leiomyosarcoma tissue throughout the abdominal cavity may result in a Stage I cancer being upstaged to a Stage IV malignancy, requiring additional surgery and chemotherapy. In cases in which open power morcellation causes the upstaging of a leiomyosarcoma, the death rate is increased.”<sup>1</sup>

Not surprisingly, the numerous statements and warnings since then have led to

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*Dr. Wertheim and Dr. Reich report no financial relationships relevant to this article.*

## AAGL recommendations on the use of power morcellation

In its position statement, the AAGL Tissue Extraction Task Force made the following main points, recommending that surgeons:

- avoid morcellation in the setting of known malignant or premalignant conditions
- consider morcellation only for patients who have undergone appropriate evaluation of the myometrium, cervix, and endometrium, and who have reassuring findings
- employ an alternative to morcellation when preoperative evaluation leads to increased suspicion of malignancy. Laparotomy should be one of the alternatives considered.
- consider alternatives to morcellation for postmenopausal women because of the risk of malignancy, including undetectable malignancy, which is increased in this population
- discuss, in a patient-centered manner as part of the informed consent process, the specific risks of encountering an undetected malignancy and the likelihood of worsening the patient's prognosis when open power morcellation is used
- allow the patient's active involvement in the decision about whether to use power morcellation
- ensure that you have the skill and experience needed to morcellate within a specimen retrieval pouch if that is the option chosen. These pouches need further investigation of safety and outcomes in a controlled manner.

Further research also is needed to determine how best to diagnose sarcomas preoperatively, the task force noted.

The full report is available on the AAGL Web site.<sup>2</sup>

—RAY A. WERTHEIM, MD

some confusion in the specialty about the safest course of action for tissue extraction during hysterectomy and myomectomy in women with a large uterus.

To explore the options more deeply and address the future of minimally invasive surgery (MIS) in women's health, OBG MANAGEMENT invited two experts to comment: Ray A. Wertheim, MD, Director of the AAGL Center of Excellence Minimally Invasive Gynecology Program at Inova Fair Oaks Hospital in Fairfax, Virginia, and Harry Reich, MD, widely known as the first surgeon to perform laparoscopic hysterectomy, among other achievements. Both Dr. Wertheim and Dr. Reich were members of the AAGL Tissue Extraction Task Force.

In this Q&A, Dr. Wertheim and Dr. Reich discuss:

- options for tissue extraction going forward

- the importance of continuing to offer minimally invasive surgical approaches to patients
- the need to educate surgeons about the safest approaches to tissue extraction.

Both surgeons believe that power morcellation should remain an option for selected cases, though neither performs the technique himself. Both surgeons also believe that minimally invasive approaches to hysterectomy and myomectomy are here to stay and should continue to be utilized whenever possible.

## AAGL convened an impartial expert panel

**OBG MANAGEMENT:** Dr. Wertheim, could you tell us a little about the AAGL position statement on the use of power morcellation for uterine tissue extraction at hysterectomy or myomectomy, since you were on the task force that researched and wrote it?<sup>2</sup> How does it compare with the ACOG and FDA statements on the use of power morcellation?

**Dr. Wertheim:** AAGL convened its task force to conduct a critical appraisal of the existing evidence related to the practice of uterine extraction in the setting of hysterectomy and myomectomy. Areas in need of further investigation also were identified.

The task force consisted of experts who had no conflicts, were not allowed to discuss or review findings with anyone, and were not reimbursed for their time. I've been practicing for almost 40 years in academic and private settings, and I found this group to be the brightest, most caring and compassionate group with whom I've ever worked. Our review is the most complete report to date, more comprehensive than the reports from the FDA, ACOG, the Society of Gynecologic Oncology (SGO), and the American Urogynecologic Society (AUGS).

Interestingly, AAGL, ACOG, SGO, and AUGS all reached the same conclusion: All existing methods of tissue extraction have benefits and risks that must be balanced.

**OBG MANAGEMENT:** How did the AAGL task force assess the evidence?

**Dr. Wertheim:** The quality of evidence and strength of recommendations were assessed using US Preventive Services Task Force guidelines. One of the problems we encountered was that there are very few good data on the issue of power morcellation for uterine tissue extraction, especially in regard to leiomyosarcoma. One needs to be careful making recommendations without good data.

At this time, we do not believe there is a single method of tissue extraction that can protect all patients. Therefore, all current methods should remain available. We believe that an understanding of the issues will allow surgeons, hospitals, and patients to make the appropriate informed choices regarding tissue extraction in individual patients undergoing uterine surgery.

### How to manage tissue extraction going forward

**OBG MANAGEMENT:** The FDA will convene another meeting on power morcellation July 10 and 11. Regardless of its final decision, what should the gynecologic specialty be doing to avoid disseminating uterine tissue in the peritoneal cavity, particularly leiomyosarcoma?

**Dr. Wertheim:** Yes, AAGL will be at the FDA's July hearing because we are the experts. MIS is a wonderful advancement in women's health care. All surgical specialties are moving toward MIS. Our challenge is to perform it as safely as possible, given the current data and instrumentation available.

In regard to leiomyosarcoma, because we lack the ability to accurately make the diagnosis preoperatively, we've identified risk factors that should be taken into consideration. Risk factors include advanced age, history of radiation or tamoxifen use, black race, hereditary leiomyomatosis, renal cell carcinoma syndrome, and survival of childhood retinoblastoma.

At this time, we have specimen-retrieval bags that can be used with power morcellation. However, it takes skill to be able to place a large specimen inside a bag without injuring surrounding organs due to limited visibility.

**OBG MANAGEMENT:** How should we go about educating surgeons about MIS alternatives to open power morcellation?

### Education, at the hospital and national level, is in the works

**Dr. Wertheim:** In my hospital, we are mentoring surgeons to help them gain the new skills needed. In addition, Dr. Reich and I, along with Albert Steren, MD, a minimally invasive surgeon from Rockville, Maryland, are hosting an educational dinner meeting on tissue extraction on July 24 in northern Virginia. I plan to give a grand rounds presentation on tissue extraction for hospitals in northern Virginia and also would like to offer a course in the near future. I'm also hoping that we'll be able to offer courses around the country before the annual AAGL meeting this November, since this is such a pressing issue.

At the annual AAGL meeting, the subject will be discussed at length, with an emphasis on identifying risk factors and conducting appropriate preoperative testing, with workshops likely to teach the skills needed to perform these surgeries as safely as possible.

### Why a return to reliance on laparotomy would be unwise

**OBG MANAGEMENT:** Given all the concerns expressed recently about open power morcellation, do you think some surgeons will revert to abdominal hysterectomy rather than rely on MIS? Would such a move be safer than power morcellation?

**Dr. Wertheim:** That would be a disaster for women. Very reliable data have shown that MIS is safer than open surgery, with much quicker recovery. Almost all of my patients are discharged within 3 hours after surgery, and most no longer require pain medications other than nonsteroidal anti-inflammatory drugs (NSAIDs) by postoperative day 2. They're usually back to work within 2 weeks.

We have worked long and hard to develop skills and instrumentation required to perform MIS safely—but nothing replaces good judgment. In some cases, laparotomy or conversion to a laparotomy may be indicated.

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New instrumentation is needed and is being developed. In the meantime, my personal bias is to rule out risk factors for malignancy and continue to morcellate with a scalpel, preferably inside a bag. After all, we know that with open power morcellation, fragments and cells are usually left behind regardless of inspection and irrigation. These fragments may cause leiomyomatosis, endometriosis, bowel obstruction, sepsis, and possible dissemination of tumor fragments. Moreover, morcellation into small fragments complicates the pathologist's ability to give an accurate report. The use of open power morcellation also subjects the patient to a risk of damage to surrounding organs—usually due to the surgeon's inexperience.

As I have said before, our challenge is to perform these surgeries using the safest techniques possible, given the current data and instrumentation.

**OBG MANAGEMENT:** Dr. Reich, you have a unique perspective on this issue, since you pioneered laparoscopic hysterectomy. How has uterine tissue extraction evolved since then? Do you think open power morcellation should remain an option?

**Dr. Reich:** Uterine tissue extraction has not evolved. The terms “laparoscopic hysterectomy” and “total laparoscopic hysterectomy” imply vaginal extraction using a scalpel, not abdominal extraction using a morcellator. Unfortunately there is no substitute for hard work using a #10 blade on a long handle and special vaginal retraction tools.

In 1983, I made a decision to stop performing laparotomy for all gynecologic procedures, including hysterectomy, myomectomy, urology, oncology, abscesses, extensive adhesions, and rectovaginal endometriosis. I was an accomplished vaginal surgeon at that time, as well as a one-handed laparoscopic surgeon, operating while looking through the scope with one eye.

Interest in a laparoscopic approach to hysterectomy began with my presentations about laparoscopic hysterectomy in January 1988. At that time I had over 10 years of experience doing what is now called laparoscopic-

assisted vaginal hysterectomy.

I wrote extensively about specimen removal using a scalpel before electronic power morcellators were available. Since then, I have asked those using power morcellators to stop calling their operation a laparoscopic hysterectomy, as it has more in common with an abdominal-extraction hysterectomy.

I have never advocated removing the uterus using power morcellators, and I still believe that most specimens can be removed vaginally without the spray of pieces of the specimen around the peritoneal cavity that occurs with power morcellation. This goes for hysterectomy involving a large uterus, myomectomy through a culdotomy incision, and removal of the uterine fundus after supracervical hysterectomy. (It is irresponsible to use expensive power morcellation to remove small supracervical hysterectomy specimens.) It is time to get back to learning and teaching vaginal morcellation, although I readily admit it is time consuming.

Nevertheless, I believe power morcellation should remain an option. Recent laparoscopic fellowship trainees know only this technique, which is still better than a return to mutilation by laparotomy.

Gynecology is a frustrating profession—30 years of MIS as a sideshow. General surgery has rapidly adopted a laparoscopic approach to most operations, after gynecologists taught them. Today the majority of gynecologists do not do advanced laparoscopic surgery and would love to get back to open incision laparotomy for their operations. We cannot go back.

**OBG MANAGEMENT:** Dr. Wertheim and Dr. Reich, do your personal views of the morcellation issue differ at all from the official views of professional societies?

**Dr. Wertheim:** Yes. However, before I share them, I'd like to emphasize that the views I'm about to express are mine and mine only, not those of the AAGL or its task force.

The issue of uterine extraction is a highly emotional and political issue, about which there are few good data.

Abundant Level 1 data strongly support

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a vaginal or laparoscopic approach for benign hysterectomy when possible. ACOG and AAGL have issued position papers supporting these approaches for benign hysterectomies. Gynecologic surgeons and other surgical specialists have embraced MIS because it is safer, offers faster recovery, produces less postoperative pain, and has fewer complications than open surgery. However, AAGL has maintained for several years that morcellation is contraindicated in cases where uterine malignancy is either known or suspected.

The dilemma with open power morcellation is that even with our best diagnostic tools, the rare uterine sarcoma cannot always be definitively ruled out preoperatively. Endometrial cancer usually can be diagnosed before surgery. However, rare subtypes such as sarcomas are more difficult to reliably diagnose preoperatively, and risk factors for uterine sarcomas are not nearly as well understood as those for endometrial cancer.

I do agree with the FDA's cautionary statement, which pointedly prohibits power morcellation for women with suspected precancer or known cancer of the gynecologic organs.<sup>3</sup> However, the AAGL task force critically reviewed about 120 articles, including the studies assessed by the FDA. Concerns arose regarding the FDA's interpretation of the data. Due to a number of deficiencies in these studies, some of the conclusions of the FDA may not be completely accurate. The studies analyzed by the FDA were not stratified by risk factors for sarcoma and were not necessarily performed in a setting of reproductive-aged women with presumed fibroids.

**Dr. Reich:** Here are my personal views about the sarcoma problem and I am sure they differ from the official views of the professional societies:

- Laparoscopic hysterectomy should always mean vaginal extraction unless a less disfiguring site can be discovered; power morcellation implies minilaparotomy and should be renamed to reflect that fact.
- Power morcellation must be differentiated from vaginal and minilaparotomy scalpel morcellation, especially in the media. Vaginal hysterectomy has entailed vaginal scal-

pel morcellation with successful outcomes for more than 100 years.

- Remember that most gynecologic cancers are approached using the laparoscope today. This certainly includes cervical and endometrial cancer and some ovarian cancers. (For example, one of my neighbors is a 25-year survivor of laparoscopically treated bilateral ovarian cancer who refused laparotomy!)
- I have removed sarcomas by vaginal morcellation during laparoscopic hysterectomy and laparoscopic myomectomy with no late sequelae. In fact, most cervical cancer surgery is done by laparoscopic surgery today. And even an open laparotomy hysterectomy can spread a sarcoma.
- The current morcellation debate arose when a single case of disseminated leiomyosarcoma became highly publicized. It involved a prominent physician whose leiomyosarcoma was unknown to her initial surgeon, and the malignancy was upstaged after the use of power morcellation during hysterectomy. After this case was covered in the media, other cases began to be reported in the lay press as well, some of which predated the publicized case. The truth is, regrettably, that sarcomas carry poor prognoses even when specimens are removed intact. And we don't know much about the sarcoma that started this debate. Was it mild or aggressive? How many mitotic figures were there per high-powered field? And what was found macroscopically and microscopically at the subsequent laparotomy? We on the AAGL task force do not know the answers to these questions, although at least some of these variables are reported in other published cases. And because this case is likely to have a powerful effect on MIS in our country and the rest of the world, it is my opinion that we need to know these details.

## What is your preferred surgical approach?

**OBG MANAGEMENT:** Do you perform open power morcellation in selected patients?

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**Dr. Wertheim:** Even though I have performed morcellation with a scalpel transvaginally or through a mini-laparotomy incision for many years, I have never used open power morcellation because of the risk of leaving behind benign or malignant tissue fragments. Morcellation with a scalpel is easily learned and can be performed as quickly as power morcellation. Morcellation with a scalpel produces much larger pieces than with power morcellation. This probably markedly decreases the loss of fragments. I cannot make a definitive statement regarding cell loss, however. Until we have improved instrumentation and are better able to make a preoperative diagnosis of sarcoma, I’m going to rule out risk factors identified by the AAGL task force, do the appropriate work-up, and continue to morcellate with a scalpel, placing the specimen in a bag, if technically possible.

**Dr. Reich:** As I mentioned, I am a vaginal scalpel morcellator. I tried power morcellation when it first was developed but was never a fan. The same techniques used for vaginal extraction using a coring maneuver can be used abdominally through the umbilicus or a 1- or 2-cm trocar site.

### What should the FDA’s next move be?

**OBG MANAGEMENT:** Care to make any predictions about the FDA’s final decision?

**Dr. Wertheim:** This has become a highly emotional and controversial issue with little good existing data. During the preoperative visit, this issue should be discussed with the patient using clear, lay-friendly language. Having said that, I also do not believe we should hide behind informed consent. The

FDA has a responsibility to keep the public safe. If open power morcellation is allowed to continue, there will be another morcellated sarcoma or complications from retained benign tissue fragments. I doubt the FDA can live with this. I believe the risk factors identified by the AAGL task force should be ruled out, the appropriate workup done and then, if power morcellation is performed, it should be done inside a bag. In addition, I think the FDA should require that complications be reported and recorded in a registry.

**Dr. Reich:** I disagree. The FDA has to back off. It’s important to note that this is an American problem, as the rest of the world cannot afford power morcellators. The data are not in yet. The decision about what kind of hysterectomy is performed will be made by the “informed” patient, who undoubtedly will be very afraid to have MIS because of the surrounding negative publicity. We must do a better job of promoting the advantages of a minimally invasive approach.

**OBG MANAGEMENT:** Thank you both for your time and expertise.

**Dr. Wertheim:** Thank you for giving us the opportunity to express our opinions regarding this highly emotional and controversial issue. 🍷

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