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## WORTH THE RISK?

*For most patients, morcellation means less-invasive surgery. For others, it can be a death sentence. Alison Motluk investigates why two former Harvard doctors are trying to ban a procedure that left one of them riddled with cancer.*

BY ALISON MOTLUK

NOV. 10, 2015

**IN THE MONTHS AFTER HER SIXTH CHILD WAS BORN**, Amy Reed didn't bounce back the way she had in the past. She continued to bleed, heavily, to the point where she had to plan her days around it. She became anemic and even climbing stairs was difficult. Some growths in her uterus, called fibroids, were now hard to ignore—not only could she feel a bulge in her abdomen when she pressed on it, she could actually see her uterus sticking out when lying on her back. When her bleeding finally stopped about eight months after the birth it was replaced with a strange watery discharge. Reed knew this wasn't normal. When she took her concerns to her obstetrician, the doctor agreed that the symptoms were alarming and recommended having the fibroids taken out.

Reed was not your average patient. She was a surgical intensive care unit (ICU) doctor and an anesthesiologist in the operating room at Beth Israel Deaconess Medical Center, a Harvard-affiliated hospital in Boston. She and her obstetrician both did their residencies at the University of Pennsylvania. Reed's husband, Hooman Noorchashm, also worked in the Harvard hospital system. He was a heart and chest surgeon at the Brigham and Women's Hospital. As a patient, Reed was about as educated, savvy and connected as a person could be.

She was forty years old, tall and sturdy, with long, dark brown hair. She radiated a warm but steely confidence when she smiled. Her husband described her as "the picture of health." Still, her symptoms made them both uneasy. She was mostly concerned about her flagging energy levels. He was fixated on cancer. Noorchashm asked a senior colleague at the Brigham to put him in touch with one of the hospital's top gynecological oncologists, and in September 2013, as a courtesy between doctors, Michael Muto saw Reed for a consultation.

Muto reviewed the biopsies and scans that had been done. He listened to Reed's detailed account of her symptoms. There were no alarm bells. Muto wrote in his notes that it was "clearly a benign diagnosis" and he referred her to Karen Wang, then a gynecological surgeon at Brigham, to remove the fibroids.

Reed asked about an abdominal hysterectomy, in which surgeons make a large cut in the abdomen and remove the uterus whole. It was the quickest option and she figured the surgeons would have a good view of what they were doing. "I'm not a vain person," she said. "I've had six pregnancies. Go ahead and make the incision." She had seen enough operations to know that

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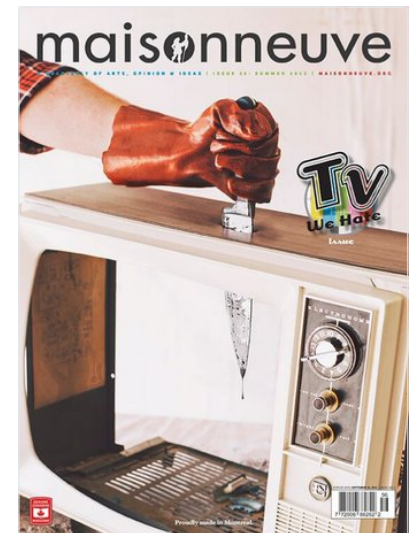
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she didn't want them "mucking around in there" for any longer than necessary. In the end, though, she was persuaded to have her entire uterus and cervix taken out through the vagina, assisted by tools and a camera inserted through tiny abdominal incisions in what is called a laparoscopic surgery. Reed said Muto told her she would be crazy to do it any other way—Reed was a busy woman (both she and her husband worked long hours and their brood was still young, between ages one and twelve) and the recovery would be quicker. As promised, the procedure was fast and easy. She spent just two hours in the operating room, was out of hospital the same day and felt pretty much herself two days after that.

One week later, Wang called Reed and asked if she was home alone. "[Those are] never words you want to hear from your surgeon," said Reed. Her doctor told her that routine tests on the excised fibroid tissue indicated a rare cancer called leiomyosarcoma (LMS). Reed had never heard of it. Wang didn't know much about it either.

Reed texted her husband, who had just flown back to Duke University in North Carolina for advanced training in lung transplantation. He was scrubbing in for a surgery, so he ignored the message, which said, simply, "Call me." A few minutes later, he was motioned out of the operating room by a nurse because his cellphone would not stop ringing. He called Reed back and she told him about the cancer. Noorchashm thought it must be a mistake. When Wang called him a few minutes later, though, she confirmed LMS.

Unlike his wife and her doctor, Noorchashm was familiar with leiomyosarcoma. He had operated on patients with sarcomas of the lung. He knew that it was absolutely critical the tumour be removed in one piece with margins of healthy tissue around it. He asked Wang if she had managed that. She said no, she hadn't. In fact, she told him, part of the tumour had been morcellated—ground into pieces.

Noorchashm was speechless. "She's telling me my wife has a twelve centimetre leiomyosarcoma and she's chopped it up inside her body," he said. That meant tissue and blood from the tumour had almost certainly been splattered inside her abdominal cavity. "At that point, I knew we were in trouble. I knew immediately it was a race against time."

**MORCELLATION IS A TECHNIQUE** for removing large body parts through small incisions. In the past, morcellation was done manually with a scalpel. But now there are special tools for the job called morcellators. They look like dainty power drills, with small, rapidly rotating cylindrical blades tucked inside the tip. Once slipped in through the tiny porthole, the device grasps and then grinds up the parts that need to be extracted, right there inside the abdominal cavity, and sucks the fragments out. Doctors occasionally do this to kidneys, spleens and adrenal glands, but it is in gynecological surgery where morcellation has flourished.

Morcellators first became available in the United States in 1993, and were approved by the Food and Drug Administration (FDA) in 1995. At the time of Reed's surgery, there were about two-dozen models for sale. Noorchashm had been a surgeon for nine years and he had never heard of the tools before he

Googled the practice while waiting at the airport to get home to his wife.

Morcellators are particularly handy for removing fibroids, those benign growths embedded in the uterine wall, as the growths can be as hard as coconuts and sometimes as large. While an ordinary uterus can usually be slipped out whole through the vagina, a fibroid-studded one often cannot. With the help of morcellators, though, doctors can remove the entire organ through holes the size of quarters.

But there is a drawback to morcellation: because most gynecological surgeons were using the tools without anything around the tissue to contain it, the procedure could leave debris behind. “Small pieces fall into the abdomen,” said Camran Nezhat, a surgeon at Stanford University who helped pioneer minimally invasive and robotic surgery, but who, for exactly this reason, does not approve of open morcellation. To make matters worse, he said, during laparoscopic procedures, the abdomen is inflated with carbon dioxide. “That circulates the cells inside the abdomen,” he explained, making the spread of tissue fragments even more likely. Although doctors do their best to remove the bits left behind—plucking out individual chunks and rinsing the abdominal space thoroughly with a saline solution—there is no way for surgeons to be certain that they have removed every cell.

About ten years ago, reports started surfacing in the medical literature of women with severe pelvic pain or unexplained bleeding who all had something in common: they had undergone morcellation years prior. Doctors reported finding growths in the abdominal cavities that could be traced back to the fibroids and uteruses that had been removed. This was troubling enough in itself—it had been assumed that missed particles, without a blood supply, would simply be reabsorbed—but it also raised the possibility that cancer could be spread too.

Between 2008 and 2010, case reports of disseminated leiomyosarcoma by researchers in New Delhi, Montreal, Boston and Osaka were published. In at least one instance, the new tumour growth was definitively linked to the original specimen. Other papers compared outcomes for women whose undetected LMS had been morcellated versus not morcellated, and they found that morcellating an LMS tumour made it more likely the cancer would spread, and, according to at least one paper, more likely that the woman would be dead within five years.

By 2011—two years before Reed’s surgery—morcellation had become a full-on conversation among cancer doctors. Jeong-Yeol Park, a gynecological oncologist at the Asan Medical Center in Seoul, Korea and the lead author on one of the morcellation comparison papers, presented his findings at the Annual Meeting on Women’s Cancer. In an *Oncology Times* article about the talk, Bobbie Gostout, chair of gynecology at the Mayo Clinic in Minnesota, commented: “I don’t think there’s an acceptable, safe morcellator out there ... We are exposing our patients to a risk that to me seems out of bounds.”

**FOLLOWING HER DIAGNOSIS** of leiomyosarcoma and the revelation that the tumour had been minced up inside her, Reed’s various doctors acknowledged that there was no obvious next step. She could have her abdomen scoped a

few weeks later to see if tumours were growing, and if they were, have them removed. She could have her ovaries and fallopian tubes taken out as a precaution. She could try chemotherapy. Many women, she was told, took a wait-and-see approach. Regardless, the prognosis was grim. She was told there was an 80 percent chance that her cancer would come back—double the odds of an unmorcellated woman—and, if that happened, she could expect to live for two more years.

What the couple wanted was urgent damage control. Noorchashm began asking his colleagues for advice. His surgical chief at the Brigham told him about a procedure he used in the chest cavity that had been pioneered by his brother, Paul Sugarbaker, to combat surface malignancies in the abdominal area. Known as HIPEC, or hyperthermic intraperitoneal chemotherapy, it involves pumping heated chemotherapy drugs directly into the affected body cavity for up to ninety minutes. Though there were no definitive studies showing that it would be effective against uterine LMS, Reed and Noorchashm decided that it was their best option. Five weeks to the day after her hysterectomy, Reed was in Washington, DC, having the procedure done by Sugarbaker himself.

The doctors opened her abdominal cavity from sternum to pubic bone. Before soaking her insides with chemo, they began removing tissue left behind from the morcellation and any traces of new cancerous growth. “There were many pieces of uterus and cervix and cancer recovered from her peritoneal cavity,” Sugarbaker said. Significantly, he removed a two-centimetre nodule from inside her left pelvic area, which pathologists subsequently confirmed as leiomyosarcoma. The lump had not been present on a pre-hysterectomy MRI but had been spotted by one a few weeks afterwards; doctors confirmed that it showed all the signs of having spread from the original tumour. The doctors also removed Reed’s gallbladder, appendix, ovaries, the two laparoscopic port sites and various membranes that held her organs in place.

The procedure lasted several hours, cost \$130,000 and left a thirty-centimetre vertical scar down Reed’s front. That first night she suffered a blood clot in her lungs. It took eight days in hospital and another two in a Washington hotel room before she felt well enough to board a plane back home. Another six weeks passed before she felt like herself again. Then she started more chemo.

Still, the couple felt lucky. Most women in Reed’s situation might not know that morcellation had dramatically worsened their prognosis—or even that they had been morcellated at all. They would not have friends and colleagues and years of medical experience to guide them, or access to the country’s finest doctors or the wherewithal to pay them. “If we can get in trouble because of this,” said Noorchashm, “you can only imagine what it’s like for other people.”

From his wife’s hospital bedside in DC, Noorchashm launched a Change.org petition calling on the American College of Obstetricians and Gynecologists to halt morcellation. In an email accompanying the link, he wrote: “Help us bring this practice clearly into the public eye.”

**ABOUT HALF A MILLION** American women have their fibroids or uteruses removed each year according to the Centers for Disease Control and Prevention. In 2014, some one hundred thousand of those operations involved morcellators. In Canada (not including Quebec), about forty thousand women have these surgeries annually and less than five thousand of those use the device. For the vast majority of women, minimally invasive laparoscopic surgery (which sometimes relies on morcellation, but not always) will mean less hospital time, less bleeding, less infection, smaller scars and a quicker return to normal life. A subset, however, of which Amy Reed was one, will have a hidden cancer lurking inside them. And grinding it up could bump them from stage I cancer, with fighting odds of survival, to stage IV, a virtual death sentence.

As recently as October 2013, when Reed had her surgery, women all over North America were being told that their risk of being in that unlucky subset was about one in ten thousand. But after Reed's diagnosis, Noorchashm, now on leave from his lung transplant training, started poking around medical databases and he got a sense that the risk might be higher. He was particularly startled to discover that an important paper on the subject by Brigham researchers had been published one year before his wife's surgery. And among its authors was Michael Muto—the very gynecological oncologist who had cleared Reed for morcellation.

That study, published in the journal PLOS One, looked at all 1,091 instances of uterine morcellation that had taken place at the Brigham and Women's Hospital between 2005 and 2010. In thirteen cases, what were thought to be benign fibroids actually had unexpected cell types, two of which were sarcomas. The authors concluded, "uterine morcellation carries a risk of disseminating unexpected malignancy with apparent associated increase in mortality much higher than appreciated currently."

Noorchashm asked Michael Paasche-Orlow, an old medical school buddy, to do a full literature search to find the real risk of morcellation. Paasche-Orlow, at Boston University School of Medicine, approached Muto and others to co-author a review paper. The oft-cited risk of one in ten thousand having a hidden cancer reflects the fact that the incidence rate for the entire US population is quite low—fewer than seven women out of every one hundred thousand are diagnosed with LMS. "But the denominator cannot be the total population of women," argued Paasche-Orlow. "It needs to be women who present with a symptomatic mass in the uterus." Those are the women who will be offered the surgery, after all. He and his co-authors gleaned data from ten studies in which presumed benign masses were morcellated and they found that the risk of having a hidden sarcoma was not the reported one in ten thousand at all. It was in fact much higher: about one in 415.

If their numbers were correct, it meant that every year, a few hundred North American women had their prognoses dramatically worsened by a single non-essential medical intervention: morcellation. For Noorchashm, it was impossible to fathom. He knew that if a surgeon left a sponge inside a patient, the surgeon would get a letter of reprimand. He knew that if a surgical stapler kept misfiring, the hospital would stop using it. Yet here doctors were routinely disseminating deadly sarcomas. He was confident that the numbers

would speak for themselves; he thought that just bringing them to the attention of any sane physician would prompt an immediate moratorium.

In mid-November 2013, after booking Reed's HIPEC surgery in DC, Noorchashm emailed some top administrators at the Brigham. "In our profession," he told me, "when some disastrous event happens to a patient and it's caused by a specific mistake, we shut things down and review it." Noorchashm wanted the hospital to label Reed's cancer spread as one of these mistakes—what is known as a "sentinel event." After informing the hospital of the scale of what he called a "public health catastrophe," Noorchashm urged its administrators to immediately take morcellators off the hospital's shelves, stop the practice and call for a national moratorium. "It is dangerous, it is unethical, it is surgically unsound!" he wrote in the email to his superiors. "Who morcellates any intra-abdominal tumour?" He reckoned that if Harvard acted first, the world would follow.

The Brigham's Chief Medical Officer (CMO) Stan Ashley soon got back to Noorchashm, saying he would like to meet to discuss the issues. Noorchashm was heartened: Ashley was a surgical oncologist. "I thought, 'If anyone's going to get it, it's this guy,'" he said. Noorchashm also aimed to include the president of the hospital, as well as the heads of obstetrics and gynecology, gynecological oncology and surgery in the meeting.

As far as Noorchashm and Reed were concerned, every day the hospital hesitated, another two or three women were put at risk. But Ashley appeared to feel less urgency and worked to set up a meeting with Noorchashm and Reed after their return from DC, a few weeks later.

After some back-and-forth by email, it began to dawn on Noorchashm that getting the Brigham behind banning morcellators might not be as straightforward as he'd expected. The first red flag was when the administration said they wanted the meeting to be confidential. Noorchashm didn't like the sound of that; he wanted a public renunciation of morcellation, one that the rest of the medical community would follow. They also said that their lawyer would be there. Noorchashm countered that if that was the case, he wanted a lawyer there too—and immediately copied one into the email chain.

While in Washington for Reed's surgery, after she was safely out of the ICU, Noorchashm started firing off emails, imploring his surgical colleagues to recognize that gynecologists were harming patients with morcellation and to speak up against it within the hospital. Ashley called Noorchashm while Reed was still recovering in the DC hospital and he requested that Noorchashm not use his professional email account to send such messages. He also encouraged Noorchashm to consider seeing a psychiatrist. "It is a standard corporate tactic," said Noorchashm. "Label people who are dissenting as people who need psychiatric help."

By the time the meeting took place on December 11, 2013, Ashley had made it clear he no longer wanted to talk about morcellation at all. Rather, he wanted to talk about a leave of absence for Noorchashm. The three other chiefs were no longer invitees. Only Raphael Bueno, one of Noorchashm's mentors and

then vice-chief of thoracic surgery—plus a security guard—were present. In the CMO's office, overlooking Harvard Medical School, Noorchashm and Reed laid out in detail what had happened to Reed and, ignoring the new agenda, made their case for a moratorium. "I told him, 'As a surgeon, as a Harvard professor, as the chief medical officer, to look at this and not stop it is unconscionable,'" Noorchashm said. Ashley reportedly said that that was a matter of opinion. (Ashley declined an interview citing legal action, by a different patient, being taken against the hospital.)

Reed, just twenty days post-op, had a hard time getting to the meeting. She was still on round-the-clock pain medication and she could not stand up straight without her forty-two abdominal sutures pulling. "Hooman's there hoping the Brigham will charge forward like a glorious leader," recalled Reed. "I said, 'I don't give a damn about the Brigham. The fact is this really sucks and I want to prevent other people from having it. That's the only reason we're here talking with you.'" Reed told Ashley that if operating room tables were falling over and killing patients at this rate, the hospital would ban them immediately. "I just assumed they'd stop when we pointed out such a glaring error," she said.

By the end of the meeting, little had been achieved. The Brigham would not lead the world in banning morcellators or even curtail their use in its own operating rooms. A few days earlier, the hospital had circulated an internal memo acknowledging that the risk of accidentally morcellating a sarcoma might be much higher than previously thought. It suggested that all surgeons get informed consent from patients before using the device. With that, the hospital felt that the matter had been dealt with.

It had been Noorchashm's lifelong ambition to be a Harvard surgeon and he had only recently become a junior member of the faculty. "It took me three generations to get here," he told me. "My grandmother came from some podunk village in the middle of Iran." He still had every intention of returning to work as a surgeon in the new year but the institution he had worked so hard to join now seemed hollow. As a symbol of his outrage, he handed back the Brigham diploma he had earned for two years of cardiothoracic surgical training. He also returned his Peter Bent Brigham tie, an elite silk necktie worn only by Brigham-trained surgeons. Bueno said he would keep them safe. As Noorchashm and Reed turned to leave the room, the security guard stopped Noorchashm—to shake his hand.

**THAT EVENING, AFTER THE MEETING WITH ASHLEY,** Noorchashm sent out a scathing email with the subject heading "Ethical Failure at the Brigham," and copied it to dozens of recipients, including all of the Brigham's cardiac and thoracic faculty, various Harvard colleagues, a handful of physicians at other institutions, the Massachusetts attorney general, myself and two other journalists. "It is a surgical crime to morcellate tumours in situ. It is an injustice to unsuspecting women with no power to see or understand what WE have imposed upon them and theirs," he wrote. He accused the administrators of failing to do the right thing because of financial interests and fear of liability. He called them "impotent," "irresponsible," an "empty shell," and invited the recipients to join the fight.



Noorchashm was already in discussion with writers from the Wall Street Journal and he now copied top Brigham doctors into taunting emails where he invited reporters to call out specific individuals. “Please contact Dr. Michael Zinner, BWH [Brigham and Women’s Hospital] surgeon-in-chief,” he wrote in one. “I believe as the leading general surgeon at BWH, he will have an opinion about the oncological safety of morcellating tumours intraperitoneally in women during minimally invasive hysterectomy. In particular, he will also have an opinion on why the BWH has not stopped the practice as of yet despite Amy’s case and the BWH’s own very large published series on this peril.”

He pressured colleagues to stand up with him. He wrote to Karen Wang, the gynecological surgeon who had morcellated Reed’s tumour: “Karen, take our tragedy and turn it into good. Stop using the morcellator, manual or power, on any other patients in your own practice. Refuse to accept the chance of another Amy happening to you.” Wang did not communicate with them again. And to Isaac Schiff, head of obstetrics and gynecology at Massachusetts General Hospital (MGH), another Harvard affiliate, he wrote: “Yours could be the act of leadership and courage. Ground it at MGH within your division. It is oncologically hazardous and there is no reason for another woman to be exposed to the possibility of being in my Amy’s shoes; there are other ways.” Schiff recalled being alarmed by the case of a morcellated fibroid turning out to be a sarcoma and he brought it up at a faculty meeting on December 12, 2013. There, he and his colleagues changed the hospital’s informed consent procedures.

Phrases like “catastrophic ethical failure,” “systemic complacency” and “surgical crime” now peppered Noorchashm’s mass emails. His language was brazen: “I exaggerate not, a morcellator is nothing but a meat grinder that efficiently sprays emulsified uterine tissue and any potential cancer cells present inside the woman’s abdominal cavity.” It was pompous and accusatory: “You will either choose to walk along with corporate liability managers and superficial leaders. Or, you will see the truth and speak for righteousness, becoming of your station as a physician, a leader and Harvard professor.” It was bossy: “Act now, deliberate later.” He says he generated thousands of emails that first month and fired them off at all times of day and night.

To say that his colleagues were uncomfortable would be an understatement. Bueno had advised him in November 2013 to tone it down. Then, a month later, he wrote in an email to Noorchashm: “This is not an effective strategy. You are going after the wrong people.”

Reed’s family was livid. Her mom thought Noorchashm ought to be spending his energy comforting his wife as she fended off cancer; the children needed their dad to be present and caring, not distracted by a crusade. Reed’s father said Noorchashm shouldn’t be sabotaging his career when he had six kids to support. Noorchashm’s brother-in-law told him that sending out emails and humiliating his bosses was not the best way to effect change. In the early days, Reed was annoyed as well. “I’d say, ‘Normal people don’t CC one hundred people. That’s not a normal thing to do.’”

As a heart surgeon, Noorchashm had been trained to trust his judgement and act quickly, overriding other people in the case of an emergency. This, he felt, was an emergency. As far as he was concerned, he was simply applying all the energy and skills of a cardiac surgeon to the urgent business of halting morcellation. Looking back, Reed said that the Brigham should have expected her husband's persistence. "This is how they built him up. They made him this," she said. Cardiac surgeons, she explained, work at the extremes. "How else would you have anyone work one hundred hours a week, stand for eighteen hours a day, work overnight, stick your hands into someone's chest, blood squirting—they're all a little nuts."

Now, though, the Brigham moved to isolate Noorchashm. The day after the December meeting with CMO Ashley, senior hospital staff circulated an internal email instructing Noorchashm's colleagues to not communicate with him directly but instead to go through official channels. His job also became a sticking point. According to his contract, he was to start in lung transplantation in the coming year, but because of Reed's health, he had not been able to finish his training, nor could he now take on the long and unpredictable hours required of a lung transplant surgeon. He asked if he could do routine cardiac surgeries instead, as another cardiac surgeon had just left and the hospital was short-staffed. The Brigham instead proposed that he primarily oversee the allocation of organs—a desk job—in addition to participating in a limited number of cardiac and thoracic cases. When Noorchashm refused, they offered him the full lung transplant job again. He declined.

His descent was steep and lonely. In a matter of weeks, Noorchashm had gone from being a Harvard-affiliated surgeon, a golden boy with a shining future, whose life and identity revolved around the operating room, who got up at 4:30 every morning and seldom made it home in time to kiss the kids goodnight, to someone whose major scheduled activities involved dropping his children off at school in the morning and listening for their buses in the afternoon. Almost all his time was now spent at home in the leafy Boston suburb of Needham. There, in the sunny office off the family living room, he badgered his elected officials, coached morcellated LMS patients and their families and pressured people to talk to the press.

**THE FIRST BREAKTHROUGH** in the morcellation campaign was on December 18, 2013, when the Wall Street Journal published a front-page article on the practice (after six weeks of communication with Reed and Noorchashm). The Boston Globe and NPR followed with stories later that day. Noorchashm emailed the Wall Street Journal story to Brigham's top brass, public officials and colleagues, reminding them in an attached message that it was their ethical duty to do something: "Allowing it to continue is medical negligence of the highest order."

The next morning he began carpet-bombing the FDA with emails subject-headed "Warning to the FDA: Severe Women's Health Hazard." He started with press officers but soon moved on to policymakers and even the then-commissioner herself, Margaret Hamburg. Late the following evening, he got an email from the administration thanking him for drawing their attention to the issue and asking him and others to report specific known adverse events

through MedWatch, the FDA's voluntary reporting program. An official inquiry was now underway.

Through his Change.org petition, Noorchashm had been finding dozens of morcellated patients and their families. One was Lisa Nielsen, from Grass Valley, California, whose tumour was morcellated in 2009. She was given a clean bill of health and walked away feeling great—until nineteen months later, when seven new tumours appeared. One quickly grew to be thirty-seven centimetres across and weighed more than eleven kilos. Gene Manley also reached out to Noorchashm. His niece, Brenda Leuzzi, was fighting for her life following a 2012 robotic hysterectomy in Rochester, New York. Leuzzi only learned about the morcellator after the Wall Street Journal article appeared. Leeann Noye of Langley, British Columbia, also got in touch. After her leiomyosarcoma was morcellated, she was told by the BC Cancer Agency to get her affairs in order. Noorchashm urged everyone to report their cases to the FDA.

It was around the end of 2013 when Noorchashm and Reed learned that Reed's case had not actually been the Brigham's sentinel event regarding the procedure: another woman, Erica Kaitz, had been morcellated at the hospital in June 2012. As Reed was being prepped for her surgery, the fifty-two-year-old Kaitz was nearing death. Four days before Noorchashm and Reed had their meeting with Ashley, Kaitz died. When Reed found out about Kaitz, she sent an email to four top Brigham doctors: "You knew," she wrote. "You knew and you handed me this sentence anyhow."

In the months after the morcellation story first hit the press, there were small, slow changes. In early 2014, a handful of hospitals, including the University of Rochester Medical Center in upstate New York and Temple University Hospital in Philadelphia, began mandating that morcellation only be done inside containment bags so that the debris might be caught rather than disseminated; by the end of March, Brigham had started doing the same. Medical journals started weighing in, with the Lancet Oncology arguing, "new techniques and devices should be proven safe before widespread acceptance, rather than being widely used until proven hazardous." Even Massachusetts Senator Elizabeth Warren started taking an interest. Noorchashm first lobbied her office in January 2014 and by March she was officially questioning the FDA commissioner about the issue. More than 3,500 people had now signed the Change.org petition. Still, Noorchashm felt frustrated by the pace of change: progress felt agonizingly slow.

Then, on April 17, 2014, the FDA dropped a bomb. With no forewarning, the agency issued a safety communication "discouraging" the use of power morcellators for taking out uteruses and fibroids. "If laparoscopic power morcellation is performed in [women with unsuspected uterine sarcoma], there is a risk that the procedure will spread the cancerous tissue within the abdomen and pelvis, significantly worsening the patient's likelihood of long term survival," it said. They put that risk at about one in 350 women.

It was a stunning advisory. On Facebook, Noorchashm posted: *A MAJOR WIN. THE FDA HAS SPOKEN!* The FDA's move, for a moment, made him feel vindicated. "It just astonishes me that the federal government has to

come in and regulate people who are supposed to be professionals,” he told me that day. But even as he was bolstered by the announcement, his mind was mostly on what still needed to be done. The FDA had not banned the device; it was instructing physicians about how they ought to use a legally available instrument. A public hearing on the matter was scheduled for July, after which the FDA would determine what further action to take.

It took less than a day for the American College of Obstetricians and Gynecologists (ACOG) to respond. It announced that the organization would undertake a thorough review of the published scientific literature and issue a formal response. But many hospitals didn't bother to wait. Within days of the FDA advisory, several hospitals across the US halted morcellation altogether. “The hospital attorneys clamped down,” explained Joseph Ramieri, chairman of the department of obstetrics and gynecology at the Morristown Medical Center in New Jersey. By the end of April 2014, Johnson & Johnson, the leading manufacturer of morcellators, announced that it was suspending worldwide sales, distribution and promotion of the devices. Victory, Noorchashm dared believe, was in sight.

**THE SENSE OF TRIUMPH** was short-lived. Many gynecologists made it clear they felt the FDA was not just overreaching but wrong. In reports, interviews, online discussion groups and blogs, they expressed their professional opposition to the advisory. Some had never seen a case of LMS in their careers but every day witnessed the benefits of morcellators in laparoscopic surgery. Acting in the interest of that one patient in 350—if you even accepted those numbers, which many did not—would force you to act against the interests of the other 349, they argued. At the very least, they said, women deserved choice.

Organizations including ACOG and the AAGL (American Association of Gynecologic Laparoscopists) did concede that there was currently no way to rule out sarcoma in advance. And they didn't dispute that morcellation would spread the disease and make it worse in those women. But, they noted, LMS is an uncommonly aggressive cancer that does not respond well to any known treatment.

Gynecologists began highlighting the risks of not opting for minimally invasive surgery and morcellation: not only was there greater chance of blood loss and infection in abdominal hysterectomies, there was a greater risk of actually dying, they said. William Parker, a fibroid specialist at UCLA Medical Center, claimed in a blog post that one in every thousand women who underwent abdominal hysterectomy would die from it. The ACOG wrote in its report that a woman was three times as likely to die from a large incision hysterectomy than from a laparoscopic hysterectomy. By the time the FDA hearing began in mid-July, the AAGL had put a number on that excess death: gynecological oncologist and spokesperson Jubilee Brown told the panel that seventeen more women would die every year of open hysterectomy compared to power morcellation. (As of press time, neither Brown nor the AAGL had provided data or their model for scrutiny, despite requests dating back to July 2014.) Their argument was clear: laparoscopic surgery, even with morcellation, saved lives and should not be discouraged. The battle lines were drawn and morcellation would not be making a quiet retreat.

**THE PURPOSE OF THE FDA HEARING**, held July 10 and 11, 2014, was to get evidence from all sides so that the agency could figure out how to proceed: it could decide to place a “black box” warning on morcellators to highlight the risks; it could change the status from class II to class III, which would require rigorous safety testing as opposed to almost none; or it could ban morcellators altogether. It could also do nothing.

The public meeting took place in a plain federal government room on the FDA campus in Silver Spring, Maryland. The panel of experts charged with weighing the testimony consisted of fifteen people (a sixteenth panelist, who dropped out, had taken \$100,000 in consulting fees from the world’s largest morcellator maker). The panel was primarily gynecologists, with a few general surgeons, oncologists and other specialists. One by one, speakers including gynecologists, morcellator manufacturers, affected patients and their families each stepped up to the microphone.

The first day was taken up with invited testimony about fibroids, fibroid treatment options, uterine sarcoma and the limits of pre-op testing. There was also debate about whether the FDA numbers about hidden sarcomas were accurate; a doctor from Wisconsin suggested the risk was much lower, around one in 7,400. So much time was spent talking about the benefits of minimally invasive surgery and ways to keep using the morcellator that Reed started to wonder if the meeting was actually about protecting the device rather than its victims.

But on the morning of the second day, the mood shifted. Noorchashm and Reed, along with other patient advocates including Nielsen and Manley, offered their testimonies. Noorchashm took issue with the gynecologists arguing that since morcellation was good for the majority of women, it should continue despite its harm to the minority with hidden cancer. “I ask you: where in our country, where in this society, have we accepted the sacrifice of a minority subset of women for the benefit of the majority?” he asked. “And what is the number that we’re going to accept? One in 350? Is it one in one thousand? Is it one in five hundred?” Reed also spoke to the panel. She demanded to know why no gynecologist had ever reported morcellator-induced complications to the FDA. The fact that none had, she said, made gynecologists unfit to sit on the panel.

“I call for the FDA to use common sense. Ask people outside of this specialty. Do not rely on gynecologists to make an informed decision on this. Do not allow them to inform your decision. Recuse them from this board and hold them personally, if not potentially criminally, liable for what you’ve done to me and these women.”

Following the lunch break that day, Craig Shriver, a surgical oncologist at the Walter Reed National Military Medical Center in Maryland, made an announcement to his fellow panelists. He confessed that power morcellation had always perplexed him because it went against everything he had learned in medicine about treating all masses as cancer until proven otherwise. He said that the testimony had only underscored his belief that there was currently no safe way to morcellate. “My position is that the device under consideration, the power morcellator, should have its class II device status

immediately withdrawn and its use in any laparoscopic surgery banned,” he said.

“I think that was the turning point in the meeting,” said Daniel Simon, a radiologist from West Orange, New Jersey, another of the FDA panelists. “That would be the moment that people realized that this is just not safe.”

In November 2014, the FDA placed a black box warning on morcellators, which read: *Uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer, and decrease the long-term survival of patients. This information should be shared with patients when considering surgery with the use of these devices.* It also said that morcellators should not be used on women who were going through or had completed menopause, or any woman suspected of having cancer. Two weeks later, Health Canada followed with a near-identical statement. Johnson & Johnson had already made a full recall and decided to get out of the morcellator business altogether. And over the next several months, various US health insurance companies announced they would no longer pay for the procedure.

Dramatic as it was, the outcome did not satisfy Noorchashm. He had hoped to see the devices banned—or at least more strictly regulated. Instead, where they could, many doctors continued to morcellate inside makeshift containment bags, such as nylon specimen bags or even large-size surgical gloves. (To date, a device for this purpose does not have FDA clearance.) “It will never disappear,” said Togas Tulandi, department chief of obstetrics and gynecology at the McGill University Health Centre in Montreal. Tulandi and other gynecologists in North America and Europe still feel there are times when the technique is warranted, mostly in younger, pre-menopausal women who have been carefully screened.

Noorchashm takes his comforts where he can. “I know that gynecologists are more careful,” he told me. Unlike before, cancer is very much on doctors’ minds when they assess women with fibroids. “There’s no such thing as a ‘benign’ fibroid anymore,” he said. But as Reed pointed out, with her young age, her health, her need to recover quickly and all the reassuring ultrasounds, MRIs and biopsies, she looked like an ideal candidate too. And she wasn’t.

**NOT LONG AFTER** the FDA hearings, Reed and Noorchashm packed up their family and moved to Philadelphia. Reed had grown up in the city, and her mom and several siblings would be nearby for support. (They are now all on board with the fight.)

The couple traded in their New England colonial-style home for an eighteenth-century farmhouse, which became a hub for extended family. They got a puppy and named it Needham, after the place they had left behind.

Noorchashm took up a position at Thomas Jefferson University Hospital as a cardiac surgeon that summer. In January 2015, Reed started work as an anaesthesiologist at the Hospital of the University of Pennsylvania. She was back with old friends and got a hero’s welcome upon her return. But toward

the end of her first week, she noticed a strange numbness on the outside of her left leg. She thought it might be a hernia or strain from the long hours she was suddenly working again. So she ignored it. But during a routine follow-up scan two weeks later, doctors saw a new tumour, later confirmed to be LMS. She had the new growth removed, along with a piece of her lumbar spine, and started radiation. "It was a big blow to us," Noorchashm said. In late spring, more new tumours appeared.

Neither the fight against the cancer nor the fight against the morcellator is over. But both experiences have changed Noorchashm, especially as a doctor. "I think of interactions I've had with specific patients over the years. Standing there with my white coat and thinking the person was just a little high-strung," he said. Now he knows better: their lives had been turned upside-down. Noorchashm had always hoped he could go back to that comfortable former self—a company man, a believer. But he hasn't been able to. He worries more about his patients, about the devices he uses everyday, about the harm he could unknowingly be causing.

He also thinks about the career that he could have had. "I was on a trajectory to become a Harvard professor," he reflected. "I had friends who were pretty powerful in the medical establishment who I'm pretty sure don't want anything to do with me now. It's not a pleasant place to be." But he doesn't hesitate when asked if his campaign was worth it. "I did step outside professional boundaries," he told me. But he doubts that he could have achieved what he did while on his best behaviour. "The only way was to use a sledgehammer."



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 **rosa** • 6 months ago

I had a robotic hysterectomy for fibroids with use of a morcellator in Dec 2008. In July of 2015 I had an appendectomy and they found my peritoneal cavity littered

with tumors/cysts. Pathology stated they were multi cystic mesothelioma (benign). When I was in the waiting room to see my original surgeon I was speaking on my cell phone to a friend telling her about the Wall Street Journal article regarding morcellation. A woman called in to see a doctor turned to me after overhearing my cell conversation and stated she had the same operation and it spread endometriosis.

3 ^ | v • Reply • Share ›



**Vivian** • 6 months ago

I think the medical profession ought to be skewered for not informing us women of what the risks were in having them morcellate our uteruses. WTF?

2 ^ | v • Reply • Share ›



**SuzieTampa** • 6 months ago

Readers should understand that this is primarily Hooman & Amy's side of the story. Here's what the article doesn't mention: The 1 in 352 figure from the FDA includes low-grade endometrial stromal sarcoma (ESS), which is often controlled with hormone therapy. The greatest danger comes from leiomyosarcoma (LMS) and undifferentiated pleomorphic sarcoma (UPS), which used to be called high-grade ESS. That's about 1 in 500 women who have surgery for suspected fibroids. But the majority of those women did not undergo morcellation in the past. So, 1 in 500 women wasn't in danger. The FDA study, co-authored by Paasche-Orlow, relied on studies with different definitions of LMS, including low-grade LMS -- a category that a number of sarcoma oncologists now reject. The study on harm came from Dana-Farber, which has a rigorous definition for LMS. This year we have gotten several studies showing that the risk of undetected LMS increases with age. Women 30 and younger have a very remote chance of having an undetected LMS, and they are the ones most likely to want to have a myomectomy with a morcellator to preserve their uterus. Dr. Jubilee Brown's study has been published, along with a thorough dissection of the FDA study. Ditto for the study on the 7,000+ figure. The author didn't need to depend on organizations to give her these studies. They can be gotten on the Internet. We also have studies that found that endometrial biopsies

[see more](#)

1 ^ | v • Reply • Share ›



**jack\_k1** • 6 months ago

"...where in our country, where in this society, have we accepted the sacrifice of a minority... for the benefit of the majority?"

We do this all the time. For example, commercial airplanes crash. We know they crash, and when they crash, they have the potential to kill hundreds of people. And yet we choose to fly anyway because (in part) it is safer than the common alternative - driving (on a per passenger mile basis). Grounding airplanes will not save lives. It will just save different lives - and not as many.

1 ^ | v • Reply • Share ›



**Damir Čolak** → jack\_k1 • 6 months ago

You are talking about accidents everyone is always aware of.

He is talking about a concuss action executed upon uninformed victims destroying their lives.

See the difference?!

5 ^ | v • Reply • Share ›



**jack\_k1** → Damir Čolak • 6 months ago

\*conscious\*

And it's all about risk. If the doctors knew a patient had cancer, then this would be a different story. Likewise, if the pilots knew the plane



would crash, they wouldn't take off. But neither the pilot, nor the patient, nor the surgeon knows what will happen - only what \*could\* happen - and what \*could\* happen if people chose to drive instead - or chose to have open surgery instead.

1 ^ | v • Reply • Share >



**Hooman Noorchashm** → jack\_k1 • 6 months ago

I'm afraid your reasoning is incorrect in this case. The analogy to the airplane crash is only partially valid. Because most air-traffic accidents are due to unforeseen events having to do with pilot error or weather. The Morcellator disaster in women's health is more like a design defect in an aircraft (do you remember the battery defect in the Airbus aircraft?). See when design defects come to light in aircraft, entire fleets have been grounded. The morcellator is a technology that was conceived and accepted on the basis of an incorrect assumption by surgeons who do not get broadly trained in the principles a surgical oncology. It is an error that avoidably sacrifices the lives of a minority one in 300-350 unsuspecting women whose lives could be saved with proper surgery. They number in the thousands world-wide since the early 1990s.

So please reconsider your analytics. You are essentially making an incorrect comparison to justify what has been a systemic act of surgical negligence.

Thank you,  
Hooman Noorchashm MD, PhD  
(Amy's husband)

3 ^ | v • Reply • Share >



**jack\_k1** → Hooman Noorchashm • 6 months ago

I appreciate your thoughtful response. How many women will die as a result of the more invasive surgery?

2 ^ | v • Reply • Share >



**SuzieTampa** → Hooman Noorchashm • 6 months ago

1 in 300-350 women aren't killed by morcellation. Please see my response above.

^ | v • Reply • Share >



**Hooman Noorchashm** → SuzieTampa • 5 months ago

You are right. To be 100% crystal clear, one in 300-350 women are exposed to an unacceptably high mortality risk from mechanical spread and upstaging of a deadly cancer using power morcellation...The majority of these women end up dying from loco-regionally disseminated abdominopelvic sarcomatosis, caused by morcellation. So, this practice is simply russian roulette and has no place in the care of women - at the very least, given your background as a self-proclaimed feminist and person of good reasoning skills, one would think you see this problem with clarity, Ms. Siegel (aka, Tampa). Alas.

Again, sometimes the truths that are most visible before us, are the ones our egos most vigorously deny. Do read with care:

<http://onlinelibrary.wiley.com...>

2 ^ | v • Reply • Share >



**Kronosaurus** → jack\_k1 • 6 months ago



Yep. Vaccinations are another. We know the very small risks involved. A few die every year from them but the benefits greatly outweigh them. Also, a few people will die every year on the operating table from knee replacements, hip replacements, cosmetic surgery...etc. Making these trade-offs is very very common in medicine. This article was frustrating because, while it brought up the counter argument - that non-laposcopic surgeries may cause more harm - it largely ignored that argument in favor of the underdog crusader angle.

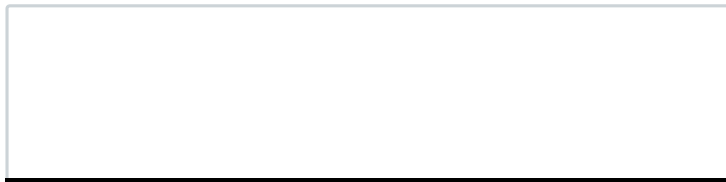
3 ^ | v • Reply • Share ›



**Hooman Noorchashm** → Kronosaurus • 6 months ago

Actually, open elective surgeries, especially hysterectomy or myomectomy and otherwise healthy women, do not have the same mortality risk as hysterectomy with morcellation. Also, more fundamentally, comparing the avoidable and deadly risk of cancer upstaging by morcellation to "unavoidable" complications associated with surgery, in general, is fully incorrect from a risk management standpoint.

In case you have not seen what morcellation is and why it is dangerous, please watch the following video. You do not have to be a physician to understand that this avoidable practice will spread occult or missed cancers:



see more

1 ^ | v • Reply • Share ›



**Adam Ramji** → Hooman Noorchashm • 6 months ago

I agree with Dr. Noorchashm. From a legal point of view, there are too often times, where pharmaceutical companies that make these devices and/or drugs, may actually know of the risks involved and the severe, yet seldom, fatal results. The only thing we ask the pharmaceutical companies to do is NOT hide this fact and label the products properly. I'm a big believer of the "greater-good" point of view. But think about it, "IF" there was a way to further minimize harm, just by labeling and disclosing to simply alert the patients that may be in a "high-risk" category, why wouldn't you?? The answer is simple: money. If several billion more can be made by slyly leaving relevant warnings off the label, isn't that ok?? OF COUSE NOT.

We represent so many people that are victims of this. It's sad, it's inhumane.

To Dr. Noorchashm, I'm sorry to hear this has happened to your family. I hope you get great legal representation. I could share more stories of other clients we have that are in terrible positions because of this avoidable harm. #nomoneyisenough

2 ^ | v • Reply • Share ›



**SuzieTampa** → Adam Ramji • 6 months ago

Pot meet kettle, Mr. No Money Is Enough. Women should not get information on leiomyosarcoma and morcellation from lawyers. I can't count how many websites and press releases have contained inaccurate information.

1 ^ | v • Reply • Share >



**haider** • 6 months ago

[www.ummulshifa.com](http://www.ummulshifa.com)

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