The Washington Post
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HEALTH & SCIENCE

Vaginal mesh has caused health problems in many women, even as some surgeons vouch for its safety and efficacy

By Susan Berger
January 20, 2019 at 8:00 a.m. EST

Regina Stepherson needed surgery for rectocele, a prolapse of the wall between the rectum and the vagina. Her surgeons said that her bladder also needed to be lifted and did so with vaginal mesh, a surgical mesh used to reinforce the bladder.

Following the surgery in 2010, Stepherson, then 48. said she suffered debilitating symptoms for two years. An active woman who rode horses, Stepherson said she had constant pain, trouble walking, fevers off and on, weight loss, nausea and lethargy after the surgery. She spent days sitting on the couch, she said.

In August 2012, Stepherson and her daughter saw an ad relating to vaginal mesh that mentioned 10 symptoms and said that if you had them, to call a lawyer.

“My daughter said, ‘Oh mom — you have every one of those,’” Stepherson, of Tyler, Tex., recalled.

Vaginal mesh, used to repair and improve weakened pelvic tissues, is implanted in the vaginal wall. It was initially — in 1998 — thought to be a safe and easy solution for women suffering from stress urinary incontinence.

But over time, complications were reported, including chronic inflammation, and mesh that shrinks and becomes encased in scar tissue causing pain, infection and protrusion through the vaginal wall.

Katrina Spradley, then 38, was about to have a hysterectomy in April 2008. She said that she told her physician that she also had urinary issues — every time she would laugh, cough or sneeze, she would leak urine. It happened so often that she would wear sanitary pads. A urologist was consulted and determined that implanting vaginal mesh at the same time as the hysterectomy would repair her bladder problem, she said.

Spradley, of Dawson, Ga., also had endometriosis — a condition resulting from the appearance of endometrial tissue outside the uterus that most commonly causes pain (painful periods, heavy bleeding, pain with sexual intercourse). And so, when after the surgery, she began having stomach cramps, she thought that was the reason. Physicians told her there was nothing wrong, she said.

In 2011, a urine test she took for her truck-driving license showed blood. Later, while having sex with her husband, his penis got scratched a few times. It took a visit to a physician with her husband to detail his discomfort to find mesh eroding through Spradley's vagina, she said.

Chrissy Brajcic, a Canadian who struggled for four years with persistent infections following a mesh implant, became the face of mesh victims with a Facebook page. Brajcic died in December 2017 from sepsis at age 42.

About 3 million to 4 million women worldwide have had mesh implanted to treat urinary incontinence and prolapse, said Shlomo Raz, professor of urology and pelvic reconstruction at UCLA school of medicine. About 5 percent — or 150,000 to 200,000 — of those have complications, he said.

"But when you have complications, it's hard to treat," Raz said.

Among the complications: chronic pelvic pain, erosion of mesh into the vagina, incontinence, obstruction, pain in the groin, hip and leg, and pain during intercourse. Raz also believes, based on his experience, that 20 to 30 percent of the complications are what he calls "lupus-type," causing runny nose, muscle pain, fogginess and lethargy. He bases this on the fact that, after removal, the patients are cured of these complications.

"If you remove mesh, and lupus-type symptoms disappear, the mesh is responsible," Raz said.

Michael Thomas Margolis, assistant clinical professor at UCLA, has removed more than 600 mesh slings in patients since 1998. He has served as an expert witness on polypropylene mesh in lawsuits for plaintiffs and most recently for lawsuits filed by the states of Washington and California.

"I have never implanted through a woman's vagina a polypropylene mesh or sling system ever, because of the complications," Margolis said. "I had concerns when they first came out — but my concerns were the tip of the iceberg."

Once the damage is done, it cannot be corrected, Margolis said.

The American Urogynecologic Society (AUGS) and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) support the use of polypropylene slings for stress incontinence. Their joint statement says that "Polypropylene material is safe and effective as a surgical implant."

Raz and Margolis disagreed. Raz, who said that many of the AUGS physicians who wrote the positive position statement were his fellows, said: "I don't agree based on my experience. I found that in the long run, we have created a monster, planting mesh in young women — some of them you can never cure."

Margolis said that many of the authors of the AUGS and SUFU joint position statement "receive substantial money from mesh manufacturers." He also said: "I have been a giant thorn in AUGS's side. They should at least acknowledge their financial conflict of interest."

According to the AUGS board of directors website, some of the directors do have financial interests in companies that make mesh.

Dionysios Veronikis, director of female pelvic medicine and reconstructive surgery at Mercy Hospital St. Louis, who has removed 250 to 300 mesh slings a year, said that problems result when a mesh is not implanted properly. He also said that women need to see a surgeon who does many of these surgeries. Their patients have fewer complications, Veronikis claimed.

He also said that "some of the [mesh] products have helped many women."

"The slings I do, although synthetic, have helped many women," he said. "I put the sling in differently. I don't follow the instructions that are outlined because I have a unique skill set that allows me to make the operation fit the patient. I don't make the patient fit the operation. That is the flaw. There is no one size fits all, and not every woman wears a size 7 shoe."

Two years ago, Roxann Bentz was 67 and had a cystocele (prolapsed bladder) and some urinary incontinence. The Bucks County, Pa., woman researched physicians to repair the problem. Bentz, a registered nurse, was aware of poor outcomes and found a surgeon who specialized in the procedure. "I knew he had done many of these," she said.

Bentz, an active woman who enjoys biking and canoeing, said the recovery was fine, and she has had no problems since the surgery.

Raz, who said he has removed 1,800 mesh implants in the past six years, said vaginal bacteria creates a potential for chronic mesh infection and pain in some patients, and mesh should not be used in the vagina.

"We took patients with pelvic pain and mesh complications and those without pain. We removed four segments. All of those with pelvic pain were positive for live bacteria in the mesh," Raz said. "Those without pain had no DNA positive for bacteria in mesh."

More than 100,000 lawsuits have been filed against makers of mesh, according to ConsumerSafety.org, making it "one of the largest mass torts in history."

In October 2016, a judge upheld a $14.3 million jury award for three women who were injured by a Boston Scientific mesh device, and in 2015, Boston Scientific announced a settlement of $457 million for 6,000 mesh lawsuits.

Kate Haranis, a spokeswoman for Boston Scientific, said the company stands behind its products and noted that "Nearly one million women have been successfully treated with Boston Scientific Urogynecologic mesh and our pelvic floor therapies are supported by more than 60 clinical publications."

Lawsuits have been filed by the states of Washington, California, Kentucky and Mississippi against mesh maker Johnson & Johnson and its subsidiary, Ethicon, saying that product marketing should have provided more detail about the risks. They accuse the company of deceiving physicians and patients, and say the mesh has destroyed the quality of life for some of them, according to the Associated Press.

In response, 63 surgeons in Washington wrote a letter in December to state Attorney General Robert Ferguson denying that they were misled, and expressing the concern that the lawsuit would "eliminate the mid urethral mesh sling as a treatment option for women in Washington." This, they said, would have a negative impact because the sling is standard surgical treatment for stress urinary incontinence.

Jeffrey L. Clemons and two other physicians who signed the letter disclosed they had been retained by the defense, but that they were not being paid nor receiving any assistance.

Ethicon called the lawsuit filed by Kentucky "unjustified" and said "the company plans to vigorously defend itself against the allegations."

Among the more notable settlements: In April, a New Jersey jury awarded $68 million to Mary McGinnis for her debilitating injuries caused by a mesh made by medical device company C.R. Bard (*Mary McGinnis v. C.R. Bard, Inc.*). The company said it would appeal, and that McGinnis was aware of the risks.

Endo International settled 22,000 mesh lawsuits in 2017 for $775 million and said its president and chief executive, Paul Campanelli, called it "a very important milestone for Endo to have reached agreements to resolve virtually all known U.S. mesh product liability claims."

In 2008, according to the Food and Drug Administration, "the number of adverse events reported to the FDA for surgical mesh devices to repair POP [pelvic organ prolapse] and SUI [stress urinary incontinence] for the previous 3-year-period (2005-2007) was 'over 1000.'" The agency said the complications included mesh erosion through the vagina, pain, infection, bleeding, pain during sexual intercourse, organ perforation and urinary problems.

From 2008 to 2010, the FDA received 2,874 reports of complications associated with surgical mesh. The FDA's literature review found that erosion of mesh through the vagina is the most common and consistently reported mesh-related complication.

According to a study published last year, all surgical meshes in the United States were cleared by the FDA's 510(k) process, "in which devices simply require proof of 'substantial equivalence' to predicate devices, without the need for clinical trials." The study also said that "recalled meshes associated with adverse effects may, indirectly, continue to serve as predicates for new devices raising concerns over the safety of the 510(k) route." The authors conclude that improvements for regulation are "urgently required."

An FDA spokeswoman said that the agency is making improvements. The agency reclassified surgical mesh in 2016 for transvaginal pelvic organ prolapse (POP) repair from Class II (which includes moderate-risk devices) to Class III (which includes high-risk devices). "FDA is reclassifying these devices based on the determination that general controls and special controls together are not sufficient to provide reasonable assurance of safety and effectiveness for this device, and these devices present a potential unreasonable risk of illness or injury," the final order reads.

In addition, the agency is, "issuing postmarket surveillance orders to 34 manufacturers who had cleared 510(k)s for transvaginal repair of pelvic organ prolapse," the spokeswoman said. As a result of the FDA's actions, she said, "all manufacturers ceased marketing of surgical mesh intended for transvaginal repair of posterior compartment prolapse (rectocele). Only three surgical mesh products intended for transvaginal repair of anterior compartment prolapse (cystocele) remain legally marketed."

The FDA is also planning an advisory meeting on Feb. 12 to share evidence and expert opinion about the safety and effectiveness of transvaginal mesh.

Margolis said removing mesh that has scarred into place is like trying to remove bubble gum from hair or rebar from concrete.

"I have seen women with their vaginas essentially mutilated. So scarred and disformed as a result of the chronic inflammation and scarring from the mesh as to be left with a nonfunctional vagina or dysfunctional bladder and urethra," Margolis said. "When tissue, the vagina, bladder or bowel is damaged enough, no surgeon can fix the tissue past a certain point — and I see that with great regularity, even after mesh was implanted years before."

If women are concerned about complications because of a mesh, what should they do if they are plagued by stress incontinence or prolapse?

There are nonsurgical options, such as Kegel exercise and pessaries, that can help with stress incontinence, Margolis said.

Raz and Margolis prefer slings made from organic, biologic material such as tissue or tendons from their own patients.

Margolis also said that the Burch procedure, a surgical procedure in which the neck of the bladder is suspended from nearby ligaments with suture is excellent, but noted that it, too, can fail.

Vaginal mesh is no longer being used in Australia, Ireland and Scotland. In July, the United Kingdom instituted a temporary ban while long-term damage is assessed.