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I'd like to thank the FDA for inviting me to speak on the serious issue of transvaginal surgical mesh complications.

My comments pertain only to the transvaginal implantation of synthetic mesh for pelvic organ prolapse and stress incontinence. These comments are based on my knowledge, experience, education and training as a Pelvic Surgeon and on observations made during scores of "salvage" operations I've performed on women who have experienced mesh complications over the last decade.

Transvaginal implantation of synthetic mesh for any reason is a surgical theory and technique that defies core surgical doctrines.

In 1982, the CDC adopted the American College of Surgeons wound classification system that classifies wounds according to the likelihood and degree of wound contamination during surgery. In this system, vaginal surgery is classified as "clean-contaminated" carrying a risk of wound infection of 3-11% as compared to clean wounds, which carry a risk of infection of 1-5%. (1)

The vagina is classified as "clean-contaminated" because normal vaginal flora cannot be surgically cleansed from the operative field. These normal flora include a diverse array of bacteria including but not limited to Staph., E. coli, Kebsiella, Streptococcus, Peptostreptococcus, and Bacteroides, all of which are found in wound infections. (2)

The implantation of contaminated synthetic mesh through the vagina defies basic surgical tenets because by definition it is not performed in a sterile manner. In fact so-called "mesh erosion", the most common mesh complication, is in reality "mesh infection with chronic wound breakdown". Time does not permit me to expound upon the plethora of other complications associated with transvaginal mesh such as damage to bowel, bladder and blood vessels, vaginal scarring, dyspareunia, need for multiple repairs and destroyed personal lives but the MAUDE database has already begun to do this.

What it's like to remove mesh from the surgeon's perspective can perhaps be appreciated by this analogy. Extirpation of vaginal mesh is akin to taking a hammer and chisel and trying to remove the rebar from a sidewalk while leaving the cement otherwise intact and not damaging the water mains and power lines below. It is difficult if not impossible to remove all the mesh and do it safely.

Nearly 20 years ago FDA Commissioner Kessler wrote, "It is not the culture of U.S. medicine to report adverse events to the FDA". (3) He speculated that only one percent of serious adverse events are reported to the FDA, an estimate consistent with a 1986 survey of hospitals by the Government Accountability Office which found that 99% of problems associated with select medical devices had not been reported to the FDA's post marketing surveillance system. (4) Thus, the recent adverse mesh findings already published by the FDA represent only a small percentage of the total number of women affected.

The counterintuitive surgical technique of vaginal mesh implantation was seemingly invented to accommodate new devices which made it easier for doctors with less surgical training to operate. These doctors were apparently seen as a target rich environment for a marketing campaign which convinced many of them that this inherently risky approach was safe. It's quite possible that some device manufacturers' financially incorporated so called "key opinion leader" surgeons into their promotional endeavors which may have further facilitated the publishing and dissemination of misleading (and sometimes fabricated) clinical data.

On a positive note, there are numerous superior options to the use of synthetic mesh for SUI and prolapse. The MMK (or Burch) is still the Gold Standard surgery for SUI as are the sacrospinous fixation and sacral colpopexy for vault prolapse. It is firmly established in the world's literature that when these procedures are combined with traditional repairs as indicated, their success rates are second to none. Furthermore, with fewer complications than mesh they are simply the best procedures in the repertoire.

In summary, synthetic mesh for prolapse and SUI produces an unacceptably high and clearly avoidable plethora of life ruining surgical complications in women and there are numerous safer surgical alternatives with superior success rates. I hope the FDA will, through firm action, help save others from the painful experiences that thousands of unfortunate women have had to suffer through so far.

Again, I'd like to thank the FDA for inviting me to speak on this important issue.

Michael Thomas Margolis, MD, FACS, FACOG

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