

FDA and Mesh Complications in Vaginal Surgery

Response to FDA Safety Communication dated July 13, 2011

To Our Patients and Women of the Community:

As many of you are aware, on July 13, 2011, the FDA released an “Update on the Safety and Effectiveness of Transvaginal Placement (TVM) of Surgical Mesh for Pelvic Organ Prolapse (POP)”. **I am writing this letter in an effort to provide you with a better understanding and a more balanced perspective of the complications that can occur with all forms of vaginal surgery. I am hoping that the following discussion will be educational and relieve you of any unnecessary concerns.**

As an expert in pelvic floor reconstruction and a valued leader in the field, I recognize the events that have led to the FDA’s report, and I agree with many of the points covered in the FDA’s Safety Communication. **However, I am of the strong opinion that the recent FDA UPDATE fails to convey an accurate perspective to the public, to the press, and unfortunately, to the legal community. I also feel that several key conclusions in the UPDATE are not consistent with the scientific literature pertaining to vaginal mesh and are inconsistent with the clinical realities we encounter as surgeons caring for women with severe prolapse and incontinence.**

In an effort to respond to the FDA UPDATE, the ***Prolapse Surgeons Network*** released a report that reviewed the evidence supporting the use of mesh in correcting pelvic organ prolapse (POP). It is a 10 page report; however, I have outlined and simplified the main points below:

1. The FDA UPDATE defines “1503 reports associated with POP repairs” from 2008 to 2010. This is 5x greater than the reports from 2005 to 2007. However, the FDA failed to mention that 225,000 TVM procedures were performed during that time period, creating a complication rate of only 0.67%. So, the complication rate has not increased; rather, it is a reflection of the wide acceptance of TVM by many specialists in POP surgery and an increase in the overall rate of the procedures that are being performed.
2. The FDA UPDATE implies that the risk of complication is higher with mesh than with native tissue repairs. This statement is not properly qualified and has been misleading to non-clinicians. Because non-mesh repairs don't use an FDA-monitored device, there is no systematic reporting mechanism in place. It is important to understand that all treatment options (with or without mesh) for POP repairs involve significant risks. The FDA UPDATE portrays mesh repairs as uniquely hazardous, providing no broader perspective regarding the significant risks and/or higher recurrence rates associated with its alternatives.
3. The FDA UPDATE lists the following complications associated with the use of mesh: mesh erosion, pain, infection, bleeding, pain with intercourse, organ perforation, and urinary problems. These risks do exist, but the FDA fails to mention that they also exist for traditional non-mesh surgery as well (with the exception of mesh erosion)
4. The FDA UPDATE states that mesh placed abdominally results in lower rates of complications than transvaginal mesh placement. The FDA does not mention that the mesh used in all cases is basically the same. The FDA does not imply that mesh erosion exists regardless of the approach (abdominally or transvaginally). The complication rates for TVM are variable, and the FDA does not mention that the variation is likely due to surgical technique (and experience),

not the mesh itself. While the rates of “complication” may be higher with TVM (compared to an abdominal approach), the severity of the complications associated with the abdominal approach may be greater (abd. wall hernias, small bowel injury or obstruction etc.)

5. The FDA UPDATE states that “mesh augmentation may provide an anatomic benefit compared to traditional POP repair without mesh”; however, the statement “this anatomic benefit may not result in better symptomatic results” is highly debatable. This is due to the fact that many of the favorable results in the literature fail to reach “statistical significance” due to study design. Given the latest data, it would be equally true to state, “this anatomical benefit *may* result in better symptomatic results.”
6. FDA UPDATE states that mesh erosion is a potential complication of TVM. However, the statement that “even multiple surgeries will not resolve the complication” is inaccurate. There are no published case reports in which mesh erosion from TVM does not resolve after 2 returns to the operating room.
7. Chronic pain after TVM may be difficult to resolve despite multiple surgeries, but chronic post-operative pain is a risk with non-mesh repairs as well, and can also be difficult to resolve.
8. In terms of clinical results, there were no studies that showed any difference in the change in vaginal length after surgery between the mesh and non-mesh arms of the studies. If there is shrinkage of the vagina with TVM, it does not appear to affect vaginal length anymore than does the trimming of the vagina wall during traditional non-mesh repairs.
9. Based on 7 randomized controlled clinical trials of TVM, one study showed that pain on intercourse was worse with the

“non-mesh” group. In all of the other studies, sexual function was reported to be the same in mesh and non-mesh groups.

10. The FDA UPDATE stated that “in *most* cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications”. This statement is very misleading. Studies actually show that, in many cases, traditional POP repairs (without mesh) have high failure rates. We agree that POP can be successfully treated without mesh in *many* cases, but not necessarily *most*.
11. There is limited long-term data on all forms of prolapse repair. The FDA fails to state that the long-term data on non mesh repairs suggests a very high failure rate. They also fail to mention that long term data on TVM for urinary incontinence does not show any untoward effects of mesh long term that were not present in the short term.

As you can see, the FDA has presented a biased view of transvaginal mesh placement. There are many considerations that are not represented in their report, creating unnecessary fear and apprehension in patients and in the community at large. We recognize the FDA’s mission to monitor manufactured devices in pelvic surgery and to advocate for patient’s safety and best interests. Certainly, most of the surgical community will agree that proper informed consent regarding the risks, benefits, and alternatives of a procedure is critical. However, the FDA UPDATE has led patients to believe that there is a “mesh problem” or that something toxic has been or will be placed within them. This is definitely not the case!!! We do not have mesh problems; rather, we have surgical skill and experience problems.

As a leader and a trainer of other doctors in vaginal surgery, I have performed over 100 pelvic floor cases per year over the last 8 years. Over the last 3 years, I have been using mesh repairs in the majority of my cases. After reviewing my own data related to mesh repairs, I can report that over 90% of our patients are satisfied with the

procedure, and we have only encountered a 3% mesh extrusion rate. All of our mesh extrusions have been manageable with simple intra-operative excision. Furthermore, we have no reported cases of chronic pelvic pain or pain on intercourse. Overwhelmingly, patients have been happy with their procedures, supporting the role that vaginal mesh provides to the “toolbox” for many surgeons who treat advanced pelvic organ prolapse.

Sincerely,

Shawn Blick, MD
President
Valley Urologic Associates
A Division of ACHO