



# Does trocar-guided vaginal mesh improve the durability of repair of recurrent pelvic organ prolapse?

**NOT WITHOUT SIGNIFICANT RISK.** Although this randomized, controlled trial found that mesh insertion was associated with a lower rate of anatomic failure at 12 months, compared with conventional repair without mesh, the Food and Drug Administration (FDA) recently concluded that serious adverse events are a significant risk after use of transvaginal mesh.

*Withagen MI, Milani AL, den Boon J, Vervest HA, Vierhout ME. Trocar-guided mesh compared with conventional vaginal repair in recurrent prolapse. A randomized controlled trial. Obstet Gynecol. 2011;117(2 pt 1):242-250.*

► **EXPERT COMMENTARY**

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A woman's lifetime risk of surgery for pelvic organ prolapse is approximately 7%; more than 300,000 prolapse surgeries are performed annually in the United States alone.<sup>1</sup> Of the women who undergo surgery, an estimated 13% will require re-operation within 5 years,

and as many as 29% will undergo another surgery for genital prolapse or a related condition at some point during their life.<sup>2</sup>

In the hope of improving the effectiveness and durability of vaginal prolapse repairs, many pelvic reconstructive surgeons have turned to reinforcement with synthetic mesh. However, because of concern about a higher risk of complications relative to other approaches, the use of transvaginal mesh for prolapse repair has come under increased scrutiny by the FDA. At this time, almost one quarter of all prolapse repairs involve placement of transvaginal mesh.<sup>3</sup>

**WHAT THIS EVIDENCE MEANS FOR PRACTICE**

No single surgical approach for the correction of pelvic organ prolapse is superior for all women, be it traditional vaginal non-mesh repair, mesh-augmented repair, or the open or laparoscopic approach. There may be circumstances when transvaginal mesh is the best choice. However, given the potential risks, it seems clear that **1)** its use should be judicious and **2)** mesh-augmented repair should be performed only by surgeons who have appropriate training and only on patients who have been fully informed of the risks and benefits of all treatment options.

» Matthew D. Barber, MD, MHS

**Details of the trial**

Withagen and colleagues enrolled 194 women from 13 Dutch medical centers. All women had recurrent pelvic organ prolapse and were randomized to either trocar-guided transvaginal mesh repair (Prolift) or conventional vaginal prolapse repair without mesh (i.e., native-tissue repair).

As in several other trials evaluating transvaginal mesh for anterior vaginal prolapse, the investigators found that it led to improved anatomic outcomes, compared with native-tissue repair, but at the expense of a higher complication rate. In this study, women in the mesh group experienced a cumulative rate of vaginal mesh exposure of 16.9% by 12 months and had a higher rate of



**Recent guidance from the FDA points to the potential for serious, unique, and life-altering complications when transvaginal mesh is used in prolapse repairs**

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## Examining the **EVIDENCE**

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hematoma and greater voiding dysfunction in the immediate postoperative period.

The most clinically relevant outcome to patients who have prolapse is resolution of their symptom of vaginal bulging; this symptom improved similarly in both treatment groups.<sup>4</sup>

### Strengths and weakness of the study

This study has a number of strengths:

- an excellent rate of follow-up (98%)
- a large number of study sites
- use of multiple validated outcome measures.

The principal weakness is the use of strict anatomic criteria as the primary outcome measure. In the general population, 40% of asymptomatic women who present for annual gynecologic examination have vaginal support of Stage 2 or higher and would have been considered failures by this definition.<sup>5</sup> Prolapse beyond the hymen appears to be a more clinically relevant threshold for defining anatomic success.

### FDA gets involved

In July 2011, the FDA issued a safety update on the use of transvaginal mesh for prolapse

repair. Its principal findings:

- Serious adverse events are *not* rare
- Transvaginally placed mesh in prolapse repair does not conclusively improve clinical outcomes over traditional non-mesh repair.<sup>3</sup>

The FDA noted that patients who undergo prolapse repair with mesh are subject to a unique set of complications, including erosion and mesh contraction, which can be life-altering and, in some women, may require multiple surgeries to correct.

Given the safety concerns regarding transvaginal mesh, the FDA is considering changing the regulatory process for the introduction of new transvaginal mesh devices. ☹

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