Does vaginal prolapse repair using synthetic mesh confer long-term benefit over native-tissue colpopexy?

Not at this time. No difference in 3-year cure rates was observed when women undergoing traditional vaginal prolapse repair without mesh were compared with those undergoing repair with mesh, according to this analysis of 65 women with Pelvic Organ Prolapse Quantification (POP-Q) stage 2–4 prolapse.

FAST TRACK

Overall recurrence rates were similar after vaginal prolapse repair whether mesh was used or not

Gutman RE, Nosti PA, Sokol AI, et al. Three-year outcomes of vaginal mesh for prolapse: A randomized controlled trial. Obstet Gynecol. 2013;122(4):770–777.

EXPERT COMMENTARY

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This is the third report from Gutman and colleagues on the outcomes of a double-blind, multicenter, randomized, controlled trial of vaginal prolapse repair using synthetic mesh versus native-tissue colpopexy in women with significant vaginal prolapse.

The trial involved 33 women who underwent mesh repair and 32 who underwent repair without mesh. (The mesh-free repair consisted primarily of uterosacral suspension and concurrent colporrhaphy.) It was halted when it reached a predetermined threshold for discontinuation, which was a mesh erosion rate of 15% or more.

Investigators found no difference in long-term cure rates between the mesh and no-mesh groups, regardless of the definition of cure (ie, anatomic, symptomatic, or combined). Nor was there a difference in the overall recurrence rate.

The author reports no financial relationships relevant to this article.

Summary of earlier reports

Three-month outcomes. The first report from this trial described 3-month objective treatment outcomes, with success described

WHAT THIS EVIDENCE MEANS FOR PRACTICE

The 3-year data presented by Gutman and colleagues should be viewed with caution, owing to the trial's reduced sample size and power. However, they may be useful in designing future trials.

In the meantime, given the limited longer-term outcomes data available at present, I would recommend continued individualized use of mesh versus native-tissue repair in women presenting with prolapse, including educating patients about the risks and benefits of both approaches. It also is important that outcomes be followed in all of our patients in a robust, unbiased fashion. The new American Urogynecologic Society Pelvic Floor Disorders Registry provides the opportunity for this.

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as prolapse no greater than stage 1.[1] It found a high erosion rate (15.6%) for vaginal mesh, with no differences between groups in overall subjective or objective cure rates, with an overall recurrence rate of 59.4% (19 cases) in the mesh group versus 70.4% (24 cases) in the no-mesh group ($P = .28$), with recurrence defined as prolapse beyond stage 1 in any compartment. Investigators also observed potential benefit in the mesh group in the anterior vaginal wall at point Ba at a median of 9.7 months after surgery.

One-year outcomes. The second report described 1-year objective and functional outcomes in all participants of the trial.[2] It found comparable objective and subjective cure rates between groups but a higher reoperation rate for mesh repairs. Prolapse recurred in the anterior department in 46.9% of women in the mesh group versus 60.6% in the no-mesh group ($P = .40$).

Subjective quality-of-life assessments continued to reflect significant improvement in symptoms from baseline. Vaginal bulging was relieved in 96.2% of women in the mesh group, compared with 90.9% in the no-mesh group ($P = .62$).

More women in the mesh group required reoperation for recurrent prolapse or mesh exposure (5 in the mesh group vs 0 in the no-mesh group; $P = .017$).

Strengths and limitations of the trial

Gutman and colleagues are to be congratulated for continuing to monitor longer-term outcomes of vaginal prolapse repairs augmented with synthetic mesh, as data are sorely needed on both early complications and those more remote from surgery. However, it is regrettable that continued attrition in this trial led to minimal power to compare outcomes between groups.

Cure rates were assessed three ways: anatomically, by virtue of symptoms, and by a combination of the two measures. Participants had documentation of at least 2-year anatomic outcomes and 3-year subjective outcomes using validated measures.

Forty-one (63%) of the original 65 women in the trial had anatomic outcomes (20 in the mesh group vs 21 in the no-mesh group), and 51 (78%) of the original 65 women had evaluable subjective outcomes (25 in the mesh group vs 26 in the no-mesh group).

Women who underwent reoperation for recurrent prolapse were removed from any outcomes analysis and considered to have failed composite outcomes measures (anatomic and subjective assessment and whether reoperation or a pessary was required for recurrent prolapse).

The length of follow-up was similar between groups (median, 3 years; interquartile range, 2.97–3.15), and both groups demonstrated significant anatomic and subjective improvement from baseline.

No difference was observed between groups in the original primary anatomic outcome, which was a POP-Q stage no greater than 1 (45% in the mesh group vs 43% in the no-mesh group; $P > .99$). Nor was there a difference between groups in any other anatomic outcome, including POP-Q point Ba (median, –1.5 for mesh [range, –2.5, 1.0] vs –0.5 [range, –3.0, 4.0] for the no-mesh group; $P = .21$) and bulge symptoms (92% for the mesh group vs 81% for the no-mesh group; relative risk, 1.4; 95% confidence interval, 0.91–1.42).

Despite small numbers and markedly reduced comparative validity (readily acknowledged by the investigators), these longer-term outcomes were assessed by examiners blinded to treatment and using validated objective and subjective outcome measures.

The only other randomized trial of mesh versus native-tissue repair with 3-year outcomes had a much larger sample size and follow-up but addressed only anterior-compartment prolapse.[3]

FAST TRACK

No difference was observed between the mesh and no-mesh groups in the original primary anatomic outcome, which was a POP-Q stage no greater than 1

References

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