October 22, 2010

Trial of Synthetic Mesh in Pelvic Surgery Ends Early

By RONI CARYN RABIN

To repair the uncomfortable and potentially dangerous condition called pelvic organ prolapse — a weakening of the muscles and ligaments that support organs like the bladder and uterus — more gynecological and urological surgeons have been turning to a synthetic mesh that shores up the vaginal wall.

But now researchers are reporting that women who received the mesh had so many complications that scientists were forced to halt a clinical trial early.

The trial randomly assigned 65 women with prolapse to undergo surgical repair either with vaginal mesh or with a more traditional procedure, colpopexy, that uses the patient's own ligaments to support the sagging muscles.

In an article in the journal Obstetrics & Gynecology, the researchers say safety reviewers observed that more than 15 percent of the patients who received the mesh experienced erosion, a potentially serious complication in which the skin splits and the mesh protrudes, often resulting in pain and infections. The trial, which began in 2007, was stopped in August 2009.

In 2008, the Food and Drug Administration had issued a warning that the vaginal mesh had been associated with complications, but it said the problems were "rare."

The lead author of the new report, Dr. Cheryl B. Iglesia, director of female pelvic medicine and reconstructive surgery at Washington Hospital Center in the District of Columbia, said it made two important points.

"The bottom line is not only there were more complications," she said, "but the mesh didn't prove any better than traditional surgery."