

## Urogynecologic surgical mesh and associated complications: Can computational biomechanics help?

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Pelvic organ prolapse is a pelvic floor disorder occurring when the tissue and muscles of the pelvic floor no longer support the pelvic organs resulting in the drop from their normal position. The pelvic organs include the vagina, uterus, bladder, urethra, and rectum. The bladder is the most commonly involved organ in pelvic organ prolapse. Pelvic organ prolapse can also be associated with stress urinary incontinence. Stress urinary incontinence is a leakage of urine during moments of physical activity that increases abdominal pressure, such as coughing, sneezing, laughing, or exercise.

Pelvic organ prolapse without or with stress urinary incontinence is a major health care problem negatively affecting patients and their quality of life. It also represents a significant socioeconomic burden. Around 200,000 women undergo one or more surgical treatment for pelvic organ prolapse in the U.S. annually [1]. The total cost for surgical interventions for pelvic organ prolapse in the U.S. was estimated to \$1 billion in 1997 [6].

Nonsurgical treatment options for pelvic organ prolapse include pelvic floor exercises and pessary, a removable device that is inserted into the vagina to support the pelvic organs that have prolapsed. Surgery may be recommended for women with significant discomfort or pain from pelvic organ prolapse that impairs their quality of life. Surgery to repair pelvic organ prolapse can be done through either the abdomen or vagina, using sutures alone or with the addition of surgical mesh.

Urogynecologic surgical mesh is a medical device used to treat pelvic floor disorder. The implant is expected to provide additional mechanical support to weakened and/or diseased tissue of the pelvic floor, thus, restoring normal physiological position of the pelvic organs. It is frequently a non-absorbable knitted textile implant made of polypropylene or polyethylene terephthalate mono or multi-filaments. Absorbable and non-woven products are also available.

U.S. Food and Drug Administration (FDA) issued a Public health notification on serious complications associated with transvaginal surgical mesh in 2008 and a notification update in 2011 warning that these complications are not rare events, the efficacy of the treatment compared to non-mesh repair is not demonstrated and patients with mesh may be exposed to greater risk [8, 7].

The most frequent complications reported include but are not limited to mesh erosion, pain, infection, bleeding, pain during sexual intercourse, organ perforation, and urinary problems. Many of these complications require additional intervention, including medical or surgical treatment and hospitalization. Erosion of mesh through the vagina was found the most common and consistently reported mesh-related complication from transvaginal pelvic organ prolapse surgeries using mesh. Mesh contraction (shrinkage) was a previously unidentified risk of transvaginal pelvic organ prolapse repair with mesh that had been reported in the published scientific literature and in adverse event reports to FDA [8].

Todros et al. [7] published a review of several computational models of pelvic floor that have been developed to investigate vaginal childbirth biomechanics or pelvic floor dysfunction. Computational models of knitted textile-based implants have recently appeared based on textile structure [5, 3] or exhaustive experimental data [4].

The authors of this publication expect that the recently developed finite element model of pelvic floor [2] will be adapted to simulate pelvic organ prolapse and its repair as well as its biomechanical performance during various physiological activities. The model [2] will need to be completed by the implant. Constitutive relations for both the tissue and implant will need to be revised to take into account possible non-linearity, anisotropy, permanent set, Mullins effect and muscle contraction. Boundary conditions will need to be assessed for relevant daily activities. It is hypothesized that material and structural plasticity of the implant under specific cyclic load leads to unexpected deformation modes which could imply inadvertent response of the implant. Thus, simulating pelvic organ prolapse repair and its biomechanical performance would provide more insight in pelvic organ prolapse repair biomechanics and could eventually contribute to explain the complications associated with transvaginal surgical mesh.

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