



REVIEW

The mesh controversy [version 1; referees: 2 approved]

Joshua A. Cohn¹, Elizabeth Timbrook Brown², Casey G. Kowalik¹,
Melissa R. Kaufman¹, Roger R. Dmochowski¹, W. Stuart Reynolds¹

¹Department of Urologic Surgery, Vanderbilt University Medical Center, 1302A Medical Center North, Nashville, TN, 37232-2765, USA

²Department of Urology, MedStar Georgetown University Hospital, Washington, DC, USA

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Abstract

Pelvic organ prolapse and stress urinary incontinence are common conditions for which approximately 11% of women will undergo surgical intervention in their lifetime. The use of vaginal mesh for pelvic organ prolapse and stress urinary incontinence rose rapidly in the early 2000s as over 100 mesh products were introduced into the clinical armamentarium with little regulatory oversight for their use. US Food and Drug Administration Public Health Notifications in 2008 and 2011, as well as reclassification of transvaginal mesh for prolapse to class III in early 2016, were a response to debilitating complications associated with transvaginal mesh placement in many women. The midurethral sling has not been subject to the same reclassification and continues to be endorsed as the “gold standard” for surgical management of stress urinary incontinence by subspecialty societies. However, litigators have not differentiated between mesh for prolapse and mesh for incontinence. As such, all mesh, including that placed for stress urinary incontinence, faces continued controversy amidst an uncertain future. In this article, we review the background of the mesh controversy, recent developments, and the anticipated role of mesh in surgery for prolapse and stress urinary incontinence going forward.

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Corresponding author: Joshua A. Cohn (joshua.cohn@vanderbilt.edu)

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Background

Pelvic organ prolapse (POP) is a condition involving the descent of the pelvic organs, such as the bladder, rectum, and uterus or proximal vagina beyond their normal anatomic location. Loss of hormonal support associated with aging, trauma from vaginal delivery, and genetic risks are major contributors to the development of POP, which has a lifetime incidence of 30% to 50%¹. Similar risks increase the likelihood of developing stress urinary incontinence (SUI), which may also result from loss of pelvic support leading to urethral descent or direct damage to the continence mechanism resulting in intrinsic sphincter deficiency. The lifetime risk of undergoing surgery for POP or urinary incontinence by age 80 has been estimated at 11%^{2,3}. Options for surgical management of prolapse include “native tissue” repair or repair with the use of a synthetic or biologic graft⁴. Repair may be performed via a vaginal or abdominal approach. Options for surgical management of SUI include retropubic suspension of the urethra to its original anatomic location via an abdominal approach, or placement of a suburethral sling made of autologous, biologic, or synthetic non-absorbable graft material to limit urethral descent or compress the urethra to increase outlet resistance, or both^{5,6}.

Even when performed by experienced providers, native tissue repairs for POP have been associated with recurrence rates of up to 40% at two years⁷. The concept behind mesh repairs for prolapse was to reduce recurrence rates by augmenting damaged pelvic support structures⁸. The initial use of mesh in pelvic floor disorders was inspired by the successful use of mesh in abdominal wall hernia repair⁹. The use specifically of monofilament, macroporous mesh in POP repair was based largely on the safety and efficacy demonstrated by synthetic midurethral slings made of this material. In the decade following the description of the transvaginal tape (TVT) sling procedure¹⁰, synthetic sling placement became an increasingly desirable option owing to its maintained or improved efficacy and decreased recovery relative to traditional abdominal approaches or autologous fascial slings¹¹. In the mid-2000s, vaginal mesh use for POP and SUI experienced a rapid uptake after the development of multiple synthetic midurethral sling and trocar-based vaginal mesh POP “kits”¹².

Facilitated by the US Food and Drug Administration (FDA) 501(k) Premarket Notification approval system for class II medical devices, which requires manufacturers to demonstrate only that a new device is similar enough to an existing or predicate device to anticipate similar results, over 100 mesh products were introduced between 2001 and 2010¹³. Coupled with unprecedented direct-to-surgeon marketing and lack of training or credentialing oversight for these products, these procedures were quickly adopted¹⁴. In 2010, about 75,000 women in the US underwent prolapse repair with transvaginal mesh and 200,000 underwent synthetic midurethral sling placement¹².

20 October 2016 will mark the eighth anniversary of the landmark FDA Public Health Notification regarding the potential hazards of vaginal mesh for the treatment of both POP and urinary incontinence¹⁵. In 2011, a thorough review of prior and interval mesh-related complications prompted the FDA to consider

significant changes to the approval process for new and existing mesh products for POP^{12,16}. In July 2011, the FDA released a second Public Health Notification, which stated that “serious complications associated with surgical mesh for transvaginal repair of pelvic organ prolapse are *not rare*”¹⁷ (emphasis in original document). However, it was not until the following year that 522 post-market surveillance studies were mandated for transvaginal mesh for POP and single-incision “mini-slings”. By February 2013, the FDA had issued 95 post-market study orders to 34 manufacturers of mesh for prolapse and 14 to seven manufacturers of mini-slings¹⁸, and on 5 January 2016, transvaginal mesh for POP was officially reclassified as a class III device¹⁹. Neither the 2011 FDA Public Health Notification nor the January 2016 reclassification applied to synthetic midurethral slings or transabdominal prolapse repair with mesh. However, midurethral slings have been the most frequent target of over 70,000 lawsuits that have impacted at least seven major manufacturers of transvaginal mesh^{20,21}. As such, all transvaginal mesh, for both prolapse and incontinence, is facing an uncertain future.

Recent developments

The 2008 and subsequent 2011 FDA Public Health Notifications impacted the frequency of transvaginal mesh procedures in the US. In 2009, 41% of all women undergoing surgical repair of POP had mesh or a graft placed at the time of surgery²², and the use of synthetic material increased significantly throughout the year²³. However, these data do not differentiate transvaginal mesh from mesh placed abdominally (that is, sacral colpopexy) for the repair of POP, an important distinction. To this end, institutional data from one of the largest health-care systems in the US demonstrated a decrease in mesh usage in transvaginal prolapse repairs from 27% in early 2008 to 15% at the time of the first FDA notification, 5% at the time of the 2011 FDA notification, and just 2% at the end of 2011²⁴. In contrast, by the end of 2011, laparoscopic and robotic sacral colpopexy represented nearly 40% of all prolapse repairs within the health-care system, substantially replacing transvaginal mesh repair.

These institutional data appeared to reflect a broader national trend among both gynecologic and urologic subspecialists. A survey of American Urogynecologic Society members found that 40% of respondents decreased and 12% stopped use of vaginal mesh for POP after the 2011 FDA update²⁵. A multi-institutional study of specialty-trained urologists at eight major academic centers with data extending to the end of 2013 reported a marked decrease in transvaginal mesh usage as well²⁶. Although survey data suggested minimal changes in practitioner attitudes toward use of synthetic slings for SUI or mesh for abdominal sacral colpopexy²⁵, synthetic midurethral sling placement also decreased significantly between 2010 and 2011²⁷.

Several professional societies, including the American Urological Association; the Society for Urodynamics, Female Pelvic Medicine, and Urogenital Reconstruction; the American College of Obstetrics and Gynecology; and the American Urogynecologic Society, have issued position statements related to pelvic mesh²⁸⁻³⁰. In general, these statements agree with the FDA’s conclusions and support

judicious use of mesh products in highly selected, well-informed patients by surgeons trained in the procedures and in the recognition and treatment of complications.

The synthetic midurethral sling continues to be endorsed as the “gold standard” treatment option for SUI by both of the leading urogynecologic and urologic subspecialty societies³¹ on the basis of high-quality safety and efficacy data. Nevertheless, because of the relative frequency of the procedure, the synthetic midurethral sling has been the most frequent target of mesh litigation. A 1% sampling of the 73,915 product liability claims against mesh manufacturers reported in the Bloomberg Law Database identified 63.3% of these claims to be related to synthetic slings, 23.2% for both mesh and slings, and 13.3% for mesh for POP³².

Mesh manufacturers have suffered major financial repercussions from litigation associated with both slings and prolapse repair. In 2012, a \$5.5 million verdict in the case of a 53-year-old woman who suffered from erosion of C. R. Bard’s Avaulta Plus BioSynthetic Support System represented the first major award to a woman suffering from mesh complications³³. The case established a precedent of large payouts associated with debilitating mesh complications, the largest of which was a \$100 million jury verdict against Boston Scientific in May 2015²¹. Each of the seven major manufacturers of transvaginal mesh products has paid out or set aside funds in anticipation of future settlements costing tens to hundreds of millions of dollars^{21,34,35}. In September 2014, American Medical Systems/Endo International agreed to a \$1.6 billion settlement to resolve over 20,000 mesh-related claims^{27,36}. The following year, Bard agreed to pay more than \$200 million to resolve 3,000 claims, a cost of approximately \$67,000 per case³⁵.

In 2012, over 600 pelvic floor specialists endorsed a document advocating the continued use of transvaginal mesh for POP³⁷. The purported advantages, according to the authors, include comparable risk relative to native tissue repair in experienced hands, decreased risk of recurrence, and decreased recovery and operative times. The authors were concerned that given the growing fears over mesh complications and impending litigation, the materials might cease to be available. Their concerns appear to have been well founded, as several mesh manufacturers have adjusted their marketing strategies or closed altogether over concern for further litigation and markedly decreased mesh use among providers. These decisions have impacted availability of both transvaginal mesh products for prolapse repair and synthetic midurethral slings for SUI.

Ethicon, the manufacturer of what has been the most widely used and longest-studied synthetic midurethral sling (TVT), dissolved its urogynecology sales force in 2014³⁸. On 31 March 2016, Endo International closed ASTORA Women’s Health (formerly American Medical Systems Women’s Health)³⁴, thereby ceasing manufacture and distribution of all transvaginal mesh for prolapse as well as SUI, including the SPARC retropubic, Monarc transobturator, and MiniArc single-incision slings³⁸. As other mesh manufacturers face similar financial decisions, subspecialists, many of whom have largely abandoned transvaginal mesh for prolapse

but continue to advocate strongly for synthetic midurethral slings in well-selected patients, are concerned about the availability of synthetic slings in the future^{27,38}.

Mesh’s current and future role

In January 2016, the FDA published updated recommendations for health-care providers regarding the use of surgical mesh for POP³⁹. The FDA recommended that providers using mesh for prolapse have specialty training in the techniques of mesh placement and management of mesh-related complications. Practitioners were urged to avoid mesh whenever possible. The FDA emphasized the importance of informed consent regarding the alternatives to and potential risks of permanent mesh placement, including “serious complications” such as “pain during sexual intercourse, scarring, and narrowing of the vaginal wall”³⁹. Separate recommendations to patients include an extensive list of questions to ensure that their physicians are adequately trained in the use of mesh, thoroughly discuss the risks of mesh surgery for prolapse and follow-up care, and consider alternatives⁴⁰. The 2013 FDA notices entitled “Information for Health Care Providers for SUI”⁴¹ and “Information for Patients for SUI”⁴² were less extensive than, but similar in tone to, the 2016 POP documents.

The language of the FDA recommendations is measured but no doubt intimidating for providers. The emphasis on informed consent is important, given that most of the mesh litigation against surgeons has centered on a failure to adequately inform women of risks associated with transvaginal mesh surgery²⁰. However, improved informed consent prior to the use of transvaginal mesh had been viewed as critically important by subspecialty societies for several years. In April 2012, the American Urogynecologic Society developed the “Informed Consent Toolkit”, a 153-page document available for free online with information for patients and providers to review prior to mesh surgery for SUI or prolapse^{43,44}. Within the document is a standardized addition to the typical informed surgical consent, where the patient acknowledges that all of the pertinent discussion points regarding the use of mesh for prolapse have been adequately addressed. Many subspecialists have incorporated this or similar documents into their clinical practice for sling placement as well.

Although improved informed consent processes have been a welcome and necessary change, the use of transvaginal mesh has decreased significantly. Its use for prolapse is likely to continue to dwindle as is its availability from manufacturers as financial risks outpace potential gains. Many women with POP may benefit from this change given the limited number of providers capable of achieving satisfactory results with mesh. However, those providers tasked with treating the most challenging cases may struggle for options, leaving some women with little hope after failed repairs. In addition, owing to the commonality of materials, manufacturers, surgeons, and transvaginal surgical approach, the availability of synthetic midurethral slings may be in danger. Furthermore, the number of surgeons who are willing to place synthetic slings may decrease as even those with low complication rates may be intimidated by the potential for litigation if the outcome is not optimal.

Future directions

An ideal treatment for both POP and SUI would restore the function of the underlying muscles, nerves, and connective tissues without the need to implant a foreign body, which presents the risk of erosion, exposure, and lasting damage. For SUI, injection of autologous muscle-derived stem cells into the urethral sphincter has demonstrated efficacy in phase I/II trials⁴⁵ and may ultimately represent a more optimal treatment. Autologous stem cells on growth-promoting scaffolds remain in development in pre-clinical studies as a potential treatment for POP as well⁴⁶. In addition to assessing the efficacy and practicality of these methods, it will be necessary to evaluate the associated costs of using human progenitor cells for treatment of pelvic floor disorders. Synthetic mesh made from slowly absorbable (1 to 2 years) material such as poly-L-lactic acid may represent an effective, safer alternative to polypropylene mesh but at this point remains in pre-clinical development as well⁴⁷. With the medical community having learned a difficult lesson with the rapid, broad adoption of polypropylene mesh kits

and slings prior to sufficient testing and training, any new materials and the surgeons implanting them will be subject to much greater scrutiny going forward⁴.

Abbreviations

FDA, US Food and Drug Administration; POP, pelvic organ prolapse; SUI, stress urinary incontinence; TVT, transvaginal tape.

Competing interests

MK is an investigator for Cook Myosite and assists Boston Scientific in resident education. RD has worked as a consultant for Medtronic and Allergan. The other authors declare that they have no competing interests.

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The referees who approved this article are:

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- 1 **Gopal Badlani**, Department of Urology, Wake Forest University Baptist Medical Center, Winston-Salem, NC, USA
Competing Interests: No competing interests were disclosed.
- 2 **Linda Cardozo**, Urogynaecology Department, King's College London, London, SE5 9RS, UK
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