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Vaginal mesh for incontinence and/or prolapse: caution required!

'Even if the rates of these devastating complications are fairly low, they are life-changing for the patient, sometimes irreversible and often sources of litigation.'

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Incontinence and prolapse are common problems experienced by many women. Over the years, various surgical procedures have been employed to treat these conditions. Although traditional methods of repair have used the patients' own tissues, foreign materials have recently been introduced in order to increase efficacy and durability, while reducing morbidity.

These materials come from xenograft, cadaveric or synthetic sources and have been employed for vaginal prolapse repairs and pubovaginal slings. Some have been taken off the market owing to early complications [1]. However, many new products are used currently despite limited scrutiny regarding their safety and long-term efficacy. Two main reasons for the success of these meshes stem from the ease of US FDA approval and astute marketing, incorporating user friendly 'kits' requiring limited training. Currently, Prolene™ (polypropylene) is the most common synthetic material in use. Originally, it was used under the urethra as a pubovaginal sling for incontinence, but its use has now been expanded to all forms of prolapse repair, including cystocele, rectocele and vault prolapse, resulting in fairly large segments of mesh being imbedded beneath the vaginal wall.

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The advantages of a synthetic mesh to repair incontinence and/or prolapse include improved perceived durability, ease of placement, shorter operating times and quicker return to work [2,3]. However, the focus of this editorial is to open up the debate on what could be called 'the dark side of mesh.'

First and foremost, there is a lack of evidence-based data regarding the safety and efficacy of these meshes. In regard to anti-incontinence procedures using Prolene mesh, the longest published study evaluated patients 7 years after placement of a tension-free vaginal tape (TVT). In 64 patients (71% of initial cohort), the objective cure rate, based on pad test and stress test, was 81.3%. In total, 22% had urgency at 7 years. No evidence of vaginal extrusion or urethral erosion was reported [4]. However, Deng *et al.* reported, from the Manufacturer and User Facility Device Experience Database (MAUDE), 32 vascular injuries (two deaths) and 33 bowel injuries (six deaths) after placement of the TVT between 1999 and 2005 [5]. Although these numbers are very low and come from voluntary reporting, they indicate that serious complications can occur. A number of other studies reported early complications of vaginal erosions, bladder and urethral perforations and erosions (FIGURE 1), *de novo* urgency, changes in flow rate and flow pattern [6], complete obstruction and blood transfusions, to name a few, with an overall failure rate nearing 20–25%, depending on the outcome measures chosen [7–20].

The transobturator tape, a more recent anti-incontinence procedure, was marketed as safer than the TVT since the lateral wings are placed through the obturator fossa instead of

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the retropubic space, thus decreasing the chances for vascular, bowel or bladder injury. Interestingly, little is known of its long-term efficacy and several serious complications have been reported already. In a 2-year follow-up study on 130 patients, a 10% failure rate of stress urinary incontinence was reported at a mean follow-up of 16 months (range 12–24 months) [21]. Other studies have described debilitating thigh and groin pain, infections of the tape causing sinus draining or even thigh necrotizing fasciitis (FIGURE 2) [14,16,17]. Furthermore, referencing the MAUDE, there have been two voluntarily reported cases of death after the transobturator tape procedure due to vascular injury [5].

For prolapse repair, many advocate the technique of open, laparoscopic or robotic mesh sacrocolpopexy either as a primary repair or in cases of prolapse recurrence. More recently, large segments of Prolene mesh have been implanted transvaginally, raising concerns for vaginal erosions and dyspareunia. Reports of vaginal erosions after this procedure have varied from 0 to 18% with short-term follow up (FIGURE 3) [22–29]. *De novo* dyspareunia has also become a serious concern, with a recent study reporting 38% and calling for physicians to stop using Prolene mesh for repair of cystocele and rectocele [30].

When facing one of these complications, the removal of these meshes, either partially or completely, through either vaginal or combined abdominovaginal approaches, has proven to be a significant challenge. There have been reports of vesicovaginal fistulas forming after mesh removal, and a recent author reported skin grafting to bridge the remaining defect in the vaginal wall [31]. Tertiary referral centers are filling their practices with mesh removals, since these centers are often the last resort for desperate patients. Even if the rates of these devastating complications are fairly low, they are life-changing for the patient, sometimes irreversible and often sources of litigation. Many women will admit they would have lived with some incontinence or prolapse rather than experiencing chronic dyspareunia, pelvic or inguinal pain, draining fistulous tracts and many unhelpful treatments and procedures trying to relieve their symptoms.

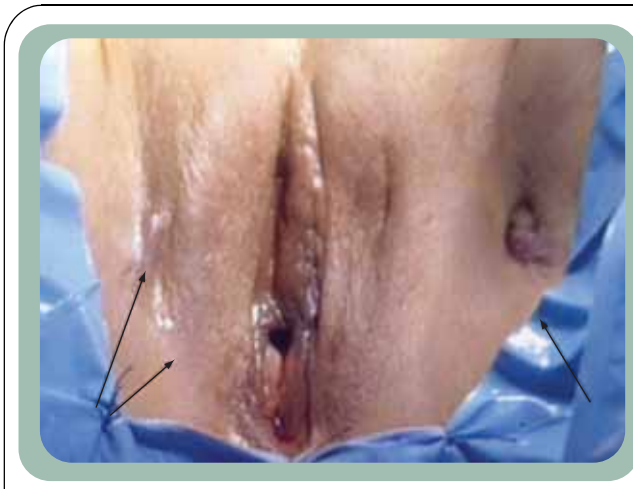

Figure 2. Patient with infected lateral wings of a transobturator tape.
The left operative site has a draining sinus for which the patient had already undergone multiple failed attempts at repair (arrow). The right operative site demonstrates a developing infection (double arrow). The wings of the tape along with the tape under the urethra were subsequently removed.

Recently, several editors have raised concerns regarding the use of synthetic materials to treat incontinence and prolapse in women. The position statement of the 3rd International Consultation on Incontinence was that there is insufficient evidence at present to make any definitive conclusions with regard to the use of prosthetic materials in prolapse surgery [32]. Likewise, the Cochrane collaboration statement regarding mesh use in prolapse surgery is that 'the evidence is not sufficient to support the use of permanent meshes or grafts at the time of vaginal repair surgery except in the context of randomized controlled clinical trials' [33]. The American College of Obstetricians and Gynecologists Committee has issued its

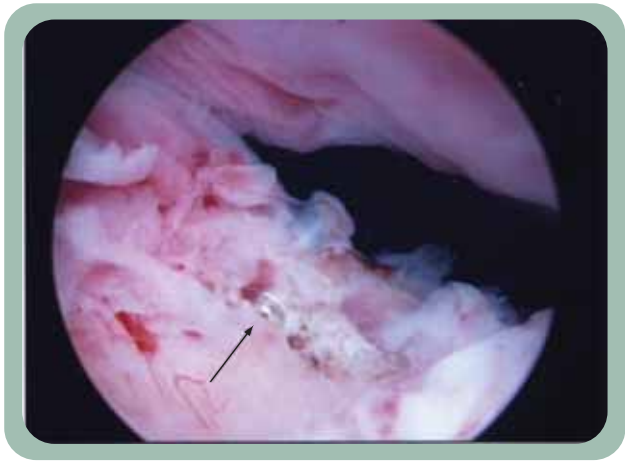

Figure 1. Cystoscopic view of mesh exposed on the floor of the urethra lumen after placement of a transvaginal tape for incontinence.
Patient presented with urge, urge incontinence, and nocturia. Mesh excision with urethral reconstruction was required.

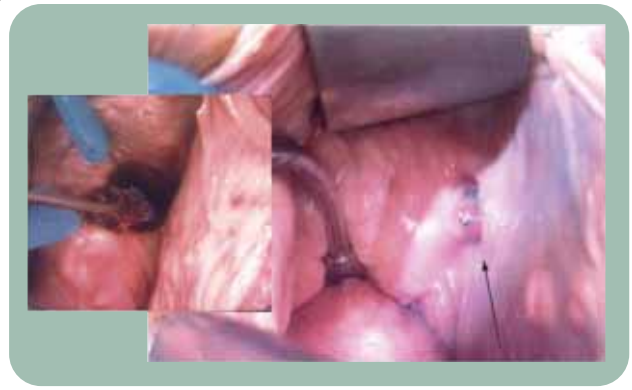

Figure 3. Vaginal erosion of mesh (arrow) after a prolapse repair using a recently marketed mesh kit.
Inset shows a clamp on a portion of the mesh after the surrounding vaginal mucosa was dissected. Patient presented with vaginal discharge, pelvic pain and dyspareunia, and required mesh removal via an abdominovaginal route.

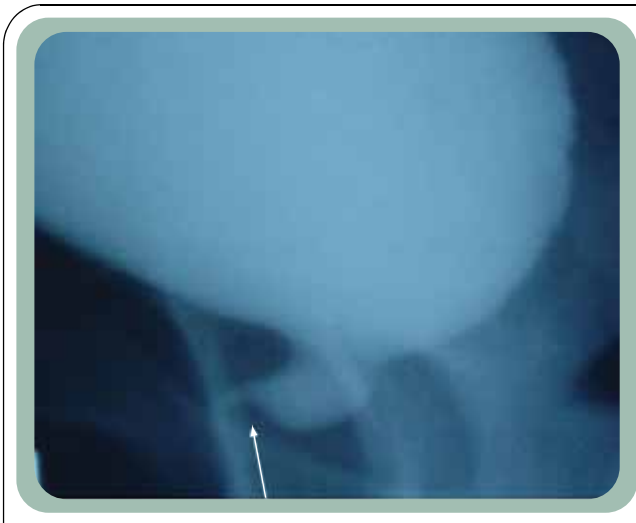

Figure 4. Lateral view during a voiding cystourethrogram demonstrating a urethral narrowing at the level of the midurethral tape (arrow) resulting in proximal urethral dilatation.
Patient presented with severe urgency and difficulty voiding after surgery.

formal statement on ethical guidelines concerning innovative practice: 'Premature adoption of innovative practices without adequate supporting evidence may promote wide acceptance of therapies that are ineffective…' and also 'may carry additional risks of morbidity in comparison with standard treatment' [34]. Donald Ostergard worried that corporate 'engineering' takes the place of a physician's clinical judgment, knowledge of anatomy and potential complications in regards to the new 'kits' for prolapse and incontinence. He advised not to let industry control how we practice medicine: 'What industry is interested in is the fact that there are billions of dollars to be made from the sales of synthetic prolapse repair materials and the kits to perform the surgical procedure that accompany them'. He also questioned the current mechanism for FDA approval of new devices, given that this approval is only for the device and not for the surgical procedures efficacy or safety [35]. Likewise, Ingrid Nygaard reported on widespread concern that surfaced at the 2006 annual American Urogynecologic Society meeting regarding the use of devices for prolapse: 'It is irresponsible to start using devices that have not yet undergone any substantial clinical testing' [36]. As evidenced previously, we are not alone in our concerns regarding the rampant use of vaginal mesh in pelvic floor reconstruction.

We still do not understand how aging vaginal tissues, which become atrophied and thin as the hormonal milieu changes, will respond to a synthetic material just under their surface. The vaginal wall is different from the abdominal wall. This obvious fact should be kept under utmost consideration in younger women and in those desiring to remain sexually active. For the midurethral tape, we have observed some delayed onset of urge and urge incontinence symptoms owing to a kinking effect in the midurethra with proximal urethral and bladder neck ballooning (FIGURE 4). Removal of the tape does not always result in an improvement in bladder dysfunction [37]. This is not the only unforeseen complication. Midurethral compression from the tape can lead to ischemia resulting in a permanently scarred and narrowed urethral lumen after tape excision (FIGURE 5). For pelvic organ prolapse, meshes placed abdominally were always away from the trigone. However, vaginal meshes to repair cystoceles are placed directly under the trigone. Erosions into the bladder could mandate excision of the trigone with reimplantation of the ureters. In addition, ureteric injuries could occur during mesh removal performed transvaginally. Other concerns are that these permanent materials may move over time and become exposed in the urinary tract, cause pain or trigger bladder dysfunction.

In conclusion, we are forced to recognize that there is no current mid- or long-term data on the efficacy and safety of vaginal meshes for prolapse. When a new drug is introduced onto the market and receives FDA approval, several safety and efficacy trials (Phase I–IV) have already taken place. Such a mechanism does not exist to test new surgical devices.

As a group, we must demand higher standards and not agree to use a product based on small, short studies published without peer review. We cannot simply jump on the 'bandwagon' and not think for ourselves. A procedure that seems simple, easy to perform and profitable today may have long-term consequences for our patients that we could never defend.

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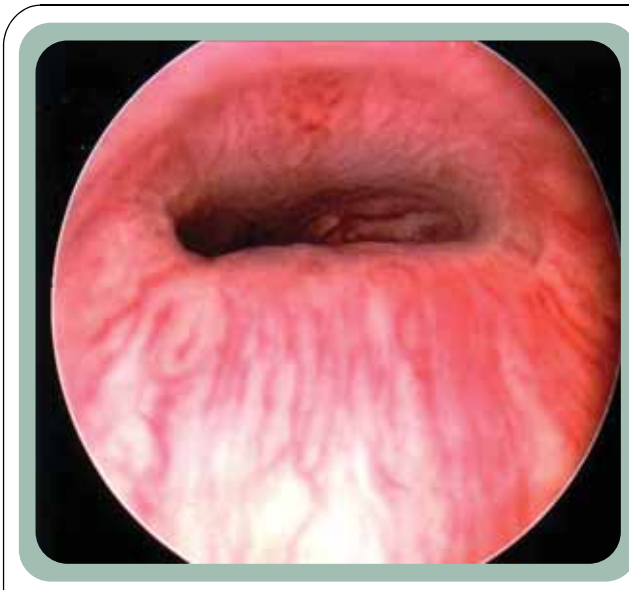

Figure 5. Cystoscopic view of urethra several months after removal of suburethral mesh demonstrating a narrowed midurethral lumen from intramural scar.
Patient complained of recurrent bladder infections and slower stream.

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