**Time to Rethink: an Evidence-Based Response from Pelvic Surgeons to the "FDA Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse"**

## Introduction

This manuscript is being written in response to the recent Safety Communication UPDATE from the FDA regarding the use of **t**rans**v**aginal placement of surgical **m**esh (TVM) for pelvic organ prolapse (POP). The authors of this response recognize the events that have led to the FDA undertaking their review and agree with many of the points covered in the FDA's Safety Communication. However, we have some significant disagreement with the conclusions reached and concerns regarding the message that it is sending to our patients, the healthcare community, and unfortunately to the legal community as well. The authors of this manuscript are physicians who have dedicated their professional careers to the gynecologic care of women and many of us are specialists in the treatment of pelvic prolapse and urinary incontinence. We have divided our response into sections mirroring the format of the FDA UPDATE.

## Regarding the Section of the UPDATE Entitled "Purpose"

In the UPDATE the FDA states, "The FDA is issuing this update to inform you that serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**." The FDA NEWS RELEASE that accompanied the UPDATE states that in 2010 "at least 100,000 POP repairs that used surgical mesh" were performed and "about 75,000 of these were transvaginal procedures." This statement suggests that at least 225,000 TVM procedures are done in a 3-year period. In the 3-year period that this update addresses there were "1,503 reports associated with POP repairs." Using these numbers the incidence of these reported complications is 0.67% (and the incidence may be even lower for TVM given that the news release states that "the reports don't always differentiate between transvaginal and abdominal procedures"). We understand that these 1503 reports represent a significant increase from the number of reports received prior to the 2008 Public Health Notification, but we believe that this does not represent an increase in the **rate** of complications; rather it is a reflection of the wide acceptance of TVM by many specialists in POP surgery and an increase in the overall rate of how often these procedures are being performed.

We also realize that many complications of TVM go unreported to the MAUDE database and that the risk of complication with TVM is higher than 0.67%. However, the UPDATE

implies that this risk of complication is higher than with native tissue repairs. Surgeons who perform native tissue repairs know that the risk of complications is certainly not <1%. In fact, when one of the "gold standard" native tissue repair techniques (the uterosacral ligament suspension) was first described, the risk of ureteral injury alone was 11%.[1] Since no FDA-monitored device is used in this and other native tissue repairs, it is difficult to know how many similar complications would be reported to the FDA if an alternative reporting mechanism were in place. Thus we find the assertion stated as the purpose of the UPDATE, that TVM "may expose patients to greater risk" than traditional non-mesh repairs is not properly qualified and may be misleading to non-clinicians. We propose that more accurate conclusion would acknowledge that although the risk of mesh-specific risks are certainly higher with TVM than native tissue repairs, the assessment 'overall' risks of TVM versus a non-mesh repair involves a complex set of considerations including the potential risks posed by repeat prolapse operations (for instance, in cases of native tissue repair failure) and the non-trivial baseline risks associated with native tissue repairs.

These comments are not intended, in any fashion, to minimize the importance of any surgical complication regardless of its precise prevalence; as surgeons caring for women each day, we are keenly aware of the gravity of adverse outcomes. We do, however, wish to highlight a fundamental reality within our daily surgical practices that we believe is not reflected or acknowledged in the current FDA verbiage: that is, in the surgical management of advanced prolapse, all treatment options involve significant risks. We are deeply concerned that the UPDATE portrays transvaginal mesh repairs as uniquely hazardous, providing no broader perspective (quantitatively or qualitatively) regarding the significant risks and/or higher recurrence rates associated with its alternatives. This introduces a huge clinical dilemma, and unjustified medical-legal exposure, for well-trained surgeons serving the vast 'denominator' of women undergoing mesh procedures and and observing high rates of patient satisfaction. The importance and value of both abdominal and vaginal mesh augmentation techniques in these surgeons' hands, as an option for women with severe prolapse who are seeking a durable, long-term solution, must not be taken for granted or our surgical field will suffer a significant setback.

**The "Summary of Problem and Scope" of the UPDATE**

This portion of the UPDATE focuses on a systematic review of the literature published between 1996 -2011 by the FDA. While it is unclear exactly which studies were reviewed, by whom, and when in 2011 the review was concluded, it is clear that an analysis of the randomized controlled trials (RCT's) and other large descriptive studies published during this time period can

lead to significantly different conclusions than were drawn by the FDA. In particular, the literature review led the FDA to draw four specific conclusions that we would like to address.

**"Mesh used in transvaginal POP repair introduces risks not present in traditional non-mesh surgery for POP repair."**

The UPDATE lists the following complications that have been reported to the FDA for TVM: mesh erosion, pain, infection, bleeding, pain during intercourse, organ perforation, and urinary problems. These risks do exist and any patient who is considering a TVM surgery should be aware of them. They should also be aware that with the exception of mesh erosion, these are all risks of traditional non-mesh surgery as well. Furthermore, the risk of mesh erosion exists regardless of how or why the mesh is placed (i.e. abdominally for POP repair or transvaginally for repair of urinary incontinence). This point could be more accurately stated as, "The risk of mesh erosion is unique to repairs utilizing mesh, and does not exist in traditional non-mesh pelvic surgery." The current statement as presently written implies that there are **multiple** risks of TVM that do not exist with traditional repairs. This is not accurate and is misleading to the public.

**"Mesh placed abdominally for POP repair appears to result in lower rates of mesh complications compared to transvaginal POP surgery with mesh."**

There is no question that mesh placed abdominally in the form of an abdominal sacral colpopexy (ASC) is an excellent procedure for treating POP. In the only published RCT comparing ASC to TVM, the authors failed to find a statistically significant difference in the rate of mesh erosion (they also failed to show a difference in quality of life measures).[2] However, most surgeons would agree that the risk of mesh erosion, in general, is higher when placed through the vaginal approach. In a comprehensive review of ASC, the authors report a 3.4% rate of mesh erosion,[3] while in a similar review of TVM a rate of 10.3% was found.[4] However, it should be noted that surgical technique appears to play a significant role in the rate of mesh erosion as these rates varied greatly between studies especially with TVM review, where the rate varied from 0 – 29.7%. In fact, in one multicenter RCT of TVM, the rate of erosion between sites ranged from 0 – 100%.[5] Since the same mesh and delivery system were used, one can assume that this variation is not a function of the mesh but in surgical technique. We believe the FDA understands that the mesh surgeons use abdominally is the fundamentally the same (and in many cases is **exactly** the same) as the mesh used transvaginally for prolapse repair, but we feel that the UPDATE does not communicate this clearly to the public.

Mesh complications are certainly not the only complication patients are at risk for when undergoing surgical repair of POP. While the risk of mesh erosion may be higher when placed vaginally, the risk of complications involving the abdominal wall (i.e. incisional hernia) and small bowel are almost certainly higher with ASC since the peritoneal cavity is traditionally not entered with TVM. Secondary analysis of one large RCT of ASC[6] concluded that one in 20 women experiences significant gastrointestinal morbidity after ASC. More than half of most mesh exposures from TVM are asymptomatic and only one third need minor out-patient operative intervention.[5] However, a small bowel obstruction following an open abdominal sacral colpopexy may require a second laparotomy and a prolonged in-patient admission. Thus while the rates of "complication" may be higher with TVM, the severity of the complications associated with ASC may be greater.

The UPDATE states that TVM does not improve quality of life outcomes over traditional non-mesh repair. Later in this response we will assert that this statement is inaccurate given recently published data. But if the data the FDA reviewed failed to show a difference in quality of life, this is most likely because it was not the primary outcome and the studies were not powered to find differences in secondary outcomes. Large numbers of subjects are needed to show such differences, and studies of ASC also fail to show a difference in these important secondary outcomes. While ASC is considered by many to be the "gold standard" procedure for POP; a recent Cochrane review[7] shows that there are only three published RCT's[8-10] comparing ASC to traditional non-mesh repair. Only one of these trials compared outcomes using validated quality of life instruments, and no difference in subjective success was noted.[10]

We want to underscore that we are not trying to imply that traditional non-mesh repair and ASC are unsafe or ineffective procedures, we are simply suggesting that this singling out of TVM by the FDA seems arbitrary based on a lack of reporting systems for the other procedures. The FDA may be sending out an inaccurate message to the public that the risk/benefit ratio of TVM is significantly worse than the other surgical options. By doing so, this UPDATE may steer individuals away from a surgical option that in **their individual case** with **their unique surgeon** may be the best option.

**"There is no evidence that transvaginal repair to support the top of the vagina (apical repair) or the back wall of the vagina (posterior repair) with mesh provides any added benefit compared to traditional surgery without mesh."**

We agree that there is a relative paucity of comparative data regarding apical and posterior support with TVM, but feel that this issue is more complex than this statement implies. Of eight[5,11-19*] RCT's of TVM (using non-absorbable mesh) vs non-mesh traditional surgery,

only three were designed to investigate the apex as an outcome. All three failed to show a difference in the apex, but they also all lacked the statistical power to confirm that this failure was not the result of a type II error. One study[17] was halted prior to reaching the necessary sample size, another[16] only had 14 subjects in the TVM arm, and the third[5] which was studying multiple compartments failed to reach the necessary sample size for apical defects.

Anatomic failure in the apical compartment is also much less common than in the anterior and posterior compartments due to eccentricities of the Pelvic Organ Prolapse Quantification (POP-Q) system. With the POP-Q system, the anterior and posterior walls only have to descend 2-3 cm to be considered failure, whereas the apex has to descend 7 -10 cm (depending on vaginal length), thus making apical failures rare. In fact, of the 287 subjects in these three trials, only 6 (2%) had apical failures. Therefore, apical failure, as defined by the POP-Q, is not a very useful parameter to assess the anatomic success of a POP procedure.

In regards to the posterior wall, again we agree that there is less data available compared to the anterior wall. Of the above-mentioned eight RCT's only three[5,15,17] were designed to investigate the posterior compartment as an outcome (but it was not the primary outcome measure in any of the them). In one study[17] recruitment was halted prior to reaching the necessary sample size. In another, the success rate in the mesh group was 81.0% compared with 65.6% of the non-mesh group (P = 0.07) which trended towards a significant difference.[15] And contrary to the FDA's UPDATE, a recently published study of recurrent prolapse repair[5] did, in fact, show superiority of mesh over non-mesh repairs in the posterior wall at one year of follow-up (4.1% failure in the mesh vs 24.5% in the non-mesh group, P = 0.003).

Lastly, many TVM procedures use the repair of the posterior compartment as a means to access the sacrospinous ligaments in order to establish apical support. Therefore, patients who have a severe POP defect that involves the anterior **and apical** compartments, more so than the posterior compartment, may still need the posteriorly placed mesh to best re-support the apical compartment in an effort to minimize overall recurrence.

**"While transvaginal surgical repair to correct weakened tissue between the bladder and vagina (anterior repair) with mesh augmentation may provide an anatomic benefit compared to traditional POP repair without mesh, this anatomic benefit may not result in better symptomatic results."**

The primary outcome of six[11-15,17-18*] of the seven[11-15,17-19*] existing RCT's on TVM versus traditional POP repair involving the anterior compartment was anatomic cure. Of these six trials, only one failed to show superior anatomic correction of the anterior wall. In this study

of anterior and posterior colporrhaphy the success rate in the mesh group 15% higher in the mesh group, but this failed to reach statistical significance (81.0% success vs 65.6% of the non-mesh group, P = 0.07).[15] These studies were not designed to detect differences in subjective (symptomatic) outcomes. To downplay the superior anatomic results found in these trials, is to do a disservice to the nearly1200 women who were willing to further the science of our field by entering a randomized trial.

To detect statistically significant differences in symptoms at just one year after surgery requires different study parameters than a study designed to detect differences in anatomic results. The only study of the seven RCT's that used a composite **primary** outcome of anatomic and symptomatic results did show a difference in both outcomes.[19] This trial randomized 410 subjects (twice as many subjects as the next largest study) to TVM versus standard anterior colporrhaphy. The composite primary outcome showed superior results for TVM at 2 months and at 1 year. The symptom of vaginal bulge between groups was not different at 2 months, but at 1 year, 37.9% of the colporrhaphy group versus only 24.6% of the TVM felt symptomatic bulging (P = 0.008).

In the next largest study (again one not powered to detect symptomatic differences), 202 women were randomized to TVM vs colporrhaphy without mesh, and at one year anatomic cure rates were different but symptomatic results were not.[11] At two year follow-up, the sensation of vaginal bulge was lower in the TVM group (P = 0.02).[14] By three year follow-up, attrition had decreased the sample size to 180, and while nearly twice as many women in the colporrhaphy group had symptoms of vaginal bulging (19% vs 10%, P = 0.07), this difference was no longer statistically significant.[18] But again, given the fact that this was a secondary outcome, failure to find a statistically significant difference is not the same as concluding that there is no difference in symptomatic results.

Using Quality of life measures as the sole outcome variable in a surgical trial will overestimate long term success and blunt our ability to interpret differences between procedures. Surgical RCT's are inherently difficult to maintain over a long number of years without substantial drop out, and anatomic measures are therefore the best surrogate for success. Patients with incipient failure do not report drop off in quality of life without a significant lag. While not all anatomic failures will go on to symptomatic failure, it is highly probable that if one arm of the study has significantly greater number of deficient anatomic results, it will be the arm of the study with eventual greater number of failures.

We therefore agree with the portion of the UPDATE that states, "mesh augmentation may provide an anatomic benefit compared to traditional POP repair without mesh" – but we find the statement, "this anatomic benefit may not result in better symptomatic results" highly

questionable. Given the latest data, it would be equally true to state, "this anatomical benefit *may* result in better symptomatic results."

Since the FDA's UPDATE does not cite its sources, we are unsure if all this data was available when the UPDATE was drafted. We hope the FDA will review the investigations currently available and reconsider this statement since it is unsupported by the evidence and contrary to the clinical findings of many pelvic surgeons in this country.

***Erosion***

We agree with the UPDATE's message that mesh erosion is a potential complication of TVM. We do, however, feel that is quite rare that "even multiple surgeries will not resolve the complication." We are unaware of any published case reports in which mesh erosion from TVM does not resolve after more than two returns to the operating room. Chronic pain after TVM may be difficult to resolve despite multiple surgeries, but chronic post-operative pain is a risk with non-mesh repairs as well and can also be difficult to resolve.

Few subspecialists in the treatment of POP would argue that there are not some clinical scenarios (i.e. severe or recurrent prolapse) in which some type of graft-based repair is necessary – whether that be done in a transvaginal or transabdominal approach. The risk of mesh erosion might be higher with TVM, but when you look at two large, multicenter trials conducted by surgeons who perform the index surgery on a regular basis, the results of the abdominal and vaginal approach are quite similar. In the TVM trial that randomized over 400 subjects, at 12 months 3.2% had undergone a procedure to correct mesh exposure.[19] In a well-know RCT of 322 women undergoing abdominal reconstruction with mesh, the erosion rate at 12 months was 4.3%.[20] We cannot emphasize enough that we are not attempting to denigrate sacral colpopexy in anyway. We are simply pointing out that mesh erosion is a risk any time mesh is used in reconstructive pelvic surgery and that surgical experience and technique play a significant role in the risk of erosion.

***Mesh Shrinkage, Pelvic Pain, and Pain with Intercourse***

The UPDATE refers to mesh contraction (shrinkage) as a previously unidentified risk of TVM. This is a controversial topic within our subspecialty. Animal models do suggest that some contraction of the mesh over time can occur, but until *in vivo* explant studies demonstrate it conclusively, the best we can do is look at imaging studies of TVM patients and compare the

effect of TVM versus traditional non-mesh repairs on vaginal length, pelvic pain, and pain with intercourse (dyspareunia).

Analysis of translabial 4-dimensional ultrasounds of forty patients who underwent anterior mesh procedures showed no evidence of mesh contraction between their first and last postoperative visits.[21] On the contrary, midsagittal mesh length at rest and on Valsalva increased by almost 10% over a period of 18 months on average.

In terms of clinical results, all but one[15] of the eight RCT's of TVM[5,11-14,16-19*] measured pre- and post-operative vaginal length. None of these showed any difference in the change in vaginal length after surgery between the mesh and non-mesh arms of the studies. If there is shrinkage with TVM, it does not appear to affect vaginal length anymore than does the trimming of the vaginal wall during standard colporrhaphy with native tissue.

None of these trials had standardized measures to assess chronic post-operative pelvic pain, and none reported any anecdotal reports of greater pelvic pain in the TVM group. Sexual function and de novo dyspareunia were much more systematically measured, often with a validated, domain-specific questionnaire, the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12). One of the eight studies did not assess sexual function.[16] The remaining seven did assess sexual function; and in one, the dyspareunia score was significantly worse in the no-mesh group at two years out.[14] In the others, no difference in sexual function was noted between the TVM and traditional repair groups.[5,12,13,15, 17-19]

**Recommendations to Health Care Providers from the FDA**

We agree with and support the majority of these recommendations in principle. However, we feel that the recommendations regarding the permanency of mesh and the risk of erosion apply to the placement of mesh regardless of whether it is being placed transvaginally or transabdominally and they apply to the use of mesh to treat urinary incontinence as well. We also feel, based on our clinical experience and our review of the literature listed above, that the remainder of the recommendations (i.e. "Inform patients about the potential for serious complications and their effect on quality of life, including pain during sexual intercourse, scarring, and narrowing of the vaginal wall in POP repair…") apply to traditional non-mesh repairs as well. The inclusion of language making that clear would increase its accuracy, fairness, and assist in avoiding the unintended consequence of increased liability. One of the additional recommendations new to the 2011 UPDATE in particular is misleading:

- Recognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications.

This validity of this recommendation depends on how "most cases" is being defined. Studies show that, in many cases, traditional POP repairs have high rates of failure.[22,23] Factors such as patient age and severity of prolapse[24] can affect the chance of prolapse recurrence and should be taken into account when counseling patients. We agree that POP can be successfully without mesh in **many** cases, but not necessarily **most**. At the very least, a statement clarifying that success in treating anterior compartment and recurrent prolapse may be more likely with the use of mesh, would lend balance to the FDA's communication.

We would also like to comment on one of the other new recommendations to health care providers in the 2011 UPDATE:

- Ensure that the patient understands the postoperative risks and complications of mesh surgery as well as limited long-term outcomes data.

We agree with this statement, but would add that there is limited long-term data on all forms of prolapse repair. We would add that the limited long-term data that does exist on non-mesh repairs suggests a relatively high failure rate. Finally, there is long-term data on the transvaginal placement of mesh for urinary incontinence that does not show any untoward effects of mesh long-term that were not present in the short-term.[25]

## Conclusion

The FDA is in a challenging position. We recognize its mission to monitor manufactured devices in pelvic surgery and to advocate for patients' safety and best interests. Surgical procedures are more difficult to compare than pharmaceuticals because they are dependent on the judgment and skills of the operator. This issue is also challenging because there is not just one type of patient. The fundamental flaw in the FDA's analysis is that it is based on the question of proof of superiority of mesh in **all** patients. No one is suggesting that mesh is recommended in all patients. However, surgeons will often recommend it to their patients when they suspect that a native tissue repair will have a higher risk of failure and when they feel that the potential benefits of a mesh repair outweigh the risks.

The purpose of our response to the FDA UPDATE is not to assert that TVM is better than traditional non-mesh surgery for POP in all cases. Our purpose is to demonstrate, based on our years of experience *and* critical review of the literature, that TVM is an important tool in our surgical armamentarium that may be the best option in some cases. From our vantage point, it appears that the FDA has presented a biased view of TVM among all POP repair procedures because of the current reporting mechanisms in place. We understand and applaud the FDA for stepping in when it appears that the welfare of women with POP may be suffering. However, in

our opinion, some of the statements made in the UPDATE could also contribute to further suffering by depriving our patients of surgical options that may be in their best interest.

In summary we believe:

1. The FDA should more accurately reflect the reality that in the surgical management of advanced prolapse, all treatment options involve risks. The UPDATE portrays transvaginal mesh repairs as uniquely hazardous, providing no broader context regarding the significant risks and/or higher recurrence rates associated with its alternatives. There is ample published evidence (arguably more robust for TVM than its alternatives) upon which physicians and patients can have a detailed informed consent process leading to an individualized decision.

2. Training guidelines and credentialing criteria lie at the core of these reported complications and need to be better defined as a collaborative effort between societies, hospital systems, and the medical device industry.

3. Transvaginal mesh, when used judiciously in experienced hands, is an essential tool for a large number of expert, high-volume surgeons, only a fraction of which have co-signed this document. All of the co-signed surgeons are committed, above all else, to advancing the safest and most effective surgical procedures. We are deeply concerned that the current process could, as an unintended consequence result in a major setback to those core goals for many providers successfully utilizing mesh and observing high rates of satisfaction and superior outcomes. This large segment of highly dedicated surgeons, using mesh in a thoughtful and selective manner in properly counseled patients, could suffer unjustified and arbitrary medical-legal exposure if the current process fails to incorporate a full and accurate perspective on these complex issues and challenging surgical conditions that we treat on a daily basis.

**References**

1. Barber MD, et al. Bilateral uterosacral ligament vaginal vault suspension with site-specific endopelvic fascia defect repair for treatment of pelvic organ prolapse. Am J Obstet Gynecol 2000;183:1402-11.

2. Maher CF, et al. Laparoscopic sacral colpopexy versus total vaginal mesh for vaginal vault prolapsed: a randomized trial. Am J Obstet Gynecol 2011;204:360.e1-7.

3. Nygaard IE, et al. Abdominal sacrocolpopexy: a comprehensive review. Obstet Gynecol 2004;104(4):805-23.

4. Abed H, et al. Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapsed repair with graft materials: a systematic review. Int Urogynecol J 2011;22:789-98.

5. Withagen MI, et al. Trocar-guided mesh compared with conventional vaginal repair in recurrent prolapsed: a randomized controlled trial. Obstet Gynecol 2011;117(2):242-50.

6. Whitehead WE, et al. Gastrointestinal complications following abdominal sacrocolpopexy for advanced pelvic organ prolapsed. Am J Obstet Gynecol 2007;197:78.e1-78.e7.

7. Maher C, et al. Surgical management of pelvic organ prolapse in women. Cochrane Database of Systematic Reviews. (4):CD004014, 2010.

8. Benson JT, et al. Vaginal versus abdominal reconstructive surgery for the treatment of pelvic support defects: a prospective randomized study with long-term outcome evaluation. Am J Obstet Gynecol 1996;175(6):1418-21.

9. Lo TS, et al. Abdominal colposacropexy and sacrospinous colpopexy for vaginal vault prolapsed: a prospective randomized study. J Gynecol Surg 1998;14(2):59-64.

10. Maher CF, et al. Abdominal sacral colpopexy or vaginal sacrospinous colpopexy for vaginal vault prolapsed: a prospective randomized study. Am J Obstet Gynecol 2004;190:20-6.

11. Hiltunen R, et al. Low-weight polypropylene mesh for anterior vaginal wall prolapse: a randomized controlled trial. Obstet Gynecol 2007;110(2):455-62.

12. Sivaslioglu AA, et al. A randomized comparison of polypropylene mesh surgery awith site-specific surgery in the treatment of cystocele. Int Urogynecol J 2008;19:467-71.

13. Nguyen JN, et al. Outcome after anterior vaginal prolapse repair: a randomized controlled trial. Obstet Gynecol 2008;111(4):891-8.

14. Nieminen K, et al. Symptom resolution and sexual function after anterior vaginal wall repair with or without polypropylene mesh. Int Urogynecol J 2008;19:1611-6.

15. Carey M, et al. Vaginal repair with mesh versus colporrhaphy for prolapse: a randomised controlled trial. BJOG 2009;116(10):1380-6.

16. Lopes ED, et al. Transvaginal polypropylene mesh versus sacrospinous ligament fixation for the treatment of uterine prolapse: 1-year follow-up of a randomized controlled trial. Int Urogynecol J 2010;21:389-94.

17. Iglesia CB, et al. Vaginal mesh for prolapse: a randomized controlled trial. Obstet Gynecol 2010;116(2):293-303.

18. Nieminen K, et al. Outcomes after anterior vaginal wall repair with mesh: a randomized, controlled trial with a 3 year follow-up. Am J Obstet Gynecol 2010;203:235.e1-8.

19. Altman D, et al. Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse. N Engl J Med 2011;364(19):1826-36.

20. Brubaker L, et al. Two-year outcomes after sacrocolpopexy with and without Burch to prevent stress urinary incontinence. Obstet Gynecol 2008;112(1):49-55.

21. Deitz HP, et al. Mesh contraction: myth or reality? Am J Obstet Gynecol 2011;204:173.e1-4.

22. Olsen AL, et al. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. Obstet Gynecol 1997;89:501-6.

23. Clark AL, et al. Epidemiologic evaluation of reoperation for surgically treated pelvic organ prolapse and urinary incontinence. Am J Obstet Gynecol 2003;189:1261-7.

24. Whiteside JL, et al. Risk factors for prolapse recurrence after vaginal repair. Am J Obstet Gynecol 2004;191:1533-8.

25. Nilsson CG, et al. Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence. Int Urogynecol J 2008;19(8):1043-7.

*References 11, 14, and 18 report on the same RCT at three different lengths of follow-up.