



Are Synthetic Slings for Stress Urinary Incontinence Safe?

Bela Kudish^{1*} and Alexander Geoffrey Anderson²

¹*Urogynecology center for women, Florida Hospital, Florida, USA*

²*Fourth year medical student, University of central Florida, Florida, USA*

***Corresponding author: Bela Kudish, Urogynecology center for women, Florida Hospital, 2415 North Orange Ave, Orlando, FL 32804, USA, E-mail: belakudish@gmail.com**

Urinary incontinence affects millions of women worldwide and is as common as hypertension, depression, or diabetes, with the prevalence estimated between 10 and 77% [1,2]. The urinary incontinence rates vary by race or ethnicity and by age. Among the various types of urinary incontinence, bothersome stress urinary incontinence is reported to occur in 15% of women, arising commonly after a vaginal delivery, with urge urinary incontinence/overactive bladder disease found in 11% and mixed urinary incontinence in up to 36% of women after the menopause [3-5]. In the United States, stress urinary incontinence can be diagnosed in up to 35% of women with the highest incidence in women ages 45 to 49 [6,7]. Not only does it create physical health problems, but it is also a costly disorder mentally and monetarily negatively impacting women's quality of life. Urinary incontinence may be associated with a higher level of shame than depression or cancer [8]. Therefore, restoration of continence is one of the greatest challenges to improve well-being and quality of life in women suffering from this disorder. Until recently, only traditional procedures were available for the treatment of women suffering from stress urinary incontinence. These traditional interventions consist of pubovaginal slings that involve harvesting autologous material to place a sling under the bladder neck or burch urethropexy that involves suturing periurethral vaginal tissue to Cooper's ligament, a retro pubic structure. Compared to midurethral slings, these traditional procedures usually result in having larger incisions, potential higher risks for major surgery complications, such as wound infections, hematomas, or venous thromboembolic events, longer hospital stay, and longer recovery with taking longer time off work. With invent of minimally invasive approaches to the treatment of stress urinary incontinence, midurethral slings offer a practical alternative to the traditional anti-incontinence procedures.

Synthetic mesh has been used for the treatment of stress urinary incontinence since the 1960s with midurethral slings being rapidly adopted by the mid-1990s [9]. These procedures utilize a narrow 1 cm mesh strip composed of monofilament polypropylene placed through the vagina under the mid-urethral region exiting from two small incisions in either the suprapubic or groin areas. There are several different types of mesh slings, which vary based on the location and include retropubic and transobturator approaches. These slings are less traumatic, done in a tension-free manner to achieve continence minimizing any urethral obstruction, simpler, rapid, and easily reproducible compared to traditional surgical interventions [10]. Mesh sling surgeries are performed mostly on an outpatient basis achieving same day results of continence. They

have been reported to be successful in approximately 70 to 80 percent of women at one year with a slight decline in success to up to 60 to 70% following the implantation in the next 5 to 10 yrs. Similar effectiveness outcomes are reported following non-mesh stress urinary incontinence surgeries [11]. As a result, synthetic midurethral slings have replaced traditional, frequently more invasive procedures in women with stress urinary incontinence who fail conservative medical management, such as pelvic floor physical therapy and/or incontinence pessary devices, or who prefer a surgical intervention.

Since the mid-1990s, the number of women undergoing midurethral sling procedures have been growing rapidly. The best data on the use of these procedures comes from Europe because in the United States the surgical coding does not distinguish between different types of slings. By 2014, 13,500 women annually underwent midurethral slings in the United Kingdom [12]. In the United States, despite the 2011 FDA warning, 99% of the members of the American Urogynecologic Society continue to use midurethral slings for the treatment of stress urinary incontinence [13]. From 2005 to 2013, 3.6 million midurethral slings were sold. Worldwide midurethral slings are now considered to be the standard of care for the treatment of stress urinary incontinence. As a result, the research community is no longer interested in comparing these multi-incision slings to traditional procedures, but instead it is interested in investigating new modifications of the slings. More recently single-incision midurethral slings have been introduced as an alternative to full-length midurethral slings and are undergoing an investigation to evaluate their safety and effectiveness. The single incision slings appear to be associated with a lower risk of groin pain, lower mesh burden, and a quicker recovery, but the adverse events, such as vaginal mesh perforations, mesh erosion, and urinary retention are still present. Therefore, given the limited data from randomized controlled trials, mini-slings are a part of an ongoing investigation into their long-term effectiveness comparing them to the original multi-incision midurethral slings.

For the first time synthetic midurethral slings came under intense scrutiny by the public in 2008 when the US Food and Drug Administration (FDA) released a public health notification regarding the use of transvaginal mesh in the repair of pelvic organ prolapse and stress urinary incontinence [14]. Between the years of 2005 and 2008, FDA received over 1,000 reports of complications associated with the use of surgical mesh primarily for vaginal prolapse repairs into the FDA Manufacturer and User Facility Device Experience

(MAUDE) database. These reports included mesh erosion through the vaginal epithelium, infections, pain, urinary problems, and recurrence or worsening of prolapse or incontinence. The notification recommended cautious use of such products and vigilant monitoring postoperatively for complications. The FDA announcement has stirred significant controversy and has been met with concern in and outside the medical community. It has also been accompanied by the profound public confusion over the benefits and risks associated with mesh slings versus surgical mesh used transvaginally for prolapse repair.

In 2011 FDA released another Safety Communication “Urogynecologic Surgical Mesh: Update on Safety and effectiveness of Vaginal Placement for Pelvic Organ Prolapse,” explicitly stating that “the FDA continues to evaluate the effects of using surgical mesh for the treatment of stress urinary incontinence and will report about that usage at a later date” [15,16]. Currently the FDA website maintains that “the safety and effectiveness of multi-incision slings is well-established in clinical trials that followed patients for up to one-year” [17]. Analysis of the scientific literature reveals that among established stress urinary incontinence surgeries, the slings have been studied as long in follow-up as any other procedure and have demonstrated superior safety and efficacy [18]. The durability of the midurethral sling procedure has been demonstrated at 17 years after the sling implantation [18]. European agencies responsible for public safety have also distinguished between meshes used to treat stress urinary incontinence and those used in transvaginal prolapse mesh repairs. The European Commission Scientific Committee on Emerging and Newly Identified Health Risks concluded in their manuscript, “The available evidence suggests a higher morbidity in treating pelvic organ prolapse (POP), which uses a much larger amount of mesh compared to stress urinary incontinence. When assessing synthetic mesh risks, there is a need to clearly distinguish between the risks associated with stress urinary incontinence sling surgery and those of POP mesh surgery. ...synthetic sling stress urinary incontinence surgery is an accepted procedure with proven efficacy and safety in the majority of patients with moderate to severe stress urinary incontinence, when used by an experienced and appropriately trained surgeon” [19]. In the most recent 2015 Cochrane review of the midurethral sling operations, the authors conclude that “Mid-urethral sling operations have been the most extensively researched surgical treatment for stress urinary incontinence in women and have a good safety profile. Irrespective of the routes traversed, they are highly effective in the short and medium term, and accruing evidence demonstrates their effectiveness in the long term” [20].

Surgical mesh is used for different urogynecologic procedures, such as transvaginal and transabdominal mesh repairs for pelvic organ prolapse and mesh slings for stress urinary incontinence. FDA emphasizes to the public that “each of these procedures has unique risks and benefits and it is important not to confuse the procedures and the risks and benefits” [15]. With over 2000 scientific publications on the treatment using midurethral slings for SUI, these procedures have been studied in almost all types of patients, with and without comorbidities, and all types of SUI [20]. Time after time multiple randomized, controlled trials comparing different types of midurethral slings, as well as comparing these slings to other traditional non-mesh stress urinary incontinence procedures, have demonstrated their effectiveness and high patient satisfaction with low complication rate comparable to non-mesh surgeries for stress urinary incontinence with the exception of mesh erosion of 2%, a unique complication of midurethral slings [18,20].

A recent 2015 JAMA publication by Welk et al. provides additional evidence on the safety of midurethral synthetic slings in experienced surgeon’s hands [21]. The authors investigated the incidence of mesh sling removal or revision after stress urinary incontinence procedures in a population-based retrospective cohort study that included all adult women (59,887) undergoing an incident procedure for stress urinary incontinence with synthetic mesh in Ontario, Canada, over a 10-year period. The primary outcome was surgical procedures related

to removal and revision of mesh slings due to erosion, fistula, pain or retention. Complication rates of high-volume ($\geq 75^{\text{th}}$ percentile for mesh implants in a given year) and low-volume ($< 75^{\text{th}}$ percentile for mesh implants in a given year) surgeons were also compared. Over this study period, 1307 (2.2%, with cumulative incidence rate of 3.29% at 10 years) women underwent mesh removal or revision. Low-volume surgeons had a 37% higher relative risk for mesh removal or revision in contrast to high-volume surgeons. The authors concluded that mesh-based slings are appropriate for most female patients with stress urinary incontinence.

We believe that synthetic midurethral slings are a safe procedure for stress urinary incontinence. Appropriate counseling should be done prior to any surgical intervention for stress urinary incontinence, especially using mesh products. Multiple scientific studies, including the most recent Cochrane review and JAMA publication, confirm the safety and effectiveness of these slings. Similar to Welk et al. findings on the reduced risk of complications with sling procedures performed by high-volume surgeons, [21] the FDA website suggests that additional training and experience are advisable in those surgeons who perform urogynecologic mesh procedures. In our practice, we regularly use synthetic midurethral slings in patients with stress urinary incontinence who have either failed conservative management with pelvic floor physical therapy or pessaries or prefer the definitive management of stress urinary incontinence. Unfortunately, many of these women have preconceived notions about the “evils of the mesh” created in part by the media. They are frequently profoundly confused regarding the differences in the mesh procedures for prolapse repair and stress urinary incontinence. This, in turn, necessitates the need for dispelling the myths associated with the use of mesh for stress urinary incontinence treatment at the time of patient counseling on the pros and cons of different types of therapeutic interventions for stress urinary incontinence. Taking into consideration the existing data on the low risk of complications associated with midurethral slings and our experience with these procedures, we believe synthetic midurethral slings are safe and effective treatment modalities for stress urinary incontinence in experienced surgeon’s hands.

References

1. Rortveit G, Hannestad YS, Daltveit AK, Hunskaar S (2001) Age- and type-dependent effects of parity on urinary incontinence: the Norwegian EPINCONT study. *Obstet Gynecol* 98: 1004-1010.
2. Offermans MP, Du Moulin MF, Hamers JP, Dassen T, Halfens RJ (2009) Prevalence of urinary incontinence and associated risk factors in nursing home residents: as systemic review. *Neurourol Urodyn* 28: 288-294.
3. Cervigni M, Gambacciani M (2015) Female urinary stress incontinence. *Climacteric : the journal of the International Menopause Society* 18: 30-36.
4. Lawrence JM, Lukacz ES, Nager CW, Hsu JW, Lubner KM (2008) Prevalence and co-occurrence of pelvic floor disorders in community-dwelling women. *Obstet Gynecol* 111: 678-685.
5. Lubner KM (2004) The definition, prevalence, and risk factors for stress urinary incontinence. *Rev Urol* 6: S3-9.
6. Wood LN, Anger JT (2014) Urinary incontinence in women. *BMJ* 349: g4531.
7. Hannestad YS, Rortveit G, Sandvik H, Hunskaar S (2000) A community-based epidemiological survey of female urinary incontinence: the Norwegian EPINCONT study. *Epidemiology of Incontinence in the County of Nord-Trøndelag. J Clin Epidemiol* 53: 1150-1157.
8. Elenskaia K, Haidvogel K, Heidinger C, Doerfler D, Umek W, et al. (2011) The greatest taboo: urinary incontinence as a source of shame and embarrassment. *Wiener klinische Wochenschrift* 123: 607-610.
9. Oliphant SS, Wang L, Bunker CH, Lowder JL (2009) Trends in stress urinary incontinence inpatient procedures in the United States, 1979-2004. *Am J Obstet Gynecol* 200: 521.
10. Chermansky CJ, Winters JC (2012) Complications of vaginal mesh surgery. *Curr Opin Urol* 22: 287-291.
11. Novara G, Artibani W, Barber MD, Chapple CR, Costantini E, et al. (2010) Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings, and midurethra tapes in the surgical treatment of female stress urinary incontinence. *Eur Urol* 58: 218-238.
12. (2014) A summary of the evidence on the benefits and risks of vaginal mesh implants. *Medicine and Healthcare Products Regulatory Agency.*

13. Clemons JL, Weinstein M, Guess MK, Alperin M, Moalli P, et al. (2013) Impact of the 2011 FDA transvaginal mesh safety update on AUGS members' use of synthetic mesh and biologic grafts in pelvic reconstructive surgery. *Female Pelvic Med Reconstr Surg* 19: 191-198.
14. <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealth-Notifications/ucm061976.htm>.
15. <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm>.
16. <http://www.fda.gov/downloads/medicaldevices/safety/alertsandnotices/ucm262760.pdf>.
17. <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/ucm345219>.
18. Nilsson CG, Palva K, Aarnio R, Morcos E, Falconer C (2013) Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. *Int Urogynecol J* 24: 1265-1269.
19. (2015) Opinion on the safety of surgical meshes used in urogynecological surgery. European Commission Scientific Committee on Emerging and Newly Identified Health Risks.
20. Ford AA, Rogerson L, Cody JD, Ogah J (2015) Mid-urethral sling operations for stress urinary incontinence in women. *Cochrane Database Syst Rev*: CD006375.
21. Welk B, Al-Hothi H, Winick-Ng J (2015) Removal or Revision of Vaginal Mesh Used for the Treatment of Stress Urinary Incontinence. *JAMA Surg* 150: 1167-1175.