Are Synthetic Slings for Stress Urinary Incontinence Safe?

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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

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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 evidence on the safety and effectiveness of biological and synthetic mesh slings 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 studies 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 (≥ 75th percentile for mesh implants in a given year) and low-volume (< 75th 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, emphasizing the multiple surgical options available and their relative merits. Patients and their physicians need to be aware of the various mesh slings and their long-term outcomes. 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


