

Joint Position Statement on Midurethral Slings for Stress Urinary Incontinence

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The purpose of this Position Statement by the American Urogynecologic Society (AUGS) and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) is to support the use of the midurethral sling (MUS) for the surgical management of stress urinary incontinence (SUI).

Developed in the 1990s, the MUS treats SUI in a minimally invasive, outpatient procedure. This technique uses a small mesh strip composed of monofilament polypropylene placed through the vagina under the midurethra and exiting from 2 small sites in either the suprapubic or groin area.¹ They are often referred to as full-length slings to differentiate them from smaller single-incision slings or mini slings. This document refers to the full-length MUS.

Stress urinary incontinence, defined as the involuntary urine leakage associated with coughing, sneezing, or other types of exertion, is prevalent, with 13.6% of women in the United States having had at least 1 surgical procedure for SUI in their lifetime, resulting in 260,000 continence surgical procedures annually.² Stress urinary incontinence is often a bothersome and even debilitating condition that can substantially reduce a woman's quality of life. Although nonsurgical treatments such as pelvic floor exercises and vaginal inserts (or pessaries) are helpful in alleviating symptoms in some women,³ many proceed with surgery, which is a more effective, durable treatment.⁴

In 2011, the U.S. Food and Drug Administration (FDA) issued a public health notification regarding adverse events associated with transvaginal mesh used to treat pelvic organ prolapse. In 2019, the FDA ordered the manufacturers of surgical mesh products indicated for the transvaginal repair of pelvic organ prolapse to stop selling and distributing their products in the United States.⁵

The media attention and litigation surrounding these FDA announcements have resulted in confusion between transvaginal mesh used to treat pelvic organ prolapse and the MUS used to treat SUI. This may have led to a negative perception of the MUS. In 2019, the FDA reaffirmed the findings of its safety panel and literature review stating that the safety and effectiveness of the full-length MUS is well established.⁵ The FDA has not recalled or published warnings against the full-length MUS. Most experts who deal with female SUI are supportive of the use of the MUS and the majority of women who have had one placed are satisfied.⁶

JUSTIFICATION FOR THE POSITION STATEMENT

1. **Polypropylene material is safe and effective as a surgical implant.** Polypropylene material has been used in most surgical specialties (including general surgery, cardiovascular surgery, transplant surgery, ophthalmology, otolaryngology, gynecology, and urology) for more than 5 decades.⁷ As an isolated thread, polypropylene is a widely used and durable suture material used in a broad range of sizes and applications. As a knitted material, polypropylene mesh is the consensus graft material for augmenting hernia repairs throughout the human body

and has had a favorable impact on the field of hernia surgery.^{8,9} As a knitted implant for the surgical treatment of SUI, type 1 mesh is a macroporous, monofilament, light weight polypropylene that has demonstrated long-term durability, safety, and efficacy up to 17 years.¹⁰

2. **The monofilament polypropylene mesh midurethral sling is the most extensively studied anti-incontinence procedure in history.** A broad evidence base, including high-quality scientific articles in medical journals across the world, supports the use of the MUS for the treatment of SUI.¹¹ These studies include the highest level of scientific evidence in the peer-reviewed scientific literature.¹¹ The MUS has been studied in a wide range of patients, with and without comorbidities, and all types of SUI. Multiple randomized, controlled trials comparing types of MUS procedures, as well as comparing the MUS with other established nonmesh SUI procedures, have consistently demonstrated its clinical effectiveness^{11–14} and patient satisfaction.¹⁴ No other surgical treatment for SUI before or since has been subject to such extensive investigation.
3. **Polypropylene mesh midurethral slings are a standard of care for the surgical treatment of SUI and represent a great advance in the treatment of this condition for our patients.** Since the publication of numerous level 1 randomized comparative trials, the MUS has become the most common surgical procedure for the treatment of SUI in the United States and much of the developed world. There have been more than 100 surgical procedures developed for the management of SUI, and there is now adequate evidence that the MUS is associated with less pain, shorter hospitalization, faster return to usual activities, and reduced costs as compared with historic options that have been used to treat SUI over the past century.¹⁵ More than 3.6 million MUSs have been placed worldwide, and a survey indicates that these procedures are used by more than 99% of AUGS members.¹⁶
4. **The FDA has stated that the polypropylene midurethral sling is safe and effective in the treatment of SUI.** In 2019, the FDA updated its communication on surgical mesh for SUI. They reported that the safety and effectiveness of the full-length MUS are well established in clinical trials for up to 1 year and that longer follow-up is available but there are fewer long-term studies. They noted that the most common mesh-specific complication is exposure of mesh through the vaginal wall. The average reported rate of mesh exposure at 1 year is approximately 2%.⁵
5. **The European Commission inquiry on the safety of surgical meshes supports continuing synthetic sling use for SUI.** In 2015, the Scientific Committee on Emerging and Newly Identified Health Risks concluded that synthetic sling SUI surgery is an accepted procedure with proven efficacy and safety in the majority of patients with moderate-to-severe SUI, when used by an experienced and appropriately trained surgeon.¹⁷

SINGLE-INCISION SLINGS

Single-incision slings, also referred to as mini-slings, were introduced to the United States in 2006. Made of the same polypropylene mesh as full-length slings, the shorter mini-slings are inserted through 1 vaginal incision. Studies comparing single-incision slings to the

full-length MUS show similar efficacy^{18,19} although these studies have shorter length of follow-up outcomes and fewer patients than the studies of the full-length MUS.²⁰

CONCLUSIONS

With its well-established safety and efficacy, the MUS has helped millions of women with SUI by allowing a simple outpatient procedure with faster recovery. In the past, concerns over failure and invasiveness of surgery caused a substantial percentage of incontinent women to live without treatment. One of the unintended consequences of the polypropylene mesh controversy was to discourage women from seeking treatment for SUI. This procedure is an important advancement in the treatment of SUI and has the full support of organizations dedicated to improving the lives of women with urinary incontinence.

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OUR ORGANIZATIONS



The American Urogynecologic Society (AUGS), founded in 1979, is a nonprofit organization representing more than 2,300 members, including practicing physicians, nurse practitioners, physical therapists, nurses and health care professionals, as well as researchers from many disciplines, all dedicated to treating female pelvic floor disorders (pelvic organ prolapse and urinary incontinence). AUGS promotes the highest quality patient care through excellence in education, research, and advocacy.



The Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) is the premier non-profit organization dedicated to improving the art and science of Urology through basic and applied clinical research in urodynamics and neurourology, voiding function and dysfunction, female urology, pelvic floor dysfunction and reconstruction, and to disseminate and teach these concepts. It is the oldest professional organization dedicated to this field consisting of interested physicians, basic scientists, and other health care professionals, and has grown to over 700 members.

ENDORISING ORGANIZATIONS



The American College of Obstetricians and Gynecologists (ACOG) is the nation's leading group of physicians providing health care for women. As a private, voluntary, nonprofit membership organization of more than 58,000 members, ACOG strongly advocates for quality health care for women, maintains the highest standards of clinical practice and continuing education of its members, promotes patient education, and increases awareness among its members and the public of the changing issues facing women's health care. www.acog.org



The American Urological Association (AUA), founded in 1902, is a premier urologic association, representing more than 23,000 members worldwide and providing invaluable support to the urologic community. The AUA's mission is to promote the highest standards of urological clinical care through education, research, and the formulation of health care policy.



The International Urogynecological Association (IUGA) is the leading international association dedicated to the global advancement of urogynecological knowledge and patient care through education and the promotion of basic and clinical research on disorders of the female pelvic floor. IUGA was formed in 1975 and has more than 3000 members from over 90 countries. In addition to holding an annual conference and publishing the *International Urogynecology Journal*, IUGA activities include conducting education programs around the world, developing consensus terminology in the field, connecting related professionals, and producing patient education materials.

SUPPORTING ORGANIZATIONS



The American Association of Gynecological Laparoscopists (AAGL), founded in 1971, is an internationally recognized medical specialty society representing more than 7100 members from 102 countries. The AAGL's mission is to assist physicians in providing the safest, most therapeutic, evidence-based and economical surgical care possible for women by providing members with first-rate education, the latest research, and the opportunity for global dialogue which ultimately serves to advance awareness and utilization of minimally invasive gynecology worldwide. Our members include physicians in practice, fellows, residents, nurses, and other health care professions. As a leader in this field, we are pleased to see that minimally invasive surgery is now a well-accepted standard that is used regularly in gynecologic cases.



The National Association for Continence (NAFC) is a national, private, non-profit 501(c)3 organization dedicated to improving the quality of life of people with incontinence, voiding dysfunction, and related pelvic floor disorders. NAFC's purpose is to be the leading source for public education and advocacy about the causes, prevention, diagnosis, treatments, and management alternatives for incontinence.



The Society of Gynecologic Surgeons (SGS) is a 501(c)3 not-for-profit organization that was originally founded in 1974 to advance the art and science of vaginal reparative surgery and to work with the American College of Obstetricians and Gynecologists (ACOG) to better educate obstetricians and gynecologists on the

procedures. The Society's current mission is to promote excellence in gynecologic surgery through acquisition of knowledge and improvement of skills, advancement of basic and clinical research, and professional and public education.

This Position Statement was developed by a joint task force between the American Urogynecologic Society (AUGS) and the Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU). This document reflects clinical

and scientific advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Its content is not intended to be a substitute for professional medical judgment, diagnosis, or treatment. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient.

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