

Position Statement

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.

Mesh Midurethral Slings for Stress Urinary Incontinence

Introduction

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 in the surgical management of stress urinary incontinence, the type of urine leakage generally associated with coughing, laughing and sneezing.

Developed in the early 1990's, midurethral slings (MUS) treat stress urinary incontinence (SUI) in a minimally invasive, generally outpatient procedure. This technique utilizes a small mesh strip composed of monofilament polypropylene placed through the vagina under the mid-urethra exiting from 2 small sites in either the suprapubic or groin areas.

SUI is a highly prevalent condition of involuntary urine leakage resulting from faulty closure of the urethra typically associated with coughing, sneezing or exertion. SUI is often a debilitating and bothersome condition that can substantially reduce a woman's quality of life. Although non-surgical treatments such as pelvic floor exercises and behavioral modification are helpful in alleviating symptoms in some women^[1], many proceed with surgery which is a more effective treatment^[2].

In July 2011, the U.S. Food and Drug Administration (FDA) released a white paper^[3] and safety communication^[4] on the safety and effectiveness of transvaginal placement of surgical mesh specifically for pelvic organ prolapse. In addition, lawyers have publicly advertised their services, targeting women with transvaginal mesh placed for both pelvic organ prolapse and stress urinary incontinence (SUI), and the media has reported on the pelvic organ prolapse mesh litigation. We are concerned that the multimedia attention has resulted in confusion, fear, and an unbalanced negative perception regarding the midurethral sling as a treatment for SUI. This negative perception of the MUS is not shared by the international medical community and the overwhelming majority of women who have been satisfied with their MUS. Furthermore, the FDA website states that: "The safety and effectiveness of multi-incision slings is well-established in clinical trials that followed patients for up to one-year."^[5]

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 over five decades, in millions of patients in the US and the world (personal communication with manufacturers of polypropylene suture and mesh). As an isolated thread, polypropylene is a widely used and durable suture material employed in a broad range of sizes and applications. As a knitted material, polypropylene mesh is the consensus graft material for augmenting hernia repairs in a number of areas in the human body and has significantly and favorably impacted the field of hernia surgery.^[6,7] As a knitted implant for the surgical treatment of SUI, macroporous,

monofilament, light weight polypropylene has demonstrated long term durability, safety, and efficacy up to 17 years.^[8]

2. ***The monofilament polypropylene mesh MUS is the most extensively studied anti- incontinence procedure in history.*** A broad evidence base including high quality scientific papers in medical journals in the US and the world supports the use of the MUS as a treatment for SUI.^[9] There are greater than 2,000 publications in the scientific literature describing the MUS in the treatment of SUI. These studies include the highest level of scientific evidence in the peer reviewed scientific literature.^[9] The MUS has been studied in virtually all types 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 to other established non-mesh SUI procedures, have consistently demonstrated its clinical effectiveness^[9-12] and patient satisfaction.^[12] Among historical SUI procedures, the MUS has been studied as long in follow-up after implantation as any other procedure and has demonstrated superior safety and efficacy.^[8, 13] 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 one randomized comparative trials, the MUS has become the most common surgical procedure for the treatment of SUI in the US and the developed world. This procedure has essentially replaced open and transvaginal suspension surgeries for uncomplicated SUI. There have been over 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 to historic options that have been used to treat SUI over the past century. Full-length midurethral slings, both retropubic and transobturator, have been extensively studied, are safe and effective relative to other treatment options and remain a leading treatment option and current gold standard for stress incontinence surgery.^[14] Over 3 million MUS have been placed worldwide and a recent survey indicates that these procedures are used by > 99% of AUGS members.^[15]
4. ***The FDA has clearly stated that the polypropylene MUS is safe and effective in the treatment of SUI.*** The midurethral sling was not the subject of the 2011 FDA Safety Communication, “Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Vaginal Placement for Pelvic Organ Prolapse.”^[3] In this document, it was explicitly stated: “The FDA continues to evaluate the effects of using surgical mesh for the treatment of SUI and will report about that usage at a later date.” In 2013, the FDA website stated clearly that: “The safety and effectiveness of multi-incision slings is well-established in clinical trials that followed patients for up to one-year.”^[5]
5. ***The European Commission enquiry 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 (SCENIHR) 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.^[16]

Conclusion

The polypropylene midurethral sling has helped millions of women with SUI regain control of their lives by undergoing a simple outpatient procedure that allows them to return to daily life very quickly. With its acknowledged safety and efficacy, it has created an environment for a much larger number of women to have access to treatment. 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 this polypropylene mesh controversy has been to keep women from receiving any treatment for SUI. This procedure is probably the most important advancement in the treatment of stress urinary incontinence in the last 50 years and has the full support of our organizations which are dedicated to improving the lives of women with urinary incontinence.

Our Organizations

The American Urogynecologic Society (AUGS), founded in 1979, is the premier non-profit organization representing more than 1,700 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). As the leader in Female Pelvic Medicine and Reconstructive Surgery, AUGS promotes the highest quality patient care through excellence in education, research and advocacy.

SUFU, the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction, is a 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 and pelvic floor dysfunction, 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 500 members.

Supporting Organizations



The American Association of Gynecological Laparoscopists (AAGL), founded in 1971, is an internationally recognized medical specialty society representing more than 7,600 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.

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The American College of
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WOMEN'S HEALTH CARE PHYSICIANS

membership organization of more than 57,000 members, The College 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. The American Congress of Obstetricians and Gynecologists (ACOG), a 501(c)(6) organization, is its companion organization. www.acog.org.

Endorsed by the American College of Obstetricians and Gynecologists (ACOG), and should be construed as ACOG clinical guidance. The American College of Obstetricians and Gynecologists (The College), a 501(c)(3) organization, is the nation's leading group of physicians providing health care for women. As a private, voluntary, nonprofit



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.



International Urogynecological Association (IUGA)

IUGA, formed in 1975 and with more than 3 000 members from over 90 countries, 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. In addition to holding an annual conference and publishing the International Urogynecology Journal, IUGA activities include conducting education programs around the world by regional symposia and exchange meetings and via its on-line Academy, developing

consensus terminology in the field, connecting related professionals and producing patient education materials as well as promoting audit of surgical outcomes via its surgical database.



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.

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