POSITION STATEMENT

This Position Statement was developed by the Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU). It 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 Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) is to support the use of the midurethral sling (MUS) in the surgical management of stress urinary incontinence (SUI), the type of urine leakage generally associated with coughing, laughing and sneezing.

Developed in the early 1990s, MUSs treat SUI in a minimally invasive, generally outpatient procedure. This technique involves placement of a small monofilament polypropylene mesh strip, through the vagina, to lie beneath the mid-urethra. The mesh strip exits 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 physical exertion. SUI is a bothersome and potentially debilitating condition that can substantially reduce a woman’s quality of life. Although non-surgical treatments such as pelvic floor exercises and other non-invasive therapies are helpful in alleviating symptoms in some women [1], many proceed with surgery, which can be a more effective treatment [2].

In July 2011, the U.S. Food and Drug Administration (FDA) released communications regarding the safety and effectiveness of transvaginal placement of surgical mesh specifically for pelvic organ prolapse [3,4]. Subsequently, lawyers have publicly advertised their services, targeting women with transvaginal mesh placed for both pelvic organ prolapse and SUI. We are concerned that the multimedia attention has resulted in confusion, fear, and an unbalanced negative perception regarding the MUS as a treatment for SUI. This negative perception of the MUS is not shared by many in the medical community and the overwhelming majority of women who have been satisfied with their MUS. Indeed, even the FDA’s 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] Subsequent literature with longer term follow up has continued to suggest safety and efficacy of the MUS [6,7], and the AUA/SUFU Guidelines on surgical treatment of SUI maintains the MUS as an option that should be discussed with women seeking treatment [8].

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. As an isolated thread, polypropylene is a widely utilized and durable suture material employed in a broad range of sizes and applications. As a woven 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. [9,10] As a woven implant for the surgical treatment of SUI, macroporous, monofilament, light weight polypropylene has demonstrated long term durability, safety, and efficacy up to 17 years.[6]
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 abroad supports the use of the MUS as a treatment for SUI.[11] 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 evidence in the peer reviewed scientific literature. [11,12] The MUS has been studied in virtually all types of patients, with and without comorbidities, and with varying clinical presentations of SUI. Multiple randomized controlled trials comparing types of MUS procedures, as well as trials comparing the MUS to other established non-mesh SUI procedures, have consistently demonstrated its clinical effectiveness [11-15] and patient satisfaction.[14] Among historical SUI procedures, the MUS has been studied with as long a follow-up after implantation as any other SUI procedure and has demonstrated comparable safety and efficacy.[10] No other surgical treatment for SUI before or since has been subject to such extensive investigation.

3. Monofilament polypropylene mesh MUSs 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.

With the publication of numerous randomized comparative trials, the MUS became the most common surgical procedure for the treatment of SUI in the US and the developed world. This procedure essentially replaced open and transvaginal suspension surgeries for uncomplicated SUI. There is adequate evidence that the MUS, for many patients, is safe and effective and associated with less pain, shorter hospitalization, faster return to usual activities, and reduced costs as compared to other options that have been used in the past. Accordingly, MUSs remain a leading treatment option for SUI surgery.[8,16]

4. The FDA has 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, in its 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]

Conclusion

The monofilament polypropylene MUS has helped millions of women with SUI regain control of their lives. The MUS is a simple outpatient procedure that allows these individuals to return to daily life quickly. With its acknowledged safety and efficacy, the MUS has made it possible for more women to have access to treatment. In the past, concerns over failure and invasiveness of existing surgeries resulted in a substantial number of women living their lives without treatment for their incontinence.

One of the unintended consequences of the polypropylene mesh controversy relating to pelvic organ prolapse has been the emergence of an obstacle to women seeking treatment for SUI. The MUS procedure has represented the most impactful and important advancement in the treatment of SUI 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. Given the substantive evidence cited, the MUS should remain a treatment option for women with stress incontinence desiring surgical therapy. The right to make an informed decision regarding her own treatment should not be taken away from any woman.

Position statements are approved by the Boards of Directors and/or the leadership of each sponsoring organization. They do not represent an endorsement for a particular procedure, product or standard of care. The applicability of position statements, as guidance for a procedure, must be determined by the responsible physician in light of all the circumstances presented by the individual patient. Adherence to these clinical position statements will not ensure successful treatment in every situation. This position statement should not be deemed inclusive of all proper treatment decisions or methods of care, nor exclusive of other treatment decisions or methods of care reasonably directed to obtaining the same results. Position statements are not intended to and should not be treated as legal, medical, or business advice.
References


Our Organization

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, and consists of over 700 physicians and other clinicians, basic scientists, and clinical researchers.

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