Global Position Statement

Statement in Support of Mid-urethral Slings for Stress Urinary Incontinence on behalf of the International Urogynecological Community

This global position statement is to support the use of the mid-urethral sling (MUS) in the surgical management of stress urinary incontinence (SUI), a debilitating condition affecting 1 in 3 women worldwide at some stage in their lives.

Developed in the early 1990's, mid-urethral slings (MUS) treat stress urinary incontinence in a minimally invasive, generally outpatient procedure. This technique utilizes a small strip composed of monofilament mesh 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 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 choose to proceed with surgery which is a more effective treatment[2].

The international urogynecological community stresses that it's important a clear distinction be made between surgical mesh placed vaginally for the treatment of pelvic organ prolapse and the mesh (better described as a tape) used to treat women for SUI. Major governmental inquiries in Scotland and the European Union have now recommended that mesh inserted vaginally for pelvic organ prolapse be used only after careful consideration of an individual patient's circumstances and after full consultation with the patient. Furthermore, the use of vaginal mesh has been discontinued in Australia and New Zealand.

We are concerned that international media attention has resulted in confusion, fear, and an unbalanced negative perception regarding the mid-urethral sling as a treatment for SUI. This has caused some women to regrettably delay or defer seeking treatment and instead suffer in silence with this debilitating condition. 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 US Food and Drug Administration (FDA) 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]

We fully support recent government inquiries (most recently the Scottish Independent Review 2017, the Australian Senate Inquiry 2018 and the European Union Scientific Committee on Emerging and Newly Identified Health Risks (SCENHIR) report in 2015), which all recommend the need for adequate surgical training for MUS use, the necessity of long-term data collection and audit follow-up and the assurance that women are fully-informed and have a solid understanding of any potential side effects prior to their procedure.

Justification for this 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 worldwide. 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 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, Type 1-microporous 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 international medical journals supports use of the MUS as a treatment for SUI.[9] There are over 2000 publications describing the MUS in the treatment of SUI. These studies include the highest level of scientific evidence in peer-reviewed scientific literature.[9] The MUS has been studied in virtually all types of patients, with and without co-morbidities, 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. ***Mesh mid-urethral slings are the first line treatment for SUI and represent a great advance 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 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 mid-urethral 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 3.5 million MUS have been placed worldwide. [15]
4. ***The FDA has clearly stated that the polypropylene MUS is safe and effective in the treatment of SUI.*** The mid-urethral 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 (SCENHIR)** ***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 mid-urethral 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 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 the global urogynecological community which is dedicated to improving the lives of women with stress urinary incontinence.

This Global Position Statement is Endorsed by the Following International *Urogynecological Organizations:*

{list organizations here}

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