"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 ongoing use of mid-urethral slings (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 1990's and widely employed for the last two decades, MUS represent effective surgical management of SUI undertaken as a minimally invasive day case surgery procedure. This technique utilizes a small strip composed of monofilament tape placed through the vagina under the mid-urethra, exiting from 2 small sites in either the suprapubic or groin areas.

SUI is the involuntary leakage of urine on coughing, sneezing or physical exertion which occurs because of a weak urethra and pelvic floor. SUI is often a debilitating condition that can substantially reduce a woman's quality of life[1]. Non-surgical treatments such as lifestyle advice, behavioral modification and pelvic floor exercises should always be offered first in the management of SUI, but maybe ineffective so many women with more severe leakage seek a surgical solution[2].

The International Urogynecological Community stresses that it is important to make a clear distinction between surgical meshes placed vaginally for the treatment of pelvic organ prolapse and the tapes used to treat women with SUI. Major governmental enquiries in Scotland and the European Union have now recommended that mesh inserted vaginally for pelvic organ prolapse should only be used after careful consideration of an individual patient's circumstances and full informed consultation with the patient.

We are concerned that international media attention has resulted in confusion, fear and an unbalanced negative perception regarding MUS as a treatment for SUI. This has regrettably led to some women rejecting or deferring surgery and choosing instead to cope with containment products such as incontinence pads. This negative perception of MUS is not shared by the International medical community and the overwhelming majority of women who they have treated have been satisfied with their MUS. This view is supported by the US Food and Drug Administration (FDA) who state "the safety and effectiveness of multi incision slings is well established in clinical trials "[4,5]

We fully support recent government enquires including the European Union Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) report in 2015, Scottish Independent Review 2017 and the Australian Senate Enquiry 2018 which all recommend the need for adequate surgical training for the use of MUS, the necessity of long term data collection with follow up to ensure that outcomes can be audited and the assurance that women are fully informed and have a solid understanding of any potential side effects prior to their procedure[7,8,9]. A small percentage of women have suffered with pain after MUS procedures. It is important that their issues are addressed, and every effort is made to help their symptoms.

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 many areas of the human body and has significantly and favorably improved the results of hernia surgery[6,10]. As a knitted implant for the surgical treatment of SUI, Type 1 macroporous monofilament polypropylene has demonstrated long term durability, safety and efficacy for up to 17 years[11].

2. The monofilament polypropylene tape 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 the use of the MUS as a treatment for SUI[12]. 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. 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 different types of MUS procedure as well as comparing the MUS to other established non mesh SUI procedures have consistently demonstrated its clinical effectiveness and patients satisfaction[11,12,13,14,15]. Among historical SUI procedures the MUS has been studied for as long in follow up after implantation as any other procedure and has demonstrated superior safety and efficacy[11,14]. No other surgical treatment for SUI before or since has been subject to such an extensive investigation.

3. MUS are the first line surgical treatment for SUI and represent a great advance 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 developed world. This procedure has essentially replaced open and trans vaginal suspension surgery 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 used to treat SUI over the past century. Full length MUS both retropubic and trans obturator have been extensively studied, are safe and effective relative to other treatment options and remain a leading treatment option and the current gold standard for SUI surgery[17]. Over 10 million MUS have been inserted worldwide.

4. The FDA has clearly stated that 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 the usage at a later date". In 2013 the FDA website clearly stated that "the safety and effectiveness of multi-incision slings is well established in clinical trials"[5].

5. The European Commission Enquiry (SCENIHR) on the safety of surgical meshes supports continuing synthetic sling use for SUI.

In 2015 the SCENIHR committee 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[7].

Conclusions

The polypropylene MUS has helped millions of women worldwide with SUI to regain control of their lives by undergoing a simple day case procedure that allows them to return to their normal activities very quickly. With its acknowledged safety and efficacy, it has enabled a much larger number of women to have access to treatment. In the past, concerns over the

failure and invasiveness of surgery caused a substantial proportion of incontinent women to live without treatment. One of the consequences of the current mesh controversy has been to prevent women from receiving any surgical treatment for SUI[18]. The most important advance in the treatment of SUI in the last 50 years has the full support of the global urogynecological community and professional health care organizations around the world which are dedicated to improving the lives of women with SUI.

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Statement on MUS for SUI- Endorsing Organizations