Midurethral slings: evidence-based medicine vs the medicolegal system

Charles W. Nager, MD

The evidence for midurethral slings

Before midurethral slings (MUS) were developed in the late 1990s, most women who needed surgery for stress urinary incontinence (SUI) were treated with what are now called traditional procedures. These traditional procedures involved suturing of periurethral tissue to retropubic structures (colpopexy) or harvesting autologous material to place a sling under the urethra (pubovaginal slings). These surgical procedures, compared to current MUS, usually involved larger incisions, more overnight hospital stays, prolonged recoveries, and more time off work, and placed the patient at higher risk for major surgery complications like venous thromboembolism and wound infections. The advent of a minimally invasive procedure like the MUS, in which a trocar system places a 1-cm wide ribbon of polypropylene mesh under the midurethra, revolutionized the management of SUI. These minimally invasive procedures result in less blood loss, less pain, fewer venous thromboembolisms, fewer surgical-site infections, faster recovery, and better cosmetic outcomes. The MUS procedure has a shorter learning curve, is standardized and reproducible, and high success rates are consistently reported in numerous studies. MUS improve quality of life[1] and, probably because of its beneficial effect on incontinence, improve sexual function.[2] Systematic reviews of numerous studies comparing MUS with traditional SUI surgical procedures confirm that the MUS has all the benefits of a minimally invasive procedure, with less blood loss, less operative time, fewer hospital stays, fewer hematomas, and fewer wound infections (Table). The MUS has equivalent or better objective or subjective success rates, and has lower rates of new-onset urinary symptoms than traditional slings. With the exception of bladder or vaginal perforations, MUS have similar or better complication rates. An intraoperative bladder perforation is managed simply by a repeat placement of the device and 1-3 days of bladder drainage, and has no long-term consequences. Vaginal perforations are also managed with repeat placement of the device and have no long-term consequences. Urinary retention after a MUS is managed with a sling release and not an extensive urethrolysis procedure that may be required after traditional procedures. The durability of the MUS is demonstrated for at least 17 years.[3] In the most recent Cochrane review the authors concluded, "Mid-urethral sling operations have been the most extensively researched surgical treatment for SUI in women and have a good safety profile. Irrespective of the routes traversed, they are highly effective in the short and medium term, and accruing evidence demonstrates their effectiveness in the long term."[1]

MUS—the worldwide standard

Throughout the world the MUS procedure became the standard surgical treatment for SUI. Because procedure codes in the United States do not distinguish between different types of slings, the best data on the types of incontinence procedures being performed are obtained outside the United States, but the trend was similar in the United States. By 2005, >7000 MUS were performed annually in the United Kingdom and other procedures totaled <1000. More women sought care because now they had a safe, effective procedure that brought back their quality of life with a minimal investment of pain, recovery, or lost time. At the time of a 2014 United Kingdom report, 13,500 women annually underwent MUS procedures.[4] In the United States, in the Urinary Incontinence Treatment Network Value of Urodynamic Evaluation trial, when 53 urogynecologists or urologists could perform whatever procedure they wanted for SUI, 93% of the procedures were MUS.[5] Surveys of members of the American Urogynecologic Society (AUGS) showed that even after 2011, 99% of AUGS members who did sling surgery for SUI use a MUS.[6] Worldwide, 3.6 million MUS were sold from 2005 through 2013. The MUS is the worldwide standard. Clinical researchers are no longer interested in comparing MUS with traditional procedures; instead, research is directed at what type of MUS is best.[7]

The Food and Drug Administration has distinguished between mesh MUS and transvaginal mesh for prolapse

Although the 2011 Food and Drug Administration (FDA) safety communication was about transvaginal mesh for *prolapse* (not for SUI) the advertisements and litigation that followed included MUS patients. Surgeons who took care of women with SUI were perplexed because for years our postoperative patients told us how this surgery changed their

From the Department of Reproductive Medicine, University of California San Diego School of Medicine, San Diego, CA.

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Corresponding author: Charles W. Nager, MD. cnager@ucsd.edu

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TABLE
Results of systematic reviews comparing midurethral slings with alternative stress urinary incontinence surgeries

MUS vs open retropubic colpopexy

Favors MUS	Favors both or no difference	Favors open retropubic colpopexy
Overall cure rates[16]	Objective cure rate by pad test[16]	Bladder or vaginal perforations[16]
Objective cure rates[16]	Subjective cure rate[16]	Return to operating room for retention, erosion, OAB symptoms, groin pain[17]
Blood loss[17]	Other complications besides bladder or vaginal perforations[16]	
Postoperative pain[17]		
Operation time[17]		
Hospital stay[17]		
Bowel injury[17]		
Wound infection[17]		
Hematomas[17]		

MUS vs laparoscopic retropubic colpopexy

Favors MUS	Favors both or no difference	Favors laparoscopic colpopexy
Objective cure rates[18]	Subjective cure rates	
Operation time[18]		
Hospital stay[18]		

MUS vs traditional (pubovaginal) sling

Favors MUS	Favors both or no difference	Favors pubovaginal sling
Subjective cure rates[17]	Overall cure rates[16]	Bladder perforations[16]
Storage lower urinary tract symptoms[16]	Subjective cure rates[16]	Vaginal perforation[17]
Reoperation[16]	Hematoma[16]	Urinary tract infection[17]
Operation time[17,19]	Voiding lower urinary tract symptoms[16]	
Blood loss[17]		
Hospital stay[17]		
Perioperative complications except for bladder perforation[19]		
Postoperative voiding dysfunction[19]		
Detrusor symptoms[19]		

MUS, midurethral sling.

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lives and how they wished they had done it earlier. The medical community failed to realize that this plaintiff attorney recruiting of MUS patients was not about science and evidence-based medicine; this was mass litigation and the simple fact is that millions of women have received a MUS compared to only tens of thousands who received transvaginal mesh for prolapse.

Since 2008, the FDA has consistently differentiated transvaginal mesh for prolapse from transvaginal mesh for SUI. The FDA safety communication in 2011 specifically excluded MUS. In 2012, when postmarket surveillance studies (522 studies) were ordered by the FDA for transvaginal mesh products for prolapse, MUS were specifically excluded. In March 2013 the FDA updated the urogynecologic surgical mesh implant World Wide Web site to include more information for patients about SUI and stated, "The safety and effectiveness of multi-incision slings is well-established in clinical trials that followed patients for up to one-year…" In 2016 the FDA up-classified transvaginal mesh for prolapse from class 2-3, but they specifically excluded mesh for SUI from this up-classification.

International agencies have distinguished between mesh MUS and transvaginal mesh for prolapse

Other international agencies responsible for public safety have distinguished between SUI mesh and transvaginal mesh for prolapse. In 2009 the French National authority approved polypropylene slings for SUI and synthetic mesh for abdominal pelvic organ prolapse (POP) surgery, but did not recommend transvaginal mesh for POP.[8] In 2014 the Medicines and Healthcare Products Regulatory Agency, the competent authority in the United Kingdom, concluded that the overall benefit outweighs the relatively low rate of complications for the use of vaginal mesh implants for SUI.[8] In 2015, The European Commission Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) concluded in their abstract, "In assessing the risk associated with mesh application, it is important to consider the overall surface area of material used, the product design and the properties of the material used. The available evidence suggests a higher morbidity in treating POP, which uses a much larger amount of mesh compared to SUI. When assessing synthetic mesh risks, there is a need to clearly distinguish

between the risks associated with SUI sling surgery and those of POP mesh surgery; sling surgery for SUI is associated with lower risks compared to POP mesh surgery. ...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. Therefore, the SCENIHR supports continuing synthetic sling use for SUI, but emphasizes the importance of appropriately trained surgeons and detailed counseling of patients about the associated risk/benefits. ...There is robust evidence to support the use of MUS from over 2,000 publications, making this treatment the most extensively reviewed and evaluated procedure for female SUI now in use."[8]

The medicolegal process—MUS, morcellation, silicone breast implants, and the availability cascade—science takes a backseat

The medicolegal process and advertisements started and there is no end in sight. Companies have spent billions of dollars on legal defense. Some decided it was just not financially sound to stay in this product area. In 2014, Ethicon, the maker of the tension-free vaginal tape MUS dissolved the gynecology sales force. In 2016, Endo International announced plans to discontinue operations of its device segment, ASTORA Women's Health (makers of the Monarc transobturator tape MUS and the MiniArc single incision sling) due to lawsuit concerns. No one knows where the situation will end but it is not inconceivable that MUS may not be available in this country and we will either have to roll back the clock 20 years or send our patients out of the country to receive the best care.

The similarity of the current negative publicity on MUS has much in common with the FDA ban on morcellation. Lisa Rosenbaum[9] writes in "N-of-1 policymaking—tragedy, tradeoffs, and the demise of morcellation": "From a policy perspective, the FDA has a mandate to keep the public safe, but medical products are associated with two types of risk: that caused by using the products and that caused by preventing their use." If we get to a situation in which minimally invasive procedures are no longer available, women with SUI could be at more of a safety risk. Siedhoff et al[10] completed a decision analysis that gives an estimate of the benefits of minimally invasive surgery vs open procedures; 100,000 laparoscopic hysterectomies compared with 100,000 open hysterectomies would result in 20 fewer perioperative deaths, 150 fewer pulmonary or venous emboli, and 4800 fewer wound infections, and women with open surgery would have 8000 fewer quality-of-life years.

Rosenbaum[9] also describes the silicone breast implants controversy in the 1990s as an availability cascade and once again there are similarities with MUS. The availability cascade[11] is explained by Rosenbaum[9] as "a self-reinforcing process of collective belief formation by which an expressed perception triggers a chain reaction that gives the perception of increasing plausibility through its rising availability in public discourse." The FDA requested in 1992 a voluntary moratorium on silicone breast implants because of concerns of possibly causing autoimmune disease. Despite no scientific evidence for this causative claim, the media, plaintiffs' attorneys, and thousands of women registered for the $4.25 billion class action settlement with Dow Corning.[12] The Institute of Medicine (IOM) is a nonprofit organization established as a component of the US National Academy of Sciences that works outside the framework of government to provide evidence-based research and recommendations for public health; they completed a 300-page independent report concluding silicone breast implants were not responsible for systemic autoimmune disorders.[13] Fourteen years after the ban, the FDA approved silicone implants for augmentation purposes and they are now widely available. Maybe it is time to ask the IOM to investigate the safety and efficacy of MUS. The loss of MUS would be more harmful for women than the loss of silicone breast implants. The availability cascade exists for MUS; there is a self-reinforcing process of collective belief giving the perception of increasing plausibility through its rise in public discourse. The silent majority of women who are satisfied with their MUS have not provided some balance to the current unbalanced discourse about mesh.

Rosenbaum[9] goes on to describe the availability cascade as "a phenomenon whereby stories inform public perceptions and anyone challenging those perceptions is vilified." Indeed, in 2014 when the board of directors from professional societies like AUGS and the Society of Urodynamics, Female Pelvic Medicine, and Urogenital Reconstruction approved and unanimously endorsed a position statement on mesh MUS for SUI,[14] attempts were made by plaintiff attorneys to discredit the authors of the draft or the entire board of directors of both organizations. Similar position statements supporting MUS have been released by the international community, including the International Urogynecological Association.[15]

Despite the advertisements and litigation against MUS most physicians continue to perform MUS as their primary operation for SUI. The reason is quite simple; most physicians are practicing evidence-based medicine and the MUS is the best procedure for their patients. Let us hope that evidence-based medicine will eventually provide some balance to the current medicolegal process and that we will always have MUS so that we can always provide the best SUI surgical treatment for our patients. It may be time for the IOM or another comparable national agency to provide evidence-based recommendations on the MUS.

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ABSTRACT

Midurethral slings: evidence-based medicine vs the medicolegal system

Midurethral sling procedures are minimally invasive surgeries for stress urinary incontinence that use a trocar system to place a narrow ribbon of polypropylene mesh under the midurethra. The peer-reviewed scientific literature on these procedures is abundant and midurethral slings are the most well-studied incontinence procedure ever. Systematic reviews of the literature demonstrate that midurethral slings are safer and more (or equally) effective as traditional procedures. The midurethral sling is the worldwide standard for the treatment of female stress urinary incontinence and >3 million procedures have been performed. The Food and Drug Administration and international scientific review agencies have consistently differentiated transvaginal mesh for stress urinary incontinence from transvaginal mesh for prolapse. In the recruitment of patients to participate in transvaginal mesh litigation, plaintiff lawyers have not made the distinction between stress urinary incontinence and prolapse procedures because more women have received midurethral slings than transvaginal mesh for prolapse by an order of magnitude. The litigation costs of defending their products have forced several companies that manufactured midurethral slings to leave the marketplace. It is not inconceivable that midurethral slings could become absent from the US market. If that happens, then US women with stress urinary incontinence will be harmed because they will not have access in this country to the best and safest stress urinary incontinence surgical procedure ever developed. It may be time for the Institute of Medicine or another comparable national agency to provide evidence-based recommendations on the midurethral sling.

Key words: evidence-based medicine, litigation, midurethral slings, stress urinary incontinence, surgery, systematic review, transvaginal mesh