

# Female Urology, Urodynamics, Incontinence, and Pelvic Floor Reconstructive Surgery



## Trends in Stress Urinary Incontinence Surgery at a Tertiary Center: Midurethral Sling Use Following the AUGS/SUFU Position Statement

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<b>OBJECTIVE</b>	To investigate trends in stress urinary incontinence (SUI) surgery before and after the 2011 Foods and Drug Administration notification and the 2014 (American Urogynecologic Society [AUGS]/ Society for Urodynamics Female Pelvic Medicine and Urogenital Reconstruction [SUFU]) position statement.
<b>METHODS</b>	A retrospective chart review was performed to identify patients presenting for evaluation of SUI by 2 Female Pelvic Medicine and Reconstructive Surgery specialists between June 1, 2010 and May 31, 2017. Rates of surgical treatment modality (synthetic midurethral slings [MUS] versus autologous fascial pubovaginal sling versus bulking agents) were analyzed at 6-month intervals.
<b>RESULTS</b>	Over fourteen 6-month intervals, the number of new patients presenting for evaluation of SUI increased consistently. There was a decrease in the proportion of new patients who underwent antiincontinence surgical procedures, specifically MUS, between December 2011 and December 2013. After the integration of the 2014 AUGS/SUFU position statement in patient counseling, this trend reverted and we noted a sustained increase in the proportion of patients electing surgical management. This paralleled an increase in new patient visits for SUI and MUS. The number autologous fascial pubovaginal sling remained stable throughout the study period. Conversely, MUS composed the highest proportion of procedures performed, accounting for 60 %-87.2% of all antiincontinence procedures.
<b>CONCLUSION</b>	After the Foods and Drug Administration Public Health Notification in 2011, we observed a decline in the number of new patients presenting with SUI electing surgical management, specifically MUS. However, after the AUGS/SUFU position statement publication and integration into counseling, we observed a reversal in the previous year's trends, noting a resurgence of MUS utilization. UROLOGY 131: 71–76, 2019. © 2019 Elsevier Inc.

Numerous surgical options can be effective in the treatment of SUI ranging from urethral bulking agents performed endoscopically to minimally invasive surgical procedure like the synthetic midurethral sling (MUS), to more invasive procedures like Burch colposuspension and autologous fascia pubovaginal slings (AFPVS).<sup>1,2</sup> Many consider the MUS the gold standard

for the surgical management of SUI.<sup>1,2</sup> The MUS gained rapid acceptance in the treatment of SUI after the introduction of the tension free vaginal tape in 1996.<sup>3</sup> In the subsequent 15 years, the MUS became the most popular operation performed for SUI.<sup>4-7</sup> Numerous studies highlighted national trends in the treatment of SUI, demonstrating an increasing utilization of MUS and a simultaneous decline in AFPVS.<sup>4-7</sup>

Amidst its popularity as an effective and minimally invasive option for women with SUI, in 2008 the Foods and Drug Administration (FDA) released a Public Health Notification and Safety Communication following over 1000 transvaginal mesh related complications reported to the Manufacturer and User Device Experience database.<sup>8</sup> In 2011, an update to this notification strongly cautioned the use of transvaginal mesh for pelvic organ prolapse repair, however a definitive advisory claim regarding synthetic

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MUS for SUI was not issued.<sup>9</sup> Although the FDA notification in 2011 did not directly address synthetic MUS, patient perception regarding utilization of transvaginal mesh was tarnished by various media sources.<sup>10</sup> Prior studies have attributed the reduced rate of MUS implantation as a result of this negative public perception.<sup>11-13</sup> In our own published series, we found an overall decrease in the number of MUS performed following the aforementioned FDA notification update in 2011 despite an increasing number of new patients evaluated for SUI.<sup>11</sup> In 2014, the American Urogynecologic Society (AUGS) and the Society for Urodynamics Female Pelvic Medicine and Urogenital Reconstruction (SUFU) released a position statement claiming that a clear distinction should be made between synthetic MUS and vaginal mesh for prolapse repair, supporting the use of the former in women with SUI after a comprehensive evidence-based assessment.<sup>12</sup> This study investigates the impact of incorporating the 2014 AUGS and the SUFU position statement into patient counseling on the type of SUI surgery performed at a high volume tertiary center following the 2011 FDA notification.

## METHODS

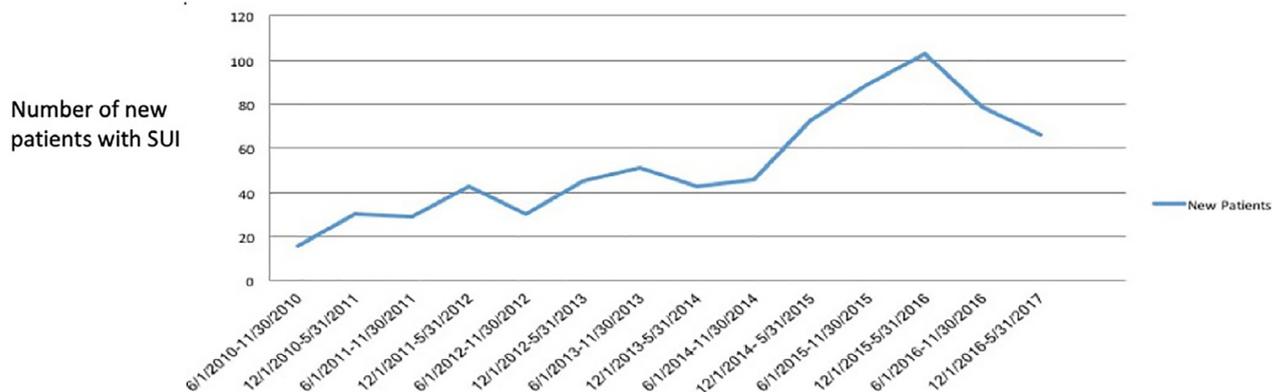
After Institutional Review Board approval, a retrospective chart review was performed to identify patients who presented to a Female Pelvic Medicine Center for evaluation of SUI by 1 of 2 Female Pelvic Medicine and Reconstructive Surgery (FPMRS) specialists. New patient visits presenting between June 1, 2010 and May 31, 2017 were identified using new patient visit codes (99,203, 99,204, 99,205, 99,243, 99,244, 99,245) and those assigned an International Classification of Diseases code 625.6 (ICD-9) or N39.3 (ICD-10) were included in the study. This database was also cross referenced with a database composed of patients who underwent surgical management for SUI using Current Procedure Terminology-Fourth Edition (CPT-4) codes 51715 (endoscopic injection of implant material into submucosal tissues of the urethra and/or bladder neck) and 57288 (sling operation for SUI) during the study period. All new patients presenting for urinary incontinence are seen and evaluated by attending surgeons, thus patients included were not referred from midlevel providers within the department. For patients undergoing sling operations (57,288), charts were reviewed to identify the type of sling utilized. Patients with pelvic organ

prolapse and occult SUI were excluded. Furthermore, if patients underwent an AFPVS, further analysis of the indications was conducted to determine if AFPVS was performed for indications that would make MUS a less desirable option based on available clinical data (simultaneous urethral reconstruction, neurogenic voiding dysfunction, prior urethral mesh erosion) and these women were excluded from analysis. Patients who had undergone prior operations for SUI prior to referral and continued to have bothersome SUI were included in the study. For patients who underwent urethral bulking procedures, only the initial injection was included in the analysis.

New patients who were seen for SUI underwent a thorough history and physical examination including a cough stress test with a full bladder. When clinically indicated, they underwent additional testing such as urodynamic testing. We discussed and offered all patients the following options for management: observation, pelvic floor physical therapy (+/- biofeedback), anti-incontinence pessary, urethral bulking, MUS, Burch colposuspension (where appropriate), and AFPVS. Risks and benefits of each option were discussed at length. Throughout the study period, patients were consistently counseled about the risks and benefits of all procedures. Complications unique to synthetic mesh (exposure, pain, erosion) and their potential severity were discussed as was the fact that the overall incidence of complications of MUS was the lowest of all surgical procedures. At each point in time, the most current relevant literature was shared with patients, including the AUGS/SUFU position statement after its release in 2014. The AUGS/SUFU position statement was discussed with patients in preoperative counseling visits and a hardcopy was provided to each patient considering surgical options for SUI. Rates of treatment modality were analyzed at 6 months intervals in order to ensure an adequate number of patients per period to identify trends over time.

## RESULTS

From June 1, 2010 to May 31, 2017, 743 new patients were assigned on ICD-9 for ICD 10 diagnosis code for SUI. We divided the study period into 6-month intervals, during which the number of new patients evaluated and the management was recorded. Over the span of fourteen 6-month intervals, the number of patients presenting for evaluation increased consistently, with a peak in the number of new patient encounters in the 12th interval (Fig. 1). During the initial study period beginning with June 2010 to November 2011, there was a simultaneous increase in the number of new patients seen as well as the



**Figure 1.** Number of new patients with SUI. (Color version available online.)

**Table 1.** New patients and treatment selection for SUI by date

Dates	# New Patients	Elected Surgical Management	Synthetic MUS	Urethral Bulking	AFPVS
6/1/2010-11/30/2010	16	7 (44%)	6 (38%)	1 (6%)	0
12/1/2010-5/31/2011	30	11 (37%)	9 (30%)	0	0
6/1/2011-11/30/2011	29	17 (59%)	11 (38%)	6 (21%)	0
12/1/2011-5/31/2012	43	17 (40%)	9 (21%)	5 (12%)	1 (2%)
6/1/2012-11/30/2012	30	10 (33%)	10 (33%)	1 (3%)	1 (3%)
12/1/2012-5/31/2013	45	16 (36%)	12 (27%)	2 (4%)	2 (4%)
6/1/2013-11/30/2013	44	24 (55%)	13 (29%)	3 (7%)	1 (2%)
12/1/2013-5/31/2014	42	8 (19%)	5 (12%)	1 (2%)	2 (5%)
6/1/2014-11/30/2014	43	13 (30%)	7 (16%)	2 (4%)	1 (2%)
12/1/2014-5/31/2015	73	30 (41%)	25 (34%)	3 (4%)	1 (1%)
6/1/2015-11/30/2015	89	46 (52%)	30 (34%)	14 (16%)	2 (2%)
12/1/2015-5/31/2016	103	52 (51%)	39 (38%)	10 (10%)	2 (2%)
6/1/2016-11/30/2016	79	44 (56%)	25 (32%)	14 (17%)	3 (4%)
12/1/2016-5/31/2017	66	41 (62%)	29 (44%)	10 (15%)	1 (1%)

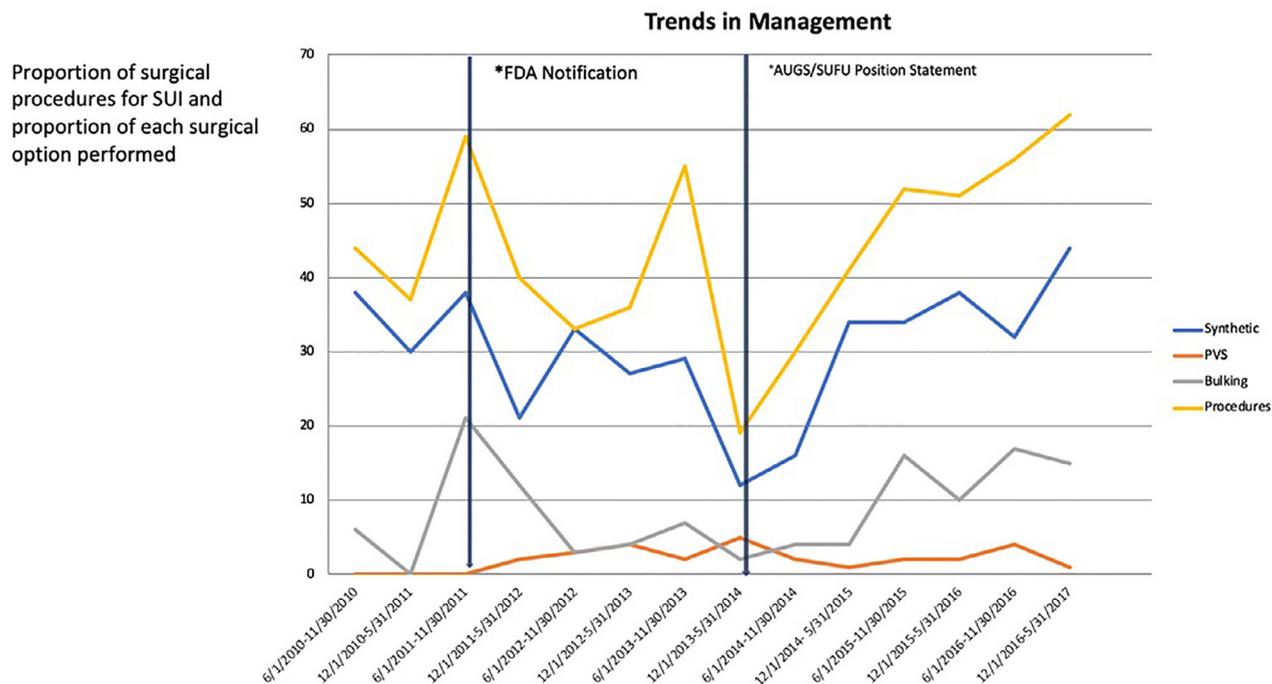
MUS, midurethral slings; AFPVS, autologous fascial pubovaginal sling; SUI, stress urinary incontinence.

proportion of new patients who underwent a surgical intervention (Table 1). There was a subsequent decrease in the proportion of new patients who underwent anti-incontinence surgical procedures identified in the following two and a half years between December 2011 and December 2013 (Fig. 2). This trend towards increased nonoperative management continued until the study interval represented by December 2013 and May 2014, where it reached the lowest during the study period (only 19% of new patients elected surgery). Throughout the study, MUS composed the highest proportion of procedures performed accounting for 60% (2nd semester 2011) to 87.2% (1st semester 2014). The decline in the number of MUS done beginning in June 2011 and ending December 2014 corresponds with the overall decreasing number of procedures done during this time period. Following this time period, there was a reversal in this trend with a sustained increase in the proportion of patients electing surgical management which paralleled an increase in

the number of new patients seen and MUS performed (Fig. 2). During the study period the number AFPVS remained relatively stable and remained a minority of the procedures performed. Nonetheless, prior to the release of the 2011 FDA notification there were 0 AFPVS performed out of concern for mesh related complications. During the study period, the number of patients electing to undergo endoscopic management with urethral bulking increased beginning in June 2015 and was used more commonly than AFPVS starting January 2014 and up to the end of the study period.

## DISCUSSION

Surgical management of SUI underwent a dramatic evolution with the advent of the MUS. Pelvic floor surgeons adopted the new technique rapidly and it quickly replaced more invasive procedures due to its utility in the



**Figure 2.** Trends in SUI management with respect to 2011 FDA notification and AUGS/SUFU Position Statement. (Color version available online.)

outpatient setting, quicker patient convalescence, lower complication rate, and demonstrable superiority in clinical outcomes. Chugthai et al investigated the surgical trends in treating female SUI amongst urologists applying for certification or recertification by the American Board of Urology between 2003 and 2012.<sup>13</sup> During the study period they found that the number of MUS performed nearly doubled and composed the majority of procedures (83%) by the end of the study. Clemons et al published the results of an electronic survey regarding the utilization of transvaginal mesh by AUGS members immediately following the 2011 FDA notification.<sup>14</sup> Over half of AUGS members responded to the electronic survey, and while the self-reported utilization of transvaginal mesh decreased by 40%, the use of synthetic MUS remained the same. This study is important as it reflects the opinion of expert implanting surgeons, however it does not reflect patient preferences in the years following the FDA notifications. In the present study we found that the utilization of MUS has decreased after the 2011 FDA notification cautioning against the use of transvaginal mesh but that this trend has reversed after the introduction of the 2014 AUGS/SUFU position statement in patient counseling. We believe this finding might be of particular interest at a time where several countries abroad are facing their own health authorities' mistrust in synthetic material use in urogynecology with similar confusions between transvaginal mesh and MUS.<sup>15</sup>

Despite the increased scrutiny over the treatment of pelvic floor disorders during the study period, we observed an overall increase in the number of new patients referred for SUI. This trend can be explained by several factors that affect the perception of pelvic floor disorders as well as incidence of risk factors. For example, greater public awareness of urinary incontinence and its treatment amongst the general population and referring providers may explain our results. Our results can also be explained by the increasing prevalence of patients with risk factors for SUI in the community, specifically obesity.<sup>16,17</sup> Furthermore, patients greater than the age of 65 continue to comprise a larger percentage of the general population as the life expectancy increases. We have not experienced a significant change in our patient population demographic including BMI and age, however this may be influenced by the local demographics. Despite the rapid adoption of synthetic MUS by pelvic floor surgeons before 2012, our results may suggest a shift in referral patterns from general urologists and gynecologists to FPMRS specialists following the FDA notifications.<sup>5,7,13,18</sup> Alternatively, this increased number of referred patients for SUI may well be simply a local phenomenon, unrelated to any of the aforementioned factors.

During the initial study period (June 2010-June 2014), there was an overall decline in the proportion of patients who underwent surgical procedures for SUI. We believe this decline was heavily influenced by the FDA notification released July 2011 and subsequent reluctance by patients to undergo procedures utilizing synthetic mesh.

Throughout the study period, synthetic MUS composed the majority of surgical procedures performed. Thus, any change in the volume of MUS performed affected the overall proportion of new patients choosing surgical treatments. Other investigators have noted similar trends in SUI management following the FDA notifications. Rac et al, performed a multi-institutional study investigating the surgical volume of MUS, sling revisions and AFPVS. The investigators noted a decrease in the utilization of synthetic MUS between 2007 and 2013, however this was not statistically significant ( $P = .25$ ).<sup>19</sup> Our results reflect similar findings, which also showed a decline in synthetic MUS during a similar time period despite the release of the updated 2011 FDA notification (which did not address synthetic mesh for SUI surgery). As discussed above, our study showed a growing number of new patients seen for SUI during the same time period thus we believe that both FDA notifications may have influenced patient's treatment choices directly or indirectly (legal advertising for potential plaintiffs, social media, etc). This conclusion is further supported by investigators who have studied patient perceptions of transvaginal mesh using questionnaire-based surveys. Koski et al, administered an 18-item questionnaire to female patients presenting with symptoms other than pelvic organ prolapse, or incontinence. They found that 33% of patients who responded to the survey had their opinion on transvaginal mesh influenced most by advertising; this was followed by medical professionals (27%). Furthermore, only 12% could distinguish between the utilization of transvaginal mesh for pelvic organ prolapse and for SUI.<sup>10</sup> The findings were echoed by Tenggardjaja et al who found that 52% of respondents to a 25-question survey believed there was a recall on transvaginal mesh. Not surprisingly, almost 70% of patients quoted television as their primary source of information regarding transvaginal mesh.<sup>20</sup> More compelling evidence demonstrating the effect of the 2011 FDA notification update was published by Souders et al when they evaluated the Bloomberg Law Database for product liability claims specifically naming mesh manufacturers as defendants between 2000 and 2014.<sup>21</sup> The group found that the number of legal claims rose from 730 in 2011 to over 34,000 in 2013 where 63% of those claims involved MUS only. The group's findings demonstrate a growing body of evidence highlighting the public's perception of MUS which is incongruent with the FDA, and medical organizations including AUGS, SUFU, and the American Urological Association.

The key finding of our study is the reversal in the trend towards nonsurgical options for SUI management beginning in mid-2014. The overall proportion of patients selecting surgical options continued until the end of the study period. This was largely driven by an increasing number of MUS performed as the number of AFPVS performed remained relatively stable. In the latter half of the study there was also an increase in the number of urethral bulking agents performed, however this was modest and greatly outweighed by the number of MUS performed.

Interestingly, AUGS and SUFU released a joint position statement regarding the use of synthetic MUS for SUI in January 2014 which we routinely used to aid in counseling patients. We believe the utilization of this tool helped address the safety concerns in the general public and helped dispel misinformation garnered by media sources.

A strength of this study is that to our knowledge, it is the first to follow the long-term effects on surgical volume of synthetic MUS in the United States following the FDA's notifications. Additionally, it included patients who were consistently counseled based on the most currently available evidence-based medicine and FPMRS board certified surgeon experience. There are several limitations to this study. First, this was a retrospective study and was not designed to investigate patient specific factors that may have influenced treatment choice. Second, patient selection was based on billing codes that may not completely reflect the clinical scenario. Although the indications for procedures were confirmed for patients included in the study, new patients with SUI may have been excluded if their billing codes did not represent this diagnosis. During the latter half of the study period, mass tort advertising also experienced public scrutiny and may have affected the public perception of synthetic MUS as time elapsed from the FDA notification in 2011. This study included a single tertiary care institution and thus may not be applicable to many surgeons throughout the country. In spite of these limitations, we believe 1 strength of our cohort in comparison to large national databases is the ability to use clinical data readily available to the investigators to provide a real-life insight into trends in SUI management.

## CONCLUSION

We observed that throughout the study period there was an increasing number of women presenting for management of SUI. During the initial study period, patients were increasingly choosing surgical management for SUI. However, following the release of the FDA Public Health Notification in 2011 we observed a decline in the number of women electing surgical management, particularly the number of patients selecting MUS as a treatment. After the release of the AUGS/SUFU position statement, we observed a reversal in the previous year's trends and noted that the utilization of synthetic MUS was experiencing resurgence.

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## EDITORIAL COMMENT



The current use of the mid urethral synthetic sling has been based on over 20 years of experience and multiple retrospective and prospective studies. The Foods and Drug Administration notification in 2011 on vaginal mesh use did have a collateral effect on the use of midurethral slings (MUSs) as the authors point out. This effect seemed to have occurred nationally as well. It remains unclear as to how the trend was reversed: if it was simply a matter of less negative advertising on mesh or hopefully the American Urogynecologic Society /Society for Urodynamics Female Pelvic Medicine and Urogenital Reconstruction statements and its use in office counseling sessions. The other options for stress incontinence in women tend to be suboptimal for a variety of reasons. Pelvic floor exercises, vaginal inserts, and urethral bulking agents have some early efficacy, however, poor long-term compliance. Despite good efficacy, the use of the autologous pubovaginal fascia sling remains infrequently used due to its morbidity and at times unpredictable outcomes (eg voiding dysfunction etc.) Regardless, the consent process and counseling on the pros and cons of mesh based MUSs is more lengthy and detailed today than in the past. The MUS (despite some infrequent unique complications) has some of the best, most reliable, and durable outcome measures available in the literature. What remains unclear is what a woman does to help her leakage if she chooses to not seek evaluation for her stress urinary incontinence based simply on negative advertising.<sup>1-3</sup>

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## AUTHOR REPLY



Thank you for your insight and the authors agree with your comments. We agree that it is difficult to ascertain the direct role media sources played on patient decision-making in this retrospective study. Overall, the American Urogynecologic Society /Society for Urodynamics Female Pelvic Medicine and Urogenital Reconstruction statements have made preoperative counseling visits more productive and helps the surgeon dispel some of the negative connotations associated with synthetic mesh products. As you mentioned, the synthetic midurethral sling has endured collateral damage from prior Foods and Drug Administration notifications on transvaginal mesh. It will be interesting to see if the Foods and Drug Administration's recent order to manufacturers of all remaining surgical mesh products indicated for transvaginal repair of pelvic organ prolapse to stop selling and distributing their products in the United States immediately, will have an equally deleterious effect on midurethral sling utilization despite our best efforts to educate our patients.<sup>1</sup>

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