Indications and Complications Associated with the Removal of 506 Pieces of Vaginal Mesh Used in Pelvic Floor Reconstruction: A Multicenter Study

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ABSTRACT

Study Objective: Synthetic mesh utilized to treat stress urinary incontinence (SUI) and pelvic organ prolapse (POP) can often result in postoperative complications. The objectives of this study were to determine: 1) the most common indications for mesh removal; 2) the incidences of the removal of specific mesh procedures (such as suburethral sling [SUS], transvaginal mesh [TVM], or sacrocolpopexy); and 3) the incidences and types of surgical complications associated with mesh removal.

Design: This was a retrospective study.

Design Classification: Canadian Task Force II-3.
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Setting: Three tertiary referral centers in the United States.

Patients: We examined data from all patients at the three centers who underwent surgical removal of synthetic materials from previous SUS, TVM, and sacrocolpopexy procedures for mesh-related complications from 2011 to 2013.

Intervention: Patients underwent vaginal, intra-abdominal, and inguinal mesh revisions by cutting, partial removal, or total removal of the mesh for mesh-related complications.

Measurements and Results: Overall, 445 patients with complications underwent mesh removal laparoscopically, via groin dissection and/or transvaginally. There were a total of 506 mesh products removed. Of these, 56.5% were slings and 43.5% were for pelvic organ prolapse (POP). Synthetic mesh removed from patients included: transvaginal mesh (TVM) anterior for anterior vaginal prolapse, TVM posterior for posterior vaginal prolapse, sacrocolpopexy mesh, and suburethral slings (SUS) for stress urinary incontinence. Synthetic SUS removed included: retropubic (RPS), transobturator (TOT), and single-incision slings (SIS). TOT was the most common type of sling removed. Patients with a sling who only complained of vaginal pain with or without intercourse underwent a vaginal approach for surgical revision/removal of the sling (86.6%). Patients with an RPS with lower abdominal/suprapubic pain and vaginal pain underwent a vaginal and laparoscopic approach for sling removal (18.4%). Patients with a TOT sling who complained of vaginal and groin pain underwent a vaginal and inguinal approach for sling removal (4.3%). In patients who had POP mesh removal, 42.3% had an anterior TVM, 30.6% had a posterior TVM, 14% had both anterior and posterior TVMs, and 13.1% underwent sacrocolpopexy mesh removal. Complications encountered during mesh revision/removal surgery were: two blood transfusions from complete RPS removal (vaginal and laparoscopic approach), three urethral injuries during TOT sling removal (vaginal approach), two ureteral injuries during anterior vaginal wall mesh removal, and two rectal injuries during posterior vaginal wall mesh removal. All injuries were repaired at the time of mesh removal without recurrence.

Conclusion: In our study, the most common indication for mesh removal was pain with or without intercourse. The most common mesh procedure resulting in removal was the TOT sling. Use of a vaginal approach only for sling removal had the lowest incidence of intraoperative complications. Laparoscopic RPS removal had the highest incidence of required blood transfusions, anterior TVM had the highest incidence of ureteral injury, and posterior TVM had the highest incidence of rectal injury. Overall, sling, TVM, and sacrocolpopexy mesh removal are safe procedures when performed by experienced surgeons.
Synthetic mesh used in the surgical treatment of stress urinary incontinence (SUI) and pelvic organ prolapse (POP) can often result in postoperative mesh complications. The postoperative complications most often cited in the literature include pain, organ erosion, vaginal extrusion, vascular injury, bladder injury, rectal injury, and infections. A systematic literature review reported that the most common complication associated with vaginal mesh was vaginal erosion, accounting for 4.6–10.7% of complications. Risk factors for mesh complications are operative technique, surgeon experience, previous prolapse repair, concomitant hysterectomy, inverted T colpotomy, total mesh repair, the mesh’s properties, young age, sexual activity, and smoking. In addition, uterine preservation can reduce the erosion rate to 1%. Patients who experience mesh complications are often treated with surgery for scar and mesh revision/removal, thereby exposing these patients to new surgical risks. Here, we conducted a multicenter study of patients with mesh-related complications who underwent surgical mesh removal. The objective of this study was to determine: 1) the most common indications for mesh removal; 2) the most common approach for mesh removal; and 3) the incidence of intraoperative surgical complications.

### MATERIALS AND METHODS

This was a retrospective chart review of all patients who underwent surgical removal of an SUS, TVM, and/or sacrocolpopexy from January 2011 to December 2013 for mesh-related complications at three tertiary referral centers in the southeastern United States (International Urogynecology Associates—Atlanta and Beverly Hills, Emory University, and the Cleveland Clinic of Florida). Databases were queried to identify potential subjects. We included all women who underwent reconstructive pelvic surgery using synthetic mesh for prolapse or urinary incontinence and had subsequent synthetic mesh revision/removal with confirmed mesh complications. The surgical procedures for mesh revisions included cutting, partial removal or total removal of the vaginal portion of the mesh, as well as removal of mesh from the groin, preperitoneal, retroperitoneal, and intra-abdominal areas. Patient complaints were confirmed preoperatively via physical examination. Patients with mesh slings and/or TVM who complained of vaginal pain with or without intercourse underwent only the vaginal approach for surgical mesh removal. Patients with lower abdominal and vaginal pain with an RPS or sacrocolpopexy underwent a vaginal and/or laparoscopic approach for mesh removal. Patients who complained of vaginal and groin pain who had a TOT sling underwent a vaginal and inguinal approach removal.

Data were analyzed with a chi-squared test for categorical data and Student’s t-test or Wilcoxon Rank Sum Test for continuous data. Effects were determined with a logistic regression analysis.

<table>
<thead>
<tr>
<th>Demographics</th>
<th>rTHA (n=100)</th>
<th>mTHA (n=100)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years (Mean) (SD)</td>
<td>63.2 (11.5)</td>
<td>61.5 (12.2)</td>
<td>0.332T</td>
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<tr>
<td>Gender – Male (%)</td>
<td>49 (49.0)</td>
<td>41 (41.0)</td>
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<tr>
<td>Body Mass Index (Mean) (SD)</td>
<td>29.5 (5.3)</td>
<td>30.0 (6.0)</td>
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</table>

**Surgical data**

<table>
<thead>
<tr>
<th>Surgical data</th>
<th>rTHA (n=100)</th>
<th>mTHA (n=100)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin-to-skin (Mean) (SD)</td>
<td>131 (23)</td>
<td>122 (29)</td>
<td>0.012T</td>
</tr>
<tr>
<td>Estimated Intraoperative Blood Loss (Mean) (SD)</td>
<td>374 (133)</td>
<td>423 (186)</td>
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<td>Side – Right (%)</td>
<td>55 (55.0)</td>
<td>51 (51.0)</td>
<td>0.671C</td>
</tr>
<tr>
<td>Follow-up Time (Mean) (SD)</td>
<td>374 (359-500)</td>
<td>367 (353-387)</td>
<td>0.013W</td>
</tr>
<tr>
<td>Complication Rate (%)</td>
<td>2.0%</td>
<td>8.0%</td>
<td>0.101C</td>
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<tr>
<td>Dislocation</td>
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<td>3.0%</td>
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</tr>
<tr>
<td>Readmission</td>
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<td>1.0%</td>
<td>---</td>
</tr>
<tr>
<td>Revision</td>
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<td>1.0%</td>
<td>---</td>
</tr>
<tr>
<td>Fracture</td>
<td>0.0%</td>
<td>0.0%</td>
<td>---</td>
</tr>
<tr>
<td>Infection</td>
<td>0.0%</td>
<td>0.0%</td>
<td>---</td>
</tr>
<tr>
<td>Venothrombotic Events</td>
<td>1.0%</td>
<td>3.0%</td>
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</tr>
</tbody>
</table>

*include sling revision. Data are shown as n (%). POP, pelvic organ prolapse.
A total of 445 patients who experienced mesh-related complications underwent mesh removal laparoscopically, via groin dissection, and/or transvaginally during the study period. There was a total of 506 mesh products removed. The mean patient age was 53.8 ± 11.2 years, and mean parity was 2.5 ± 1.2. The majority of patients were Caucasian (82.0%), postmenopausal (72.8%), sexually active (52.1%), and insured (76.4%). Additionally, 82.9% had previously undergone hysterectomy, 92.6% had previously been seen by at least one other physician, 25% were current smokers, and 28% had previously undergone surgery for mesh revision or removal.

Of the 445 patients, 373 (83.3%) had a synthetic SUS for SUI, 178 (40%) had a transvaginal mesh, and 38 (8.5%) had sacrocolpopexy for treatment of POP. Some patients had more than one type of mesh implanted. Slings were categorized as previously described into RPS, TOT, and SIS. Patients who had received TVM were categorized into the anterior vaginal wall mesh and posterior vaginal wall mesh groups. The most common indication for mesh revision was pain with and without intercourse (Table I). Of the 506 pieces of mesh removed, 56.5% were slings and 43.5% were mesh for POP (Table II). The TOT was the most common type of sling removed. TOT patients were 60% more likely to have pain than were RPS patients (odds ratio 1.6, 95% confidence interval 0.9–2.7).

Patients with a sling who complained of vaginal pain with or without intercourse were subjected only to a vaginal approach for mesh removal (86.6%). Patients with lower abdominal/suprapubic pain and vaginal pain who had an RPS underwent a vaginal and laparoscopic approach for mesh removal (18.4%). Patients with a TOT who complained of vaginal and groin pain underwent a vaginal and inguinal approach for sling removal (4.3%). Patients who underwent POP mesh removal included: anterior vaginal wall TVM (42.3%), posterior TVM (30.6%), both anterior and posterior TVM (14.0%), and sacrocolpopexy mesh (13.1%) patients.

The median intraoperative estimated blood loss was 50 mL (range 0–800). Complications encountered included: two (0.5%) blood transfusions (both were the result of laparoscopic RPS removal), three urethral injuries (all of which occurred during TOT removal), two ureteral injuries (both of which occurred during anterior TVM removal), and two rectal injuries (both of which occurred during posterior TVM removal).

### DISCUSSION

It has been shown that some mesh techniques used for POP and SUI have long-term successful anatomical and physiologic outcomes. However, the benefits of using synthetic mesh should be weighed against the risk of potential mesh-related complications.

There are several reasons why a patient may experience a mesh complication, such as an infection, erosion (into a viscus structure), extrusion (through vaginal epithelium), and/or pain. Complications are a result of the type of mesh and its inherent properties, the mesh structure (including weave, density, thermal bonding, and porosity), associated scar tissue, mesh contracture, the mesh delivery system, and the surgeon’s technique. Previous publications suggest that the most common mesh-related complications are erosion and dyspareunia. Other publications suggest the most common reason for mesh removal is pain with or without intercourse. Mesh removal from pain or dyspareunia vary from 0.9% to 31.2%. However, our findings show that the most common indications for sling and POP mesh removal were vaginal pain with and without intercourse, which collectively accounted for 73% of our patients.

Management of mesh-related complications is challenging. Conservative management includes topical estrogen therapy, trigger-point injections, pelvic floor physical therapy, and vaginal dilators, and these are not always successful. Early diagnosis and surgical treatment (such as removing the mesh) is essential for reducing chronic pain. A delay in surgical treatment will result in more aggressive scarring, contraction, myofascial contortion, and secondary nerve entrapment.

Among the three types of synthetic slings, the TOT was the most common type of sling removed. The second most common type of mesh removed in our study was the anterior TVM. Though collectively our study demonstrated that vaginal pain with or without intercourse was the number one reason for mesh removal, this is especially interesting when considering the anatomical pathway of the anterior TVM and TOT sling.

The two most common types of mesh removed in this study have similar anatomical mesh delivery pathways. Both the anterior TVMs and TOTs have mesh arms that traverse the obturator foramen to exit the skin.
in the inguinal region. This pathway allows the mesh arms to penetrate multiple layers of tissue, including but not limited to the obturator internus, obturator membrane, and obturator externus, which are not traversed in any other urological or gynecological mesh procedure. Investigators have suggested that a chronic inflammatory reaction to mesh and its resulting muscle fibrosis underlies the etiology of secondary nerve entrapment and chronic pain. Not removing the mesh in a timely fashion from patients experiencing pain will most likely subject the patient to a lifetime of chronic neuropathic pain.\(^{14}\)

The documented injuries to internal organs, including the ureters, urethra, and rectum, were unwanted yet predictable consequences of mesh removal surgery. These injuries are occasionally expected as the mesh, specific to the site of removal, becomes aggressively scarred and adheres to the adjacent organ. None of the patients who experienced intraoperative organ injuries during mesh removal experienced sequelae due to the injuries.

The strength of our study is that it is a large multi-center study with a large cohort of patients with confirmed mesh-related complications. The limitations of our study are its retrospective approach, the lack of a standardized surgical technique for transvaginal mesh removal (i.e., cutting, partial, or total removal), and a lack of a standardized approach (laparoscopic, inguinal or vaginal) for mesh removal. In addition, this cohort may not represent the general population because each of the three centers involved in this study are tertiary care centers for advanced urogynecologic procedures.

**CONCLUSION**

In our study, the most common indication for mesh removal was pain. The most common type of mesh procedure removed was the sling, and the most common type of sling removed was the TOT. The most common type of POP mesh removed was the anterior TVM. Transvaginal sling revisions/removal had the least amount of surgical complications. Laparoscopic RP removal had the highest incidence of blood transfusion, anterior vaginal wall mesh removal had the highest incidence of ureter injury, and posterior vaginal mesh removal had the highest incidence of rectal injury. Overall, sling, TVM, and laparoscopic sacrocolpopexy mesh removal are safe procedures when performed by experienced surgeons.\(^{14}\)

**AUTHORS’ DISCLOSURES**

Dr. Davila receives grant/research support from Coloplast Corp., Cook Medical Inc., and ACell. He is also on the Speaker’s Bureau for Cogentix Medical, Inc.

All other authors have no conflicts of interest to disclose.

**REFERENCES**