

# Mesh Excision: Is Total Mesh Excision Necessary?

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**Abstract** Nearly 29 % of women will undergo a secondary, repeat operation for pelvic organ prolapse (POP) symptom recurrence following a primary repair, as reported by Abbott et al. (Am J Obstet Gynecol 210:163.e1–163.e1, 2014). In efforts to decrease the rates of failure, graft materials have been utilized to augment transvaginal repairs. Following the success of using polypropylene mesh (PPM) for stress urinary incontinence (SUI), the use of PPM in the transvaginal repair of POP increased. However, in recent years, significant concerns have been raised about the safety of PPM mesh. Complications, some specific to mesh, such as exposures, erosion, dyspareunia, and pelvic pain, have been reported with increased frequency. In the current literature, there is not substantive evidence to suggest that PPM has intrinsic properties that warrant total mesh removal in the absence of complications. There are a number of complications that can occur after transvaginal mesh placement that do warrant surgical intervention after failure of conservative therapy. In aggregate, there are no high-quality controlled studies that clearly demonstrate that total mesh removal is consistently more likely to achieve pain reduction. In the cases of obstruction and erosion, it seems clear that definitive removal of the offending mesh is associated with resolution of symptoms in the majority of cases and reasonable practice. There are a number of complications that can occur with removal of mesh, and patients should be informed of this as they formulate a choice of treatment. We will review these considerations as we examine

the clinical question of whether total versus partial removal of mesh is necessary for the resolution of complications following transvaginal mesh placement.

**Keywords** Cystocele · Rectocele · Vaginal vault prolapse · Exposure · Perforation · Sling obstruction

## Introduction

Nearly 29 % of women will undergo a secondary, repeat operation for POP symptom recurrence following a primary repair [1]. A variety of risk factors for this have been identified including age, parity, smoking, comorbid conditions, and tissue quality. In efforts to decrease the rates of failure, graft materials have been utilized to augment transvaginal repairs. Following the success of using polypropylene mesh (PPM) for stress urinary incontinence (SUI), the use of PPM in the transvaginal repair of POP increased.

However, in recent years, significant concerns have been raised about the safety of PPM mesh used in procedures to treat SUI and pelvic organ prolapse. Complications following POP repair, such as exposures, erosion, dyspareunia, and pelvic pain specific to mesh, were reported with increased frequency. In response, the Food and Drug Administration (FDA) released public health notifications in 2008 related to transvaginal mesh and SUI [2]. After further investigation, the FDA released a second public health notification in 2011 pertaining to transvaginal mesh insertion for POP repair. As a result of these investigations, the FDA Device Panel recommended reclassification of transvaginal PPM for prolapse to class 3 but recommended no change in classification or the use of multi-incision slings (retropubic and transobturator) [3]. Many women are currently seeking guidance about previously placed mesh for POP, some experiencing complications and

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others who are asymptomatic. Unfortunately, there is little evidence-based material to definitively guide recommendations and treatment decisions. This review provides an overview of mesh biology after implantation and places these principles in context when discussing the concept of total versus partial mesh removal in women following mesh placement for POP.

In preparation of this manuscript, we approached the discussion surrounding the amount of required mesh excision by addressing two global questions. Are there intrinsic properties of the mesh that warrant total excision? And, is total mesh removal necessary to correct complications that may arise after mesh implantation. It is the authors' premise that in the absence of intrinsic reasons to remove all of the vaginal mesh, a partial excision is preferred if the likelihood of symptom eradication is projected to be the same.

### Biology of Mesh Implantation

Polypropylene mesh (PPM) is a nonabsorbable synthetic graft material with uses not limited to transvaginal surgery. Often used in the repair of abdominal wall hernias, surgeons have long noted the adhesive fibrotic reactions, which make adjacent dissections somewhat difficult after implantation. In addition to providing permanent support, a process of tissue ingrowth takes place, which may add support and enhance compatibility of the graft. The host-tissue interaction leading to tissue ingrowth is likely dependent on host factors as well as on the material and structure of the graft. PPM is a macroporous mesh (>75  $\mu\text{m}$ ), and this large pore size theoretically facilitates macrophage and fibroblast infiltration into the mesh. This ingrowth facilitates the incorporation of host tissue into the mesh and promotes host defenses against infection

Questions have been raised as to the intrinsic safety of polypropylene in vivo [4]. Sternschuss et al. have noted that additives added to the mesh can create toxicity in adjacent tissues and that direct oxidation may lead to degradation of mesh after implantation. They reported that PPM mesh is "not inert" and that the quest for a biocompatible mesh continues. However, in this study, many of the models cited were in laboratory models that involved placement of the mesh (or polymers) under extreme conditions that are unlike in vivo conditions. Additionally, as Goldman and Petros point out, the mesh samples used in these studies were vaginally exposed pieces of mesh—none had been extracted from a normally healed setting. It has been pointed out in the clinical setting of mesh placement for prolapse that direct toxicity of PPM has not been reported [5]. Polypropylene mesh has undergone multiple FDA-mandated biocompatibility tests to ensure that there is no immune response beyond that required for healing and that the material is inert nontoxic and noncaustic.

In balance, it should be mentioned that the safety of the mesh material has been demonstrated in several experimental small and large animal models [5].

Recent animal studies have looked at tissue responses to type 1 meshes of varying degrees of stiffness. Stiffer meshes were associated with more evidence of maladaptive tissue remodeling [6]. It was postulated that these changes could possibly result in increased mesh-related complications. However, it is unclear whether these histologic changes have any clinical applicability to human responses to vaginal mesh and their overall clinical significance. Woodruff et al. performed histologic examinations on slings of 24 varieties explanted for revision. At 2–24 months postimplantation, PPM was not associated with degradation or encapsulation, and PPM had the greatest degree of host infiltration as evidenced by neovascularization and fibroblast ingrowth [7]. Elmer et al. prospectively evaluated the histological inflammatory response in 10 patients and eight controls 1 year after undergoing prolapse surgery with type 1 mesh. They found that compared to preoperatively, the vaginal tissue with mesh had increased counts of macrophages and mast cells postoperatively. There were no differences in cells associated with infectious responses or in collagen or elastin. They concluded that 1 year after surgery, the type 1 mesh activated an enduring but nonsevere foreign body response in human vaginal submucosal tissue [8].

To date, there is no compelling evidence linking PPM to local or systemic reactions or toxicities that would warrant explanation in the asymptomatic patient. In addition, there is also no clinical evidence of a carcinogenic or systemic immune response after vaginal implantation of PPM. Thus, to date, there appear to be no intrinsic mesh properties warranting removal of asymptomatic vaginal mesh to "prevent" future complications. These sentiments are echoed in the American Urologic Association's (AUA) position statement on the use of vaginal mesh for the repair of pelvic organ prolapse [9] and was reiterated as one of the statements in the AUA "Choosing Wisely" Campaign. Specifically, the AUA recommends against removing synthetic vaginal mesh in asymptomatic patients. They state that there is no clear benefit to such a procedure and that removal could expose patients to additional morbidity and serious complications like bladder or rectal injury or fistula formation [9].

### Mesh Removal for Postoperative Complications: Indications

Various approaches to vaginal mesh and tape removal have been reported [10–12]. The approach to mesh removal depends on the indication for mesh removal, patient factors such as comorbidities and immunosuppression, and the type of mesh originally implanted. Having addressed the intrinsic

properties of PPM mesh, we will now address the necessity of total versus partial PPM mesh removal by examining specific complications warranting surgical intervention.

## Infection

Vaginal meshes are foreign bodies introduced through the nonsterile vaginal compartment. Theoretically, this nonsterile environment may increase the probability of mesh infection [13]. Prior work with mesh slings refutes that vaginal flora contributes to infection. Mesh slings exposed in the vagina for 6 to 12 weeks, even in the presence of purulence, had only “mixed organisms” with scant or no growth [5]. Clinical evidence regarding polypropylene mesh inciting infectious complications is exceedingly rare. Infectious complications are reported with a higher frequency from other mesh types such as knitted polyester or silicone types (0 and 5 %, respectively) [13]. The reported rate of mesh infection with polypropylene mesh is about 0 %. Deffieux et al. reported zero cases of mesh infection and zero cases of urethral or bladder infections in 138 women undergoing anterior repairs with transvaginal, tension-free soft polypropylene mesh [14]. Lim et al. reported zero cases of infection in 90 women within the first 4 months after undergoing posterior colporrhaphy with absorbable PPM mesh composite graft [15]. Furthermore, many of the reported cases of infection with PPM have been associated with vaginal exposure of the mesh. Milani et al. reported one infectious complication in 63 women undergoing anterior or posterior prolapse repairs with PPM. This patient had a vaginal exposure following posterior repair that was associated with a pelvic abscess. This complication was managed with antibiotics and partial removal of the exposed mesh [16]. Thus, it seems that the overall risk of purulent infection is small with PPM. In the scant amount of evidence, these infections appear confined to exposed areas of mesh—not extending into the adjacent well-incorporated mesh. Thus, it appears that adequate drainage and debridement of the infected area as well as partial mesh excision appear to be the preferential treatment in the small number of reported cases. Infections with earlier-generation non-PPM meshes often necessitated complete removal of the mesh [17]. Based on the extremely limited body of evidence, it does not appear necessary to remove the entire mesh following a PPM infection.

## Mesh “Exposure”—Vaginal “Extrusion” of Mesh

In women experiencing exposure or vaginal extrusion of PPM mesh, there are a number of studies to assist in guiding our practice. The absolute rate of mesh exposure is unknown due to “inadequate” follow-up in many studies as well as the lack of systematic registries and high attrition rates. The Australian

Urogynecology working group recently reported the results from their transvaginal mesh registry. Seven hundred twenty-six procedures with 10 different transvaginal kits were registered. Over a 5-year period, the rates of mesh erosion were 11 % at 3 months and 12 % at 12 months [18]. Multiple management approaches to vaginal exposure of midurethral slings have been reported. Options include observation, use of topical estrogen or antiseptics, systemic or topical antibiotics, office-based trimming of the extruded material, and partial mesh excision or total mesh excision. Kobashi et al. reported on a series of 90 patients who underwent retropubic midurethral sling placement. Four of these patients had small vaginal exposures of less than 1 cm in size noted at 6 weeks follow-up. At this early point in the postoperative course, all patients were treated with observation alone and had complete spontaneous epithelialization over the mesh [19]. All of these patients were evaluated and treated within 6 weeks of their original surgery. Other studies with longer follow-ups have reported much lower success rates with expectant management alone. Tjldink et al. reported on their retrospective cohort of 75 patients who had undergone surgery for mesh-related complications. All had undergone mesh implantation for correction of stress urinary incontinence (SUI) or for pelvic organ prolapse (POP). These materials included PPM and other mesh types. Fifty-one patients had vaginal exposure of the mesh. Sixty-eight percent failed expectant management [20]. These patients were seen between 2 months and 18 years following their mesh insertion. Other groups have reported similarly disappointing results with conservative management [11, 21]. In our opinion, expectant management will be unlikely to resolve the problem in the majority of patients with symptomatic mesh exposure. In patients highly motivated to attempt expectant management, there should be appropriate counseling regarding the likely possibility of failure to resolve the exposure and the possible need for further treatment. Medical treatment alone for vaginal exposure of vaginal mesh for POP is similarly disappointing. Caquant et al. reported on a retrospective cohort of 684 patients who had transvaginal mesh prolapse repair. They reported a rate of 11.3 % for vaginal extrusion and of those only 42 % resolved with medical management alone with antibiotics, antiseptics, and topical estrogens [22]. De Landsheere et al. report an even lower success rate in their cohort of 524 patients. Thirteen of the 14 patients with mesh exposure required surgical intervention after a median 3 years follow-up [23].

Various operative approaches have been described for operative removal of exposed vaginal mesh. The approach will depend upon the type of mesh used, the location and extent of exposure, and the quality of the surrounding tissue. Office-based limited mesh excision with local anesthesia has been described. This can be challenging, however, due to limited visualization and patient discomfort. It should be explained to the patient that the minimal amount of exposed mesh will be

removed and recurrences are probably highest in this setting. Nevertheless, for minimal mesh exposures, this may be the ideal option to excise the involved mesh only. A more formal mesh excision is the approach preferred by the authors. The exposed portion of the mesh is excised as well as enough surrounding vaginal wall. This facilitates the creation of local “flaps” of adjacent normal vaginal tissue mesh to allow for an interrupted, tension-free closure of the vaginal epithelium. Data on partial excision is much more favorable with newer type 1 polypropylene than with earlier series of other synthetics [11]. Failure rates of 0–8 % requiring repeat excision have been reported for partial excision for vaginally placed PPM meshes [11, 20].

Vaginal extrusions following sacrocolpopexy can be more challenging given the more proximal location of the mesh, its attachment to the sacrum, and its vicinity to major intra-abdominal structures. One study reported a success rate of only 53.3 % for transvaginal removal of ASC mesh, as well as significantly more adverse events occurring in the patients who proceeded to open abdominal exploration [24]. However, in the absence of other indications for abdominal exploration, partial removal of the exposed vaginal mesh at the apex seems like a reasonable operative approach.

## Perforation

The International Continence Society defines a “perforation” as an abnormal opening into a hollow organ or viscus [25•]. Although the definition is generalizable to many organs, including bowel, the germane structures in this discussion will be bladder and urethra, as the skill set for removal is generalizable to pelvic surgeons. This complication, though potentially more severe, is much less commonly seen, and while urethral or bladder perforations have been described in numerous studies, their exact incidence is unknown. A recent Cochrane review reported an average bladder and urethral perforation rate of 2.54 % for all midurethral slings (retropubic and transobturator) [26]. However, a more recent series at tertiary referral centers has shown rates as high as 33 %, albeit involving a skewed population [27]. Similarly, bladder and urethral perforations secondary to mesh placed for POP are also low. In the majority of instances, they are dissection- or trocar-related perforations and have been reported to be between 0.6 and 0.73 % [22, 23]. In a retrospective review of patients referred to Vanderbilt for management of mesh exposures and perforations of the urinary tract, multivariate logistic regression analysis was performed to identify risk factors [27]. They concluded that trocar injury, diabetes, and bleeding complications at the time of surgery were associated with a higher risk of mesh perforation.

Sequelae from perforations can be present in many different ways. Obstruction may occur if the mesh were in the

urethra or bladder neck, or the mesh could serve as a nidus for hematuria, recurrent urinary tract infections, stone formation, pain, or urinary urgency and frequency. Fistula formation may even result in more advanced cases. Although most pelvic surgeons would agree that perforated mesh necessitates removal, there is no consensus on the approach or whether partial or total mesh removal is necessary.

Several small, retrospective case series have described their techniques for mesh removal from the urethra and bladder. Transvaginal, endoscopic, and laparoscopic techniques have been reported. Velemir et al. described a purely endoscopic removal of tape from the bladder and urethra in four patients. Secondary to partial removal of the mesh, two of the four patients required repeat excision and three presented with recurrent SUI [28]. Other small series have shown similarly high reoperation rates with purely endoscopic management [29, 30]. Open, laparoscopic, and transvaginal removal has also been described. In these techniques, a larger portion of the mesh is generally removed. Marks and Goldman describe taking enough mesh to avoid protruding edges that may encroach upon the perforated organ or into the vagina [11].

Unfortunately, there is no guide to direct the extent of mesh removal resulting from perforation. With only small case series to rely upon, it is evident that mesh removal must be tailored to the patient’s needs and comorbidities, as well as the extent and location of the perforation. The perforated portion of the mesh should absolutely be removed; however, there is a paucity of evidence to prove superior outcomes with removal of the entire prosthesis. It is the practice of the authors to remove the mesh that is contributing to the problem and as much as is reasonably safe beyond that. Complete removal does not appear to be required once the perforated mesh has been removed. However, before undertaking partial mesh excision, the clinician should document that there are no other problems associated with the noneroded mesh such as obstruction and/or pain.

## Pain

One of the more controversial and frequent indications for the removal of mesh is for the indication of pain. The incidence of pelvic pain after sling and transvaginal mesh placement has been cited in the literature to range from 0 to 30 % [31, 32]. The published studies on outcomes after surgery, especially pain, tend to be retrospective surgical cohorts, and there are no randomized controlled trials comparing total and partial mesh removal. Pain often presents in conjunction with the other complications such as obstruction, exposure, or perforation. It is essential that the patient be thoroughly evaluated for other potential etiologies of pain. Unfortunately, the causes of pain in the absence of other identifiable factors following mesh placement are poorly understood. Some have postulated that

mesh placed in close proximity to a nerve may be contributing to an induced neuropathic pain of the pelvic floor [33]. Case reports or small series of patients with obturator neuralgia have been described. The obturator nerve enters into the upper part of the obturator foramen and is close to the arms of a transobturator sling and occasionally those of a malpositioned retropubic sling. Patients often complain of sharp, electric, or burning pain in the groin and in the anterior and internal thigh. This type of pain is often aggravated by certain movements and by walking [33]. Marcus-Braun reported that removal of the mesh resulted in resolution or improvement in the obturator-related pain. Another identified source of pain is pudendal neuralgia, which has also been well described. The pudendal nerve crosses the sacrospinous ligament close to the ischeal spine. It can be impinged upon where the trocar pass for posterior mesh exit or when suture fixation of the mesh is too deep or too close to the ischial spine. Pain occurs in the anatomic territory of the pudendal nerve from the anus to the clitoris and is exacerbated by sitting. Generally, it does not wake the patient up at night, and there is no patient-reported sensory loss on exam. Temporary pain relief following nerve block can confirm this diagnosis [34]. Disappointingly in the Marcus-Braun series, this pain did not resolve following mesh removal; both partial and complete removal techniques were utilized. In many respects, depending on the chronicity of the neuralgia, it seems that pain will likely remain, the longer the inciting mesh is present.

In our clinical experience, the majority of the pain following transvaginal mesh placement is not neuropathic but related to a pelvic floor muscular dysfunction induced by mesh placement. This mesh may be placed under tension, which may alter the dynamic muscular state of contraction. This may elicit hyperspasticity of the muscle, which can lead to localized or even diffuse pain. The physical examinations of many of these women resemble that of high tonus pelvic floor dysfunction. Many of these women will not have pain of a neuropathic variety—but one of muscle spasm creating dysfunction of one or more of the pelvic organs. “Trigger points” are areas of localized pelvic muscle pain and can be seen directly emanating from mesh “arms” or points of insertion of the mesh into the pelvic muscle complex. If these areas are localized to the mesh, it has been our experience that partial removal of the offending mesh attachment or area(s) of tension are highly associated with resolution of pain.

Hou et al. reported on their series of 123 patients (54 with suburethral sling and 69 with vaginal mesh for POP) who underwent surgical removal for the sole indication of pain. Reported locations of pain were vagina, inner thigh, lower abdominal or buttock, and/or pain during intercourse. Partial implant removal was performed. In the transobturator patients, the lateral arms past the inferior edge of the pubic ramus were left intact. In the retropubic group, the arms extending toward the retropubic space were left in place. The vaginal mesh was

removed vaginally as far laterally as possible. Pain was assessed using a simple visual analog scale (VAS) with a range from 0 to 10. Interestingly, they found a marked pain improvement after excision in all groups. The VAS score decreased from a mean of 5.3 to 1.5 in the sling group and from 7.9 to 0.9 in the mesh group. Total pain-free status was achieved in 81 % of patients after sling removal and in 67 % after mesh removal [35]. Rigaud et al. followed a group of 32 patients undergoing removal of sling (retropubic and transobturator) for chronic pelvic and perineal pain. Retropubic slings were removed by transperitoneal laparoscopy leaving the suburethral mesh in place, and transobturator slings were removed transvaginally utilizing both partial and complete removal techniques. The practice of removing the retropubic mesh and leaving the suburethral portion is less commonly performed—with many clinicians removing the vaginal mesh initially with the intent of correcting tension and sexual pain. Interestingly, they found abnormal mesh position intraoperatively in 88 % of the retropubic group (in the levator ani and/or the detrusor muscle). In the transobturator group, two cases revealed tape in the adductor longus muscle with fibrosis surrounding branches of the obturator nerve. Pain relief was achieved in 68 % of patients as defined by at least 50 % improvement in the VAS scale. Mean VAS scores decreased from 7.3 and 3.4 postoperatively. They analyzed pain improvement in the transobturator group and found no statistical difference between the partial and complete tape removal. Either way, this study did not demonstrate any advantage to complete tape removal. As expected, incontinence recurred in 22 % of their patients (7 of 32) [31]. In contrast, Crosby et al. reported on 90 patients undergoing surgical removal of vaginal mesh for POP for a variety of indications. Sixty-four percent (58 patients) presented with pain only. Mesh was removed vaginally and “as much mesh as possible” was taken out. Concomitant prolapse repairs or anti-incontinence procedures were performed as indicated. They had excellent results regarding exposures with a 95 % success rate. Patients with only pain symptoms did not do as well though, unfortunately. Fifty-one percent of patients had persistent pain symptoms following surgery, and of the 43 patients that reported dyspareunia, 30 % had persistent symptoms. Those who had removal of all vaginally accessible mesh were not more likely to have pain improvement than those who had partial removal (58.1 vs 70.1 %) ( $P=0.4$ ) [36]. However, it is not clear how to identify those patients who should be offered total mesh removal as the primary procedure.

Pain can sometimes resolve on its own or be successfully treated with analgesics or physical therapy. When these first-line interventions fail, the patient may choose to undergo surgery for removal of the tape or mesh. Patients may also be more motivated to have removal of the mesh given the publicity and litigation related to the FDA warning about vaginal mesh. When counseling patients, it is important to explain that

there is clearly not enough quality data to determine best practices when surgically intervening for pain. A number of studies have demonstrated that the majority of patients do well with partial excision of the offending mesh. However, subsequent procedures may be necessary due to persistent pain. This risk must be balanced with the complexity of total mesh removal which may increase the risk of complications and in era of insufficient evidence of necessity—it has been our practice to remove the offending mesh and as much adjacent mesh as safely possible after extensive consultation.

## Conclusion

In the current literature, there is not substantive evidence to suggest that PPM has intrinsic properties that warrant total mesh removal in the absence of complications. There are a number of complications that can occur after transvaginal mesh placement that do warrant surgical intervention after failure of conservative therapy. In aggregate, there are no high-quality controlled studies that clearly demonstrate that total mesh removal is consistently more likely to achieve pain reduction. In the cases of obstruction and erosion, it seems clear that definitive removal of the offending mesh is associated with resolution of symptoms in the majority of cases and constitutes reasonable practice. There are a number of complications that can occur with removal of mesh, and patients should be informed of this as they formulate a choice of treatment.

## Compliance with Ethical Standards

**Conflict of Interest** Gillian F. Wolff and Ryan M. Krlin each declare no potential conflicts of interest.

J. Christian Winters was an investigator for Solace and consultant for Allergan and Astellas.

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