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EDITORIAL

Safety of synthetic mesh in pelvic surgery

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Abstract

Mesh in the form of a midurethral sling is an acceptable and generally safe treatment option for stress urinary incontinence in patients who have failed conservative treatment options such as weight loss and pelvic floor muscle training. In patients with pelvic organ prolapse, when outcomes are measured in terms of improvement in postoperative physical exam (anatomic success), many studies have demonstrated that mesh augmented repairs are superior to prolapse repairs not using mesh (native tissue). However, from a symptomatic standpoint, the outcomes of mesh and native tissue repairs are equivalent. This means that even though the physician may see more prolapse on physical exam after native tissue repair, most patients do not perceive this as a problem because their sensation of a vaginal bulge is gone. The vaginal bulge is one of the most common complaints of a patient prior to pelvic organ prolapse repair. Based on interpretation of the available literature, it does not appear that mesh is superior to native tissue repair for anterior (cystocele) and posterior (rectocele) compartment pelvic organ prolapse repair. However, for apical repairs the native tissue repairs are more technically challenging and it appears that suspension of the apex of the vagina with mesh to the sacrum (sacrocolpopexy) may yield better outcomes. Unfortunately, like all mesh surgeries there is a significant risk of mesh complications with sacrocolpopexy. Surgeons should thoroughly counsel their patients about the permanent nature of synthetic mesh and the potential serious complications related to its use. Mesh augmented pelvic organ prolapse repairs carry unique complications that are not present with native tissue repairs and may not provide better outcomes.

Key words: Complication; Prolapse; Incontinence; Sling; Prosthesis; Graft

Core tip: Mesh does not provide superior results to native tissue repair and has higher rates of dyspareunia and unique potential serious complications. In general, native tissue repairs are more technically challenging than mesh augmented repair and require the surgeon to have a greater understanding of the anatomy of pelvic organ support.

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In the field of pelvic reconstruction, synthetic mesh is commonly used for the treatment of pelvic organ prolapse and stress urinary incontinence (SUI). The use of mesh during pelvic organ prolapse surgery is not more effective for symptomatic relief than native tissue repair and has unique potentially serious complications. Though mesh for stress incontinence also has unique complications, these surgeries appear to be less morbid and equally efficacious to traditional surgeries for stress urinary incontinence.

The most common complications of mesh surgery are mesh exposure and dyspareunia, and the most serious complications are perforation of organs such as the bladder, urethra and bowel. In 2010 the International Continence Society and International Urogynecological Association released a report intended to clarify and standardize the terminology related to complications from insertion of synthetic and biological materials in female

pelvic floor surgery[1]. According to this report, synthetic mesh is termed a prosthesis and a biological implant is termed a graft. Mesh located in the bladder or urethra is termed a perforation and extrusion of mesh through the vagina or skin is termed exposure.

Research has shown that pelvic organ prolapse effects 2.9% of women over the age of 20 and though only 2% of women are symptomatic, women have an approximately 30%-50% lifetime risk of developing pelvic organ prolapse[2,3]. The current prevalence of urinary incontinence in adult women in the United States is much higher than pelvic organ prolapse and is estimated to be between 47% and 51% and increasing[4,5]. Not surprisingly, the rates of surgery for urinary incontinence and pelvic organ prolapse are also increasing[6,7].

Prior to 1998, the most common surgeries for stress urinary incontinence were needle suspensions, autologous pubovaginal slings and collagen injections[8]. In 1998, the Food and Drug Administration (FDA) approved the first midurethral sling for stress urinary incontinence. Then, over the next 10 years the utilization of the midurethral sling increased almost 30 fold and multiple studies have shown its benefit over traditional surgeries for stress urinary incontinence not utilizing mesh[8,9]. However, as the utilization of synthetic mesh increased, problems with mesh exposure and perforation started to become apparent[10].

With interventions such as pelvic floor muscle training, weight loss and pessaries, the initial treatment of symptomatic pelvic organ prolapse should be conservative. When conservative measures fail, the ideal pelvic organ prolapse procedure would restore the body's normal support structure while returning the prolapsed organ to its normal anatomic position with minimal side effects[11]. Prior to 2001, the majority of pelvic surgeons sought to achieve this ideal using native tissue repairs. However, following successful outcomes for mesh for SUI, researchers started looking at mesh to help with pelvic organ prolapse. Starting in 2001, multiple studies were published showing the benefits of mesh augmented repairs for pelvic organ prolapse[12,13]. From 2001 to 2008 mesh augmented pelvic organ prolapse repairs were commonly performed with little discussion regarding the safety of mesh. However, in October 2008, the United States FDA released a public health notification (PHN) alerting the public about potential "rare" complications and problems related to transvaginal mesh for pelvic organ prolapse[14]. In 2011, the FDA modified this alert by removing the term "rare" and stating that surgical mesh does not conclusively improve outcomes over traditional non-mesh or native tissue repair[15]. Paradoxically, after the initial PHN the rate of vaginal mesh implantation increased[16].

The FDA became aware of problems related to synthetic mesh because of information contained in the manufacturer and user facility device experience (MAUDE) database. MAUDE is a database that houses medical device reports (MDRs) of adverse events submitted to the FDA by manufacturers and healthcare professionals. According to MAUDE data, in regards to midurethral slings, from 2008 to 2010 there were 1371 voluntary and involuntary self reported medical device reports of complications[17]. Bladder and urethra perforation were some of the most common reported MDR's. Similarly high, over the same time period, there were 1503 MDRs for synthetic mesh used during pelvic organ prolapse surgery. In July 2011, the FDA released a statement that summarizes their opinion entitled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse"[17].

Today, polypropylene is the most commonly used type of synthetic mesh for pelvic surgery. However, surgeons have been using mesh during pelvic surgery for over 50 years. In 1955, Moore and colleagues reported their experience with a screen made from the metallic element tantalum[18]. They found a 100% anatomic cure rate with an unfortunate 40% graft exposure rate. More contemporary studies have shown a 75% to 91% cure rate and a 0% to 5.6% mesh exposure rate[12,19,20].

Polypropylene has become the most commonly implanted material because it is a monofilament with minimal tissue reactivity that can be formatted into mesh with large sized pores. The standard system for classifying mesh was proposed by Amid[21] in 1997 and emphasizes pore size and filament type. Amid classified mesh into four different categories. The ideal mesh type according to Amid is type 1 mesh. Type 1 mesh is made of a monofilament mesh loosely woven with large pores. Mesh is considered to have large pores if the open space between the fibers is greater than 75 μm. This large pore size promotes flexibility, angiogenesis and macrophage penetration[22,23]. Multifilament material can theoretically harbor and promote the growth of bacteria and result in more infection and inflammation. This problem was seen in a 2001 study by Falconer *et al*[24] that showed significantly more histological evidence of inflammation in patients with mersilene suburethral slings compared to patients with polypropylene. In addition, it seems that mesh with smaller pore sizes such as Gore-tex do not become incorporated into tissue and have a high rate of perforation or exposure[25,26].

The management of mesh exposure is within the scope of practice of most pelvic surgeons, however, mesh perforation may require tertiary referral. There are several studies that propose observing any exposure of mesh less than 1 cm because the area may heal spontaneously with mixed results[27-30]. Depending on the preference of the surgeon and the size of the exposure, the next step for intervention may be operative management. Operative management involves excision of the exposed mesh, thorough irrigation with antibiotic solution and closure of vaginal flaps. The addition of topical antibiotics and estrogen may theoretically improve tissue quality prior to surgical intervention. In a series of 48 patients who underwent partial mesh excision, only 6 had persistent exposure[29].

Perforation of mesh slings into the urethra or bladder should be managed with more extensive mesh excision

to the level of the pubic bone or ischiopubic rami. This type of excision leaves behind the arms of the mesh that tunnel into the retropubic space or obturator fossa. It is typically not necessary to enter these spaces because the mesh at this location is no longer under tension and is far from the urethra or bladder. The authors prefer an inverted-U incision because this allows for a vaginal epithelial flap that avoids overlapping suture lines and should decrease the risk of a fistula. In general, reconstruction should involve non-overlapping suture lines and interposition of tissue such as a labial fat pad, greater omentum or autologous fascial sling. In rare cases of mesh complications from slings, when non-operative therapy has failed, such as extreme pain or infection it may be necessary to attempt a complete mesh excision from both sides of the bone. In the case of retropubic slings this involves an abdominal and vaginal incision and in the case of the tans-obturator slings this involves a medial thigh and vaginal incision.

If mesh placed to augment pelvic organ prolapse repair perforates into the bladder or urethra, this is usually best managed with a midline incision and raising flaps of vaginal epithelium. Similar to mesh perforation from slings, prolapse mesh perforation should also be managed with non-overlapping suture lines and interposition of another tissue. Unlike slings, it is often difficult to remove all of the prolapse repair mesh to the level of the pubic bone and ischiopubic rami. The authors attempt to remove the mesh as far away from the bladder or urethra closure as possible and try to avoid tension on any suture lines.

Ranging from 2.7% to 5.7% in the literature, vaginal exposure rates are relatively high with midurethral slings[31,32]. The rate of bladder or urethral perforation with a trocar at the time of surgery is as high as 5.3% and 5.4%[32,33]. Though widely reported, the rate of mesh perforation into the bladder or urethra during midurethral sling surgery is unclear and ranges from 0.6% to 0.75% in the literature[34,35]. Ranging from 3% to 20%, dyspareunia and worsened sexual function are common after midurethral sling surgery[36,37]. The traditional non-mesh repairs for stress urinary incontinence are autologous pubovaginal slings and burch colposuspension. These two procedures are similarly efficacious to midurethral slings, but, have complication rates requiring surgical intervention as high as 13% and 20% in randomized clinical trials[38]. The rates of dyspareunia and sexual dysfunction after a pubovaginal sling and bladder neck suspension in the literature are lower than midurethral slings[39,40]. In another multicenter randomized clinical trial comparing bladder neck suspension to midurethral slings, the former was found to have more postoperative complications and longer recovery with equal efficacy[9].

Mesh exposure rates of synthetic mesh for pelvic organ prolapse range from 0% to 16.9%[12,19,41,42]. Dyspareunia rates after prolapse repair with mesh are as high as 20% with anterior mesh and 63% with posterior mesh[43]. However, a thorough Cochrane review of surgical management of pelvic organ prolapse from 2011 found that mesh repair and native tissue repair had similar rates of dyspareunia[44]. Mesh perforation rates are as high as 0.7%[45]. *De novo* SUI may be more common after mesh POP repair than native tissue repair[46]. Due to concerns about dyspareunia and efficacy, some surgeons advise against the use of synthetic mesh in the posterior compartment and mesh augmentation does not improve outcomes[47]. The lack of benefit from graft use in the posterior compartment might be due to the durable nature of the fascia in the posterior compartment. Abdominal sacral colpopexy with mesh has a lower complication rate than transvaginal apical support surgeries utilizing mesh[48].

When comparing the outcomes of native tissue repair and mesh-augmented repairs using anatomical results only, mesh surgeries have better outcomes[12,49]. However, when focusing on patient reported symptomatic outcomes, the difference between native tissue repair and the use of mesh is minimal[13,28,42]. An analysis of the data from the CARE trial in 2009 found that the absence of vaginal bulge symptoms had the strongest correlation with patient perception of treatment success[50].

It does not appear that transvaginal mesh for pelvic organ prolapse provides more symptomatic benefit than native tissue repair and has common, unique potentially serious complications that are not present with native tissue repair. Unlike mesh for pelvic organ prolapse, mesh with midurethral slings has similar efficacy with less overall morbidity than needle suspensions and pubovaginal slings for SUI. The current perception of many patients is that mesh for vaginal prolapse is a safety concern. Even if future literature demonstrates the safety of transvaginal mesh, some patients may still be reluctant to have foreign material placed in their bodies. Therefore, physicians may need to return to a time when native tissue repairs were more common. Lastly, a reevaluation of how we define a successful outcome may be necessary as many surgeons move away from the use of mesh for pelvic organ prolapse.

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