Mesh complications in female pelvic floor reconstructive surgery and their management: A systematic review

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ABSTRACT

We reviewed the incidence, predisposing factors, presentation and management of complications related to the use of synthetic mesh in the management of stress urinary incontinence and pelvic organ prolapse repair. Immediate complications, such as bleeding, hematoma, injury to adjacent organs during placement of mesh and complication of voiding dysfunction are not discussed in this review, since they are primarily related to technique. A PubMed search of related articles published in English was done from April 2008 to March 2011. Key words used were urinary incontinence, mesh, complications, midurethral sling, anterior prolapse, anterior vaginal repair, pelvic organ prolapse, transvaginal mesh, vault prolapse, midurethral slings, female stress urinary incontinence, mesh erosion, vaginal mesh complications, and posterior vaginal wall prolapse. Since there were very few articles dealing with the management of mesh-related complications in the period covered in the search we extended the search from January 2005 onwards. Articles were selected to fit the scope of the topic. In addition, landmark publications and Manufacturer and User Facility Device Experience (MAUDE) data (FDA website) were included on the present topic. A total of 170 articles were identified. The use of synthetic mesh in sub-urethral sling procedures is now considered the standard for the surgical management of stress urinary incontinence. Synthetic mesh is being increasingly used in the management of pelvic organ prolapse. While the incidence of extrusion and erosion with midurethral sling is low, the extrusion rate in prolapse repair is somewhat higher and the use in posterior compartment remains controversial. When used through the abdominal approach the extrusion and erosion rates are lower. The management of mesh complication is an individualized approach. The choice of the technique should be based on the type of mesh complication, location of the extrusion and/or erosion, its magnitude, severity and potential recurrence of pelvic floor defect.

Key words: Anterior vaginal repair, mesh complications, mid-urethral sling, pelvic organ prolapse, stress urinary incontinence

INTRODUCTION

Increasing use of biomaterials, most often non- absorbable meshes, resulted in a dramatic shift in surgical techniques, use of commercial kits and

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publications in the recent era. The minimal invasiveness and availability of kits resulted in a substantial increase in the number of these procedures by both urologists and gynecologists, often with minimal training. This exponential use of synthetic material gave rise to a wide variety of complications. These complications can be broadly classified as technique (procedure or surgeon)-based and productbased [Figure 1].

In this review article, we identified various predisposing factors, clinical presentation and management strategy of these mesh-related complications. Recurrent or persistent urinary incontinence or development of postoperative voiding dysfunction is not included in this review. Intra- operative complications, such as bleeding, hematoma, injury to adjacent organs during placement of mesh etc., are also not discussed since all these complications are mostly related to technique rather than directly to the use of mesh. These mesh-related complications could have a significant

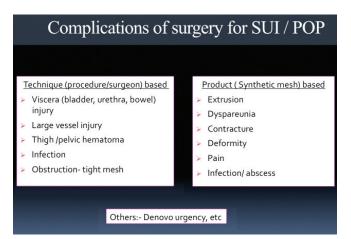


Figure 1: Classification of complications of surgery for female stress urinary incontinence and pelvic organ prolapse surgery employing prosthetic material

impact on the patient's quality of life and add to the cost of healthcare. Clinicians' understanding of mesh-related complications and their proper management would result in improved outcome.

Clinical need for use of mesh in stress urinary incontinence and pelvic organ prolapse

Procedures for pelvic reconstruction utilizing native tissue are associated with a high recurrence rate.^[1-4] This treatment failure can be attributable to the technique or defect in native tissues. Scarring and sclerosis produced by the standard pelvic reconstructive surgical procedures can restore only 50% of the preoperative tissue strength.^[5] Reduced amount of collagen in connective tissue matrices in stress urinary incontinence (SUI) women compared to unaffected women has been demonstrated. Data suggest that the process responsible for reduced collagen content in the tissues of women with SUI is not limited to the pubocervical fascia, but represents a systemic process detectable in tissues not involved in support of pelvic organs. Collagenase activity in the conditioned media from skin and pubocervical fascia biopsy explant cultures is higher in biopsies taken from women with SUI; that circulating collagenolytic activity is higher in women with SUI and that urinary levels of collagen degradation products are higher in women with SUI, all provide supportive evidence for increased collagenolysis in the etiology of SUI.^[6,7] Hence, in a recently published randomized control trial, recurrences of anterior vaginal prolapse were higher in the colporrhaphy group vs. reinforcement by mesh.^[1-4]

To overcome these disadvantages of local tissue, autologous material like autologous fascia lata or rectus sheath were employed. But these required secondary harvesting procedure with increased operating time and its attendant morbidity, and furthermore have a size limitation for their use in prolapse surgery. Hence, non-autologous, biodegradable material came into use. However, the main problem with these materials was the unpredictability of grafts, variable preparation (retained DNA), cost of biomaterials and bacterial adherence to some, e.g. bovine pericardium.^[8]

Over the last decade, synthetic materials have gradually become the primary material of choice for managing SUI in females. Their popularity is related to the avoidance of a secondary harvesting site, decreased surgical time and similar efficacy in comparison with autologous slings. The safety and durability of tension-free vaginal tape (TVT) has been confirmed by various meta-analyses and long-term (up to 11.5 years) data [Tables 1 and 2].^[9-14] The use of synthetic mesh in prolapse repair is widespread, however, it remains controversial.

MATERIALS AND METHODS

A PubMed search was made with key words "urinary incontinence"," mesh", "complications", "mid-urethral sling", "anterior prolapse", "anterior vaginal repair", "pelvic organ prolapse", "transvaginal mesh", "vault prolapse", "female stress urinary incontinence", "mesh erosion", "vaginal mesh complications", "posterior vaginal wall prolapse" for all available English literature from April 2008 to March 2011. All the articles reporting on the use of graft in female pelvic reconstructive surgery (SUI and/ or pelvic organ prolapse (POP) were selected to assess incidence and type of various complications associated with these surgeries. Since there were very few article dealing with the management of meshrelated complications in the period covered in the search we extended the search from January 2005 onwards. Articles were selected to fit scope of the topic, i.e. dealing with mesh complications and their management. In addition, landmark publications on the etiopathogenesis and management of mesh complications before 2008 and Manufacturer and User Facility Device Experience (MAUDE) data were included on the present topic.^[15] A total 170 articles were identified.

Types of synthetic mesh

In 1997, Amid categorized synthetic materials used in abdominal hernia based on their properties including pore size and fiber type.^[16] Unique mesh characteristics that are necessary in pelvic organ reconstruction include ease of use, the capability to incorporate host tissue with reduced risk for erosion, infection and extrusion, and non-carcinogenic. Grafts differ in their sources (synthetic or biological), composition (mono-filament or multi-filament), pore size, flexibility and architecture (knitted or woven). Type I monofilament, macroporous polypropylene mesh is the currently preferred synthetic material for use as graft since the large pore size (> 75 μ m) facilitates infiltration of the mesh by macrophages, fibroblast and blood vessels. Thus host tissue in-growth is promoted resulting in good support and minimizing the risk of infection. A "light-weight" Type 1 mesh is created by decreasing the polypropylene density thereby causing less foreign-body response and

Author/ Year	Country	Number	Mean follow-up	Cure rate	Complications				
of publication		Patients	(yrs)	(%)	Intraoperative (surgeon related)	Mesh related	Others	Comments	
Nilsson CG ^[9] 2008	Finland	90	11.5	90	Not specified	No erosion	Not specified	Safe and effective	
Song PH ^[10] 2009	Korea	306	>7 (92.3 months)		Bladder perforation & hemorrhage 6.2%	Inguinal/suprapubic pain 0.9%; mesh exposure 5.2%	Denovo urgency 21.6%	Complications 23.4% (1 month) & 2.6% (7 yrs)	
Olsson I [11] 2010	Sweden	147	11.5		Bleeding 2.7%; Bladder perforation 2.7%;urethral injury 1.4%; UTI-7.2%; Retention needing mesh section-2.4%	No erosion	Denovo urgency 21.2%	Safe & effective; Durable	

Table 2 : Review of Metaanalysis evaluating safety and efficacy	of various midurethral slings for SUI published in last 3 years
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Author/ Year of	Number Patients/	Type of Mesh	Cure rate (%)/ follow-up		Complic	ations	
publication/ Studyperiod	Article included	Or kit		Intraoperative (surgeon related)	Mesh related	Others	Comments
Long CY ^[12] / 2009/ Jan 08 to March 09	11 RCT included/not specified	TVT vs. (TOT + TVT-O)	TVT better that TOT/TVT-O since more obstructive; especially if max. urethral closure pressure is < 40.	Vaginal perforation	0	TVT more obstructive as evident by residual urine estimation and Urodynamic study; Denovo urgency and UTI- similar in both groups	
Latthe PM ^[13] / 2009/ All studies till Dec 08.		TVT vs. TOT vs. TVT-O	TVT-O & TOT cure rate similar to TVT at 1 to 44 month follow-up.	Bladder injury, hematoma more in TVT; Vaginal injury more with TOT group.	Mesh erosion similar in all groups. Groin/thigh pain more in TOT group	Denovo urgency and voiding difficulty similar	Cure reporting inconsistent and outcome assessed at variable period (1- 44 months)
Rehman H [14]/ 2011/ NS	26 trials 2284 patients	Traditional suburethral slings	Sling better then retropubic colposuspension; Traditional and minimally invasive sling equally effective.	NS	NS	NS	Traditional slings as effective as minimally invasive slings, but had higher rates of adverse effects.

improving tissue compliance. This might cause less contraction or shrinkage of the mesh and allow for better tissue incorporation. Type II monofilament microporous mesh allows bacterial infiltration; however, angiogenesis and fibroplasias are prevented because macrophage infiltration of the mesh and fibroblast incorporation is deterred due to small pore size (< 10 μ m). These result in higher risk of infection that is difficult to treat. Type III multifilament mesh have interstices that are <10 μ m and bacteria (<1 μ m) can replicate within these interstices. However, access to macrophages and ability to fight bacterial colonization within the interstices is impaired. There is also increased risk of bacterial adherence due to increased surface area

of mesh. Type IV meshes are sub-microporous coated biomaterials with pores of <1 μ m. They are sparingly used in pelvic reconstructive surgery.

MESH COMPLICATIONS

Mesh erosion

Recently, the International Urogynecological Association (IUGA) and International Continence Society (ICS) jointly published the terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts in female pelvic floor surgery.^[17] The important definitions given by them include-

Exposure

A condition of displaying, revealing, exhibiting, or making accessible (e.g., vaginal mesh visualized through separated vaginal epithelium).

Extrusion

Passage gradually out of a body structure or tissue (e.g., a loop of tape protruding into the vaginal cavity).

Perforation

Abnormal opening into a hollow organ or viscus.

They recommend, "the generic term of erosion (medically defined as the "state of being worn away, as by friction or pressure"), does not necessarily suit the clinical scenarios encountered and hence its use should be best avoided". However, most publications reviewed have used the term erosion synonymously with extrusion. Hence while reviewing the literature and in tables, we have used the term "erosion" to include exposure, extrusion and perforation.

Incidence

Incidence of mesh erosion (including exposure, extrusion and perforation) initially described in the literature varies widely from 0–33%.^[18] In a recent meta-analysis, Abed *et al.*, studied 110 articles that included 11,785 patients and noted that the mean incidence of graft erosion was 10.3%. ^[19] In the last three years, the reported rate of mesh erosion after surgery for female SUI was 0–7.3% [Tables 3-7].^[20-49] This was low in comparison with the 0–21% incidence reported in various randomized control trials and prospective studies published on POP surgeries by vaginal approach [Tables 8 and 9].^[1-4,50-62] By virtue of its inherent limitation, the retrospective studies published on POP surgeries by vaginal approach noted relatively lower incidence (0–11.9%) of mesh erosion [Table 10].^[63-75]

Risk factors

There are no studies powered to look at the risk factors for mesh erosion following pelvic reconstructive surgery with synthetic mesh. These risk factors can be broadly divided into patient-related, mesh-related and technique or procedure-related.

Patient-related: Patient-related risk factors include extreme of age and estrogen deficiency, severe genital atrophy, prior surgical scarring, diabetes, steroid use, and smoking. Kaufman *et al.*, identified younger age and sexual activity as a risk factor for mesh erosions.^[57] However Kim *et al.*, noted similar extrusion rates in patients younger or older than 70 years. ^[35] In two retrospective series dealing with the outcome of POP repair on patients with age > 80 years, no mesh erosions were identified.^[74,75] Cindiff GW *et al.* noted smoking to be associated with increased risk of mesh erosions.^[76]

Mesh related:- Type and size of mesh may have an implication

on the rate of erosions. Cindiff et al., noted that expanded PTFE meshes (Type II) were associated with a higher rate of mesh erosion then non-PTFE meshes (19% vs. 5%).^[76] Silicone-coated polyethylene or polyester (Type IV) can also serve as a focus for chronic infection increasing the possibility of erosions and infections up to 23.8%.[77,78] Yamada et al., noted high vaginal erosion with the use of polypropylene non-knitted, non-woven mesh (Obtape).^[79] It was hypothesized that composite mesh might minimize mesh-related complications. However, this was not noted in clinical practice [Table 11].^[80-84] Other modifications of commercially available kits like trocarless mesh system and non-anchored mesh system were also associated with mesh exposure of 5% and 8% respectively [Table 11].^[85,86] This proves that no mesh material is immune to erosions. Kavvadias et al., compared tissue reaction between eroded macroporous polypropylene mesh from five eroded sub-urethral sling patients with non-eroded material from a similar group of patients needing mesh removal for indications other then erosion.^[87] Authors found that eroded Type 1 mesh showed a significantly more intense aggregation of macrophages at the perifilamentous area, which may indicate a stronger inflammatory reaction of the vaginal wall in eroded slings. Authors postulated that the detected foreign body reaction might be the actual trigger for the erosion. However, it is also possible that it may be a result of bacterial colonization.

Although most of the studies confirm the safety and cost-effectiveness of surgeon-tailored mesh for vaginal reconstructive surgery, Finamore *et al.*, found lower erosion rate with commercial kits as compared with surgeon-tailored mesh (1.4% vs. 23.6%).^[88-90] In contrast to this isolated series a recent meta-analysis done by Murray *et al.*, confirmed the safety and cost-efficacy of surgeon-tailored mesh.^[91]

Recently available mini-slings for the management of SUI are associated with a lower rate of mesh erosion (0–2%) [Table 7].^[43-49] An exception is an article by North *et al.*, who reported that minitape was associated with a mesh exposure rate of 11.7% and cure rate of 10% at two-year follow-up.^[46]

Procedure or surgeon-related:- Concomitant surgery, especially hysterectomy was found to increase the risk of mesh erosion.^[72,76] Contrary to these reports, Stepanian *et al.*, found that there was no increase in the risk of mesh extrusion or other mesh-related complications with concomitant hysterectomy.^[92] Similarly, combining surgery for SUI and POP were not associated with any increase in mesh-related complications [Table 12].^[93-99]

Ganj *et al.*, believe that the most important factor to reduce mesh complications is to minimize the length of the incisions and closure of the incisions without tension^[72]. Anchoring the mesh may also be associated with a lower mesh erosion rate by preventing 'puckering' movement and extrusion through the vaginal incision. Margulies *et al.*, identified

Author/ Year of	Number of Patients & Type	Cure rate (%)/ follow-		Complicatio	ns
publication	of procedure	up	Intraoperative (surgeon related)	Mesh related	Others
Guerrero KL ^[20] 2010*	TVT (72) vs. Pelvicol (50) vs. autologous fascia (72)	Dry rate 55% (TVT), 22% (Pelvicol), 48% (fascia) at 1 year	Bladder injury 5.5% (TVT)	Not specified	Intermittent self catheterization 9.9% high in autologous sling; Reoperation 19.5% with pelvicol
Wadie BS ^[21] 2010	Pubovaginal sling (39) vs. TVT (24)	Pubovaginal- 93.6% TVT- 95.2% at 54 month	Hematoma- 1.6%	Extrusion - 4.1% (TVT)	NS
Freeman R ^[22] 2011 Multicentric	TOT (85) vs. TVT (95)	TOT 65.5%; TVT 63.4% at 1 year	Bladder perf (2.1% with TVT only); vaginal wall perf (4.7% with TOT only); voiding difficulty 5.2% (TVT), 5.9% (TOT);	Extrusion 3.5% (TOT), 2.1% (TVT); groin pain 9.4% (TOT), 1% (TVT);	UTI 7.3% (TVT), 2.3% (TOT); denovo urgency 4.2% (TVT), 4.7% (TOT); wound infection 2.3% (only with TOT); vaginal discharge 4.7% (only with TOT
Hinoul P ^[23] 2011 † Multicentric	TVT secur (96) vs. TVT-O (98)	TVT-S- 83.6%, TVT-O 97.6%	Blood loss (1% TVT-O only); bladder injury (1% with TVT-S only); vaginal perf (1% with TVT-S only); Retention 2.2% (TVT-O), 3.1% (TVT-S).	Exposure 7.3% (TVT-S), 1% (TVT-O)	UTI 6.3% (TVT-S), 2.1% (TVT-O)
Paparella R ^[24] 2010	34- Uretex TO (synthetic) vs. 36- Pelvilace TO (biological)	Uretex TO- 88.2%, Pelvilace TO 88.8% at 3 year	No retention	No extrusion or erosion or pain	No infection
Deffieux X 2010 ^[25] Multicentric	75/74 TVT vs. TVT-0	TVT- 94%, TVT-O 97 % at 24 month	Bladder injury 5% (TVT), 2% (TVT-O); Urethral injury 0.7% (TVT); No bowel injury, bleeding or hematoma	Erosion 0.74% (TVT-O)	NS
Total	850 patients			Erosion/ exposure 0-7.3%; pain- 0-9.4%	

Table 3 : Review of RCT on various treatments for SUI	oublished in last 3 ye	ears (except mini-slings and	adjustable slings)
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mesh folding in nine out of 13 patients suffering from vaginal mesh extrusion. Authors believed that mesh folding might be an important contributing factor in mesh exposure because a folded mesh does not lie flat against the vaginal wall.^[98] Placement of sling in a plane too close to the urethra or the presence of inadequate vaginal tissue coverage, poor vaginal tissue vascularity, or bacterial infection secondary to a draining hematoma or seeding of the mesh may lead to early sling erosions/extrusions.^[99]

In a meta-analysis of 11 randomized control trials (RCT), Long *et al.*, noted a higher incidence of vaginal erosions after mid-urethral sling placement by transobturator route. However, this was not confirmed by Latthe *et al.*, in their meta-analysis of 31 RCT [Table 2].^[12,13] Lee *et al.*, modified the technique and recommended "canal transobturator-tape (TOT)" in which two oblique lateral incisions were made in the anterior vaginal wall and a suburethral canal was created between the incisions.^[38] Mesh was transferred beneath the canal. Authors felt that canal TOT more precisely dissects the layer between the periurethral fascia and the urethra thereby reducing the rate of erosions. Adjustable slings were introduced to minimize the incidence of postoperative voiding dysfunction after surgery for SUI. Surprisingly, there was no incidence of mesh erosion in 365 patients reportedly treated with these slings in the last three years [Table 6].^[39-42]

On comparing various approaches for POP repair, laparoscopic or robotic approach was associated with a lower incidence of mesh-related complications when compared with vaginal approach [Table 13].^[100-107] A crucial factor, which has made the most significant impact on the extrusion rate, is the depth of the vaginal dissection, i.e.- raising fullthickness vaginal flaps is believed to minimize erosions.

Clinical presentation

The presenting symptoms vary depending on the organ involved. For example, vaginal mesh extrusion may result

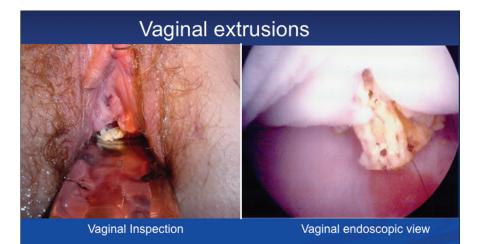


Figure 2: Mesh extrusion

Table 4 : Review of comparative studies (prospective and retrospective) evaluating safety and efficacy of various midurethral slings for SUI published in last 3 years

Author/Year of publication/	Number Patients/	Cure rate (%)/ follow-up	Complications						
Study type	Type of Procedure		Intraoperative (surgeon related)		Mesh related	Others	Comments		
Dyrkorn OA ^[26] 2010; multicentric prospective (Norwegian national incontinence registry)	5942; 4281 (TVT), 731 (TVT-0), 373 (TOT)	TVT- 87.7%, TVT-O- 80.1%; TOT- 82.1% at 8 months	Bladder perforation 3.5% (TVT), 0.8% (TVT-O),).5% (TOT); Hematoma 1.2% 0.55(TVT-O), 0% (TOT); Retention 1.6 0.5% (TVT-O), 1.6% (TOT).	(TVT),	NS	NS	TVT more effective		
Liapis A ^[27] 2010 Prospective	82 TVT Secur (43- hammok vs. 39 -U tape technique)	Hammok- 62.8% U tape- 71.8% at 1 year	Nil		Nil	UTI 4.6% (hammock), 5.1% (U tape)	Efficacy of TVT- Secure lower than other TVT procedures		
Chen X ^[28] 2011 Prospective	150 (95- TVT-O gynemesh vs. 55- TVT)	TOT-O- 96% TVT- 95%	Bladder injury -3 (TVT); vaginal perfo 2 each;	oration	Erosion 1.05% each; pain 13.7% (TVT), 40% (TVT-O).	Denovo urgency -6 (TVT), 10 (TVT-O); Retention 12 (TVT), 8 (TOT-O)	Surgeon tailored mesh has economic advantage		
Jeong MY ^[29] 2010 Retrospective	64 (31 TVT-Secur vs. 33 Monoarc)	TVTSecur- 71% (21.6 month); Monoarc 84.8% (25.8 month)	No significant complications						
Zugor V ^[30] 2010 Retrospective	208 (100 - TVT vs. 108 - TOT)	TVT- 81%, TOT- 77.7%	bleeding 2% (TVT only); Hematoma (.45% (TOT), 2% n 5.6% (TOT),	Residual urine >100 ml - 2.8% (TOT), 5% (TVT)	Less complications with TOT		
Chae HD ^[31] 2010 Retrospective	615 (376- TOT vs. 239- TVT-O)	TOT- 87.8% TVT-O- 85.3% At	(TVT-O); Urine retention 3.4% (TOT),(3.3% (TVT-O)	(TOT), 2.5	sion 2.14% 1% (TVT-O); Leg (TOT), 2.1%	Denovo urgency 5.59% (TOT), 6.7% (TVT-O)	Both procedures equally effective and safe		
Total	7061 patients			Erosion 0- 0-40%.	-2%; pain				

in vaginal bleeding, abnormal discharge, dyspareunia or vaginal pain [Figure 2]. Symptoms of mesh erosion into the bladder/urethra include painful voiding, urinary frequency, urgency, hematuria, recurrent urinary tract infection, urinary calculi and urinary fistula.

Treatment

There is limited data on the optimal cost-effective management of mesh exposure. No single approach is suitable for all cases, and the choice of the technique used should be based on the location of the extrusion, its

Author/Year of	Number	Cure rate	Complications					
publication	Patients Type of procedure	(%)/ follow- up	Intraoperative (surgeon related)	Mesh related	Others	Comments		
Groutz A ^[33] 2011 Prospective	353 TVT-0	95% at 30 month	Retention needing CIC- 4.5%	Erosion- 2%; Thigh pain 9.9%	UTI 7.9%; denovo urgency 2.8%	Elderly patient increase risk of urgency and UTI		
Lee JH ^[38] 2009 Prospective	105 Canal TOT	98% objective & 89.9% subjective cure at 1 year	No hematoma	No erosion; 4%- dyspareunia; 1%- inguinal pain	8.1% denovo urgency; no retention	Technique especially useful in patients with cystocele, obesity or prior vaginal surgery. It might decrease bladder injury, hematoma, dyspareunia, erosions & voiding dysfunction.		
Kaelin Gambirasio I ^[37] 2009 Prospective	233 Obtape/ Aris/ TVT-O	72.1% at 28.3 months	5.2%- Hemorrhage; vaginal perf 0.9%; bladder perf- nil.	Erosion- 7.6%; dyspareunia 6.2%, pain- 2.2%	Denovo urgency 6.2% retention- 2.6%	No erosion with TVT-O		
Feng CL ^[32] 2008 Retrospective	102 TVT-O	95% at 1 year	3.4%- lateral vaginal sulcus perforation; no bladder perforation	0.9%- mesh erosion; 16.6%- inner thigh pain	5.1%- Denovo detrusor instability; no voiding difficulty or retention	TVT-O procedure is a safe, effective, with a low rate of complications		
Kristensen I ^[34] 2010/ Retrospective	778	NS	Retention 16.5%,; hematoma 0.8%; bladder perforation 6.6%; blood transfusion 0.6%; voiding difficulty 5.6%	NS	UTI 3.1%; fever 15.6%;	Complications after discharge from hospital not specified		
Kim J ^[35] 2010/ Retrospective	337 SPARC sling	71.1% (age <70yrs); 42.9% (age >70yrs) at 45.2 months	Hematoma 0.3%; bowel injury 0.3%; blood transfusion 0.6%	Extrusion 1.8%; granulation 0.6%;	NS	Older patients have less success		
Sun MJ [36] 2011/ Retrospective	73 Monoarc	98.6% at 48 months	No perforation, hematoma; voiding difficulty 6.8%	No erosion	Denovo urgency 2.7%; UTI 23.3%	-		
Total	1981 patients			Erosion/ extrusion 0-7.6%; dyspareunia 0-6.2%; pain 0-16.6%				

Table 5 : Review of case series using various midurethral slings for SUI published in last 3 years

magnitude and severity and associated recurrence of SUI and/or urinary retention [Tables 14-16].^[108-148]

Management of mesh exposure /vaginal extrusion

In all the cases of mesh exposure, it would be pragmatic to rule out simultaneous erosion into the urethra or bladder by cystoscopy.

Conservative management

It should be initially attempted, especially in small

vaginal mesh exposure. Patient is advised to abstain from intercourse.^[108] Local application of estrogen cream might allow a layer of vaginal mucosa to grow and cover the sling.^[114] Based on patient selection, this may be helpful in 0–100% cases [Table 14].

Vaginal approach

It is the most preferred approach and usually performed under general or spinal anesthesia in order to have adequate exploration of mesh [Table 14].

Partial removal of mesh

The extruded part of the mesh is removed and the remaining mesh is carefully examined for signs of infection. The vagina is closed with mobilized flap to cover the defect using absorbable sutures [Figure 3].

Complete removal of mesh

A midline full-thickness incision is performed on the anterior vagina, extending up to 2-3 cm from the urethral meatus. The bladder is dissected away from the vaginal wall, and the arcus tendineous of the levator ani are reached. The body of the mesh is trapped and the surrounding tissues are carefully dissected away. The mesh is then removed from under the bladder, and the arms from the para-vesical fossas. The vagina is closed with running locked absorbable suture. This can be done in the acute or immediate postoperative situation of hematoma and/ or infection resulting in mesh exposure. This is extremely difficult later on when done for graft-related pain or contracture. Biological mesh can be used to manage the defect following complete explantation of synthetic mesh immediately or in a staged fashion.

Conservative mesh-preserving approach

This includes vulval pad graft coverage over the exposed mesh as recently described by Shaker *et al.*^[119]

Laparoscopic approach

Extraperitoneal approach is usually adapted to reach the Retzius space. The dissection is carried out until the Cooper's ligaments and the urethra are reached anteriorly and the arcus tendineous fascia pelvis posteriorly, followed by dissection of mesh from the pelvic walls. In case of urinary obstruction, the remaining mesh is removed through vaginal approach. It is usually employed for cases in which previous vaginal approach has failed.^[148] Transvesical laparoscopic port can also aid in transurethral endoscopic removal of mesh that has eroded in the bladder [Table 15].^[136-141] Recently, even single-port laparoscopic surgery has been described for the removal of mesh eroded in the bladder. ^[146] The details of various series reported on laparoscopic or robotic mesh removal are summarized in Table 16.^[142-148]

Management of intravesical/intraurethral mesh erosion The recommended management is removal of the mesh from the bladder or urethra.

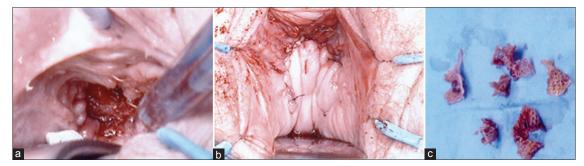


Figure 3: (a) Partial excision of mesh extrusion by vaginal approach; (b) final appearance of vagina after mesh excision; (c) excised mesh pieces

Author/Year	Number	Туре	Cure rate	Postoperative	Complications			
of publication	Patients Type of procedure		(%)/follow- up	adjustment needed (%)	Intraoperative (surgeon related)	Mesh related	Others	
Youn CS ^[39] 2010	103 (63- TOT vs. 40- TOA)	RCS	TOT- 90.5% TOA- 95% At 3 months	10	Urethral perf-1 (TOA)Vaginal wall injury- 3 (TOT)	No erosion Thigh/groin pain 6.3%(TOT), 5%(TOA)	Obstructive voiding- 4.8%(TOT), 2.5%(TOA)	
Errando C ^[40] 2011	130 (recurrent SUI or ISD) Remeex adjustable sling	PS	87% at 38 months	16.1	Nil	Nil	8%- <i>denovo</i> urgency; 0.8% infection	
Lee SY ^[41] 2011	65 (severe SUI or SUI + voiding dysfunction TOA	PMS	84.4% at 6 month	41.5	mesh division for retention 1.5%	nil	1.5% mesh infection needing removal	
Maroto JR ^[42] 2008	64 TVA/TOA adjustable sling	PS	94% objective & 56% subjective cure at 40 months	44	Not specified	No erosion/ infection	15%- Denovo urgency	
Total	362 patients					No erosion; pain 0-5%		

RCT- randomized control trial; PS- prospective study; PMS-prospective multicentric study

Open surgery (Vaginal or abdominal approach)

Open cystotomy through suprapubic or retropubic approach can be used for intravesical erosion. Some patients may need partial cystectomy if significant amount of mesh had eroded in the bladder wall.^[113] Urethral erosion may need open excision and urethral reconstruction via vaginal approach [Figure 4]. Anjulo *et al.*, described three patients of sub-urethral erosion and secondary severe urethral stricture who needed total extirpation of the mesh and complete reconstruction of the urethro-vaginal septum. The technique included combined urethroplasty with bladder flap and vaginal reinforcement with pediculated vaginal flap transferred in a mini-sling fashion.^[149] Interposition of the Martius graft has been advocated in such a scenario to reduce the risk of urethrovaginal fistula.^[150]

Laparoscopic approach

Pure laparoscopy or laparoscopic-assisted endoscopic removal of mesh in the bladder has been described [Tables 15 and 16]. There are no major intraoperative complications, but it is associated with postoperative recurrent incontinence in up to 65.7%. ^[148]

Table 7 : Revie	w of literature	on mini-slings fo	or SUI published in	last 3 years		
Author/	N/ procedure	Cure rate (%)/		Co	mplications	
Year of publication	type	follow-up	Intraoperative (surgeon related)	Mesh related	Others	Comments
Oliveira R ^[43] 2011 RCT	90 TVT-O vs. TVT-secur vs. MiniArc.	TVT-O- 83%, TVT Secure- 67%. Miniarc 87%. at 1 year	No bleeding, hematoma, urethral injury or vaginal perforation. Retention 6.6% (TVT-O) 3.3% (TVT-S & Miniarc);	Thigh pain 6.6% (TVT-O), 3.3% (Miniarc), nil (TVT-S)	Denovo urgency 10% (TVT-S & Miniarc each), 16.6% (TVT-O); UTI 3.3% (TVT-S & Miniarc each).	Miniarc offer cure similar to TVT-O whereas TVT-S may yield inferior outcome.
De Leval J ^[44] 2011 * RCT	84/96 Modified TVT-O vs. TVT-O	Modified – 91.7%, TVT-O 90.7%.	Retention 1.1 % (each)	Groin pain higher in TVT-O Exposure (1.1% in TVT-O only)	NS	Modified procedure has shorter tape and scissor / guide dose not perforate obturator membrane.
De Ridder D ^[45] 2010 * RCT	131 (75- MiniArc vs. 56- Monoarc)	Miniarc- 85% Monoarc- 89% at 1 year	Bladder perf- nil, bleeding 2% (Monoarc only); Voiding dysfunction 4% (MiniArc), 5% (Monarc);	Erosion 2% (monarc only); groin pain 4% (each).	UTI 5% (MiniArc), 4% (Monarc); Denovo urge 9%(Miniarc), 20% (Monarc)	Both equally effective
North CE ^[46] 2009† PS	60 Minitape	33% at 1 month & 10% at 2 years	Not specified	mesh exposure 11.7%; pain needing mesh removal 8.3%	Not specified	Mini-sling had substantially lower cure rate. ?? technique related
Oliveira R ^[47] 2010/ PS	119 Miniarc	80% at 12.4 month	No bladder, bowel injury; no hematoma or bleeding; retention 2.5%	Exposure- 2%; Dyspareunia 3%; groin pain 0.8%	<i>Denovo</i> urgency 6%	-
Pickens RB [48] 2010/ PS	120 Miniarc	94% at 1 year	Bladder perf 2.5%; retention 1.7%; no bleeding	No erosion, pain	No infection; denovo urgency 4.1%	-
Kennelly MJ ^[49] 2010 ± PMS	188 Mini-arc	90.6% at 1 year	0.5% -vaginal perforation	Mesh extrusion 1.6%; dyspareunia 2.1%;	<i>Denovo</i> urgency 2.7%; urgency 2.1%, UTI 4%; urinary retention 1%	-
Total ^{††}	676	80-94%		Erosion/ exposure-0-2%; pain 0-3.3%; dyspareunia 0-3%.		

RCT- randomized control study; PS- prospective study; PMS- prospective multicentric study; *-consultant to company; †-sponsored only for 2 years; ± - company sponsored study; ††-excluded reference 46

Author/ Year of	Study type		Ν	Type of Mesh Or	Follow- up	Cure rate (%)	(Complications		Comments
publication				kit	-		Intraoperative (surgeon related)	Mesh related	Others	-
Diwadkar GB ^[50]	Review 1985-	vaginal repair	7827	Not applicable	32.6 month	Not specified	Hemorrhage, hematoma-2.8%	Dyspareunia- 1.5%	UTI-3.5%	Reoperation for prolapse 3.9%
2009	2008 (249 articles/19 abstracts)	sacral colpopexy	5639	Not applicable	26.5 month		Visceral injury 1.7%, pain 2.3%	Erosion 2.2% Dyspareunia- 1.5%	Wound complication 1.5%	Reoperation for prolapse 2.3%
		mesh kits	3425	Not specified	17.1 month		Visceral injury 1.8%	Erosion/ infection 5.8% Dyspareunia- 2.2%	Not specified	Reoperation for prolapse 1.3% ; But Total reoperation rate 8.5%
Maher C ^[51] 2010	Cocharane metaanalysi surgical mgt 40 RCT inclu	of POP.	3773	Not applicable	NS	ACS better then vaginal; Anterior prolapse- standard repair more recurrence;	NS	Less dyspareunia with ASC; Data on morbidity of mesh in anterior vaginal repair lacking	NS	-
Jia X ^[52] 2010	Systematic r sacrocolpop studies		7054	Uterine/ vault prolapse	23 month	94 - 100%	NS	Mesh erosion 0-21%	NS	-
Nieminen K ^[1] 2010	RCT No mesh vs.	mesh	215	Parietene light	3 year	59%- no mesh; 87% -mesh	Not specified	19% mesh exposure	denovo SUI 5% (no mesh) 7% (mesh)	Number needed to treat = 4
Ignjatovic I ^[2] 2010	RCT No mesh vs.	mesh	76	No mesh- 39 Prolift- 37	1 year	48%- colporrhaphy 89% prolife	No blood transfusion	Extrusion 10.8%	Not specified	Prolift superior to colporrhaphy in grade 3,4 POP.
Nguyen JN ^[3] 2008 ***	RCT No mesh vs.	mesh	75	No mesh- 38 Perigee- 37	1 year	58%- colporrhaphy 87%- Perigee	Blood transfusion 3% both group	Extrusion 5%; leg pain 3% (mesh)	UTI 18%(mesh) 115(mesh); Urine retention 5% both group	Mesh reinforcement lowers anatomi recurrence
	RCT no mesh vs.	mesh	169	93- mesh 76- no mesh	1 year	54.8%- no mesh; 91.4%- mesh	Bladder injury (2%- mesh); Hematoma 6% (mesh),1% no mesh; retention 16% (mesh), 5% no mesh	Mesh exposure 16.9%; Dyspareunia 10% (no mesh), 8% (mesh); <i>Denovo</i> pain 4% (no mesh), 7.5% (mesh)	Denovo SUI 9% (no mesh), 10% (mesh).	-
Long CY ^[53] 2010	RCT- multice Perigee &/o vs. Prolift an posterior	r apogee	108	Perigee &/ or apogee- 60 Prolift - 48.		96.3%	No Intra-Op. Complication Hematoma-0.9%	Dyspareunia 20.3% Erosion 12.9%	UTI -13.8%	Similar efficacy and safety
Total incide	nce of mesh	related com	plicati	ons			Erosion/exposur	e-0-21%: dvspa	reunia 1.5 – 20	.3%: pain 3-7.5%

Table 8 : Review of RCT & prospective multicentre studies using synthetic mesh for transvaginal pelvic reconstructive surgery published in last 3 years

Endoscopic approach

Mechanical removal with scissors- Cystoscopic excision of mesh eroded in bladder or urethra is described using endoscopic scissors [Table 15]. Transurethral nephroscopy with use of laparoscopic scissors has also been described. ^[138] It also may be of advantage to have a suprapubic transvesical

Author/	Number	Cure rate(%) /		Complications	
Publication year / Study type	Patients/ Procedure or mesh type	follow-up.	Intraoperative (surgeon related)	Mesh related	Others
Elmer C ^[54] 2009/ multicentric	261; POP; Prolift	79%- ant 82%- post / 1 year	Bladder/rectal perforation 3.4%Bleeding needing BT -1; Hematoma- 5	Erosion 11% Groin/buttock pain- 1.9%	Not specified
Ek M ^[55] 2010/ multicentric *	121; anterior prolapsed; Prolift	UDI score declined 91 to 31 / 1 year	Not specified	Not specified	<i>Denovo</i> SUI- 11%; SUI aggravated 56%
Moore RD ^[56] 2010/ multicentric†	114; anterior prolapsed; Perigee	88.5 / 2 year	Not specified	Erosion-10.5%; groin/pelvic/vaginal pain 4.4%; denovo dyspareunia 5.26%	<i>Denovo</i> urgency 3.5%
Kaufman Y ^[57] 2011	114; Prolift	94.7 / 7.5 month	Bladder injury- 1.7%; Retention 3.5%; Hematoma 0.9%;	Exposure- 12.3%; Granulation 8.8%; Dyspareunia 20.2%	UTI & fever- 11%; <i>denovo</i> SUI 6.1%; denovo urgency 17.5%
Fayyad AM ^[58] 2010	36; Prolift	53 / 24.6 month	NS	Mesh exposure 19%	<i>Denovo</i> SUI 13.8%; <i>denovo</i> urgency 2.7%
Lawndy SSS ^[59] 2010	386 POP; Prolift or titanium coated mesh	90 / 1 year	No hematoma or infection	Erosion- 5.7%; Shrinkage- 0.25%	NS
Cosma S ^[60] 2011	118 (Posterior intravaginal slingplasty)	96.6 / 58.6 month	Hematoma 3.4%,fistula 2.5%	Erosion- 8.5%; (all with multifilament mesh)	Denovo urgency 8.5%; denovo SUI 5.9%.
Lo TS [61] 2010	128; anterior Trans- obturator mesh & sacrospinous fixation	91.8 / 30 month	No intraoperative complication; CIC 7.8%	Mesh extrusion 4.1%; gluteal / perineal pain 7.8%; Mesh folding 3.9%.	Fever 2.3%
Jacquetin B ^[62] 2010†	90; total vaginal prolapsed; TVM	80 / 3 year	NS	Vaginal extrusion 14.4%; Dyspareunia 8.8%; pelvic pain 7.1%; vesicovaginal fistula 1.1%	-
Total incidence of mes	h related complications		Erosion/exposure- 4.1	- 19%; dyspareunia 5.2 - 20.2%	6; pain 1.9 - 7.8%

Table 9: Review of prospective studies using synthetic mesh for transvaginal pelvic reconstructive surgery published in last 3 years

+- company sponsored; *-author advisor to ethicon

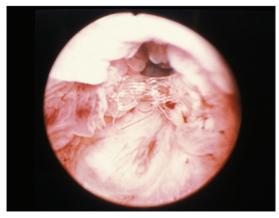


Figure 4: Urethral mesh erosion

laparoscopic port to give traction on mesh thereby assisting in excision with endoscopic scissors. ^[136-141] Use of transurethral nasal speculum or Metzenbaum scissors by the side of an endoscope may also be useful in some scenarios.^[127]

Transurethral resection (TUR) of mesh – It completely resects intravesical mesh as well as the infiltrated muscle around the mesh with a resectoscope loop similar to transurethral surgery of bladder tumors. Although the polypropylene mesh itself is not an insulator, muscle infiltrated mesh can be resected with high-voltage electric current. Oh et al., employed this technique in 14 patients and noted that mesh could be completely removed in 13 patients with only one patient developing

Author/Year	Number Patients/	Follow-up; Cure	Complications				
of publication	Prolapse type	rate(%)	Intraoperative (surgeon related)	Mesh related	Others		
McDermott CD ^{63]} 2011	89; 64 total prolift colpopexy) 24 (total prolift hysteropexy)	xxy) 24 (total (colpopexy), 135 ysteropexy) hysteropexy; Dyspareunia 26 (colpopexy), 195 (hysteropexy)		Dyspareunia 26% (colpopexy), 19%	NS		
Lau HY ^[64] 2011	115; perigee + TVT-O (68); Colporapphy + TVT-O (47)SUI + cystocele	1 year; POP- 98.5(perigee), 86.9 (colporrhaphy); SUI- 91 both	Hematoma- 0.8 %	Erosion – 4.5% (perigee), 2.2% (colporapphy); pain 2.9% (perigee), 2.2% (colporapphy); Dyspareunia 4.5% (perigee), 4.3% (colporapphy).	UTI 2.9% (perigee), 4.3% (colporapphy)		
Vaiyapuri GR ^[65] 2011	254; POP/ Prolift	1 year; 96.2	Bladder injury 2.8%, anal perforation 0.4%; hematoma 2.4%.	Mesh erosion 11.5%; thigh pain 16.5%; pelvic pain 1%; buttock pain 10.2%; Dyspareunia 1.4%.	Fever 24%, UTI 1.6%.; denovo SUI 9.1%; <i>denovo</i> urgency 5.3%		
Huang WC ^[66] 2010	65; Prolift	24.5 month; 97	Bladder perforation 1.5%; bowel perforation 1.5%; retention 6%; BT 12%	Erosion 2%	Pelvic infection 1.5%; denovo urgency 5%		
Shveiky D ^[67] 2011	4; full thickness rectal prolapsed with POP/ Vaginal mesh colpopexy with prolift elevate	6-44 month; 100	NS	NS	NS		
Eboue C ^[68] 2010	123; anterior prolapse / Surgipro- 57 patients had associated symptomatic or occult SUI	pro- 57 patients - SUI Urethral injury 1.6%; Dyspareur sociated hematoma 3.25%;		Erosion 6.5%; Dyspareunia 11.1%	Denovo SUI- 24%; Denovo urgency 17.5%		
Park HK ^[69] 2010	10; anterior prolapse + SUI/ Prolift + TVT	7.1 month; 50%- prolapse 100% SUI	2- retention nil		1- <i>denovo</i> urgency		
Gagnon LO ^[70] 2010	56; POP/ prolift	21 months; 91 %	Rectal injury 2%; prolonged bleeding 2%; urinary retention 18%;	No mesh erosion; pain 4%	3- <i>denovo</i> urge incontinence		
Argirovic RB ^[71] 2010	67; POP / Gynecare	3 month; 92.5%	1 bladder injury	Vaginal erosion- 11.9%; mesh shrinkage 8.7%; granuloma 5.9%	4.5% <i>denovo</i> urinary incontinence		
Ganj FA ^[72] 2009	127; POP / Gynecare	18.7 month;Not specified	Bladder injury 2.4%; rectal injury 1.6%;	der injury 2.4%; 10.2% mesh erosion;			
Caquant F ^[73] 2008 *	648; POP / Gynecare	6 month;	6 month; Bladder injury 0.7%; Exposure 11.3%; rectal injury 0.15 retraction 11.7%; %; bleeding-1% ; hematoma 1.9%; fistula 0.15%		<i>Denovo</i> SUI 5.4%; relapse of prolapse 6.9%		
Gabriel B ^[74] 2010†	62; (age > 80 yrs)/ Prolift	6.2 month; 91.7	Increase residual urine 25.8%;	Erosion- nil; mesh retraction 10%; pain 17.7%	UTI 3.2%		
Ghezzi F ^[75] 2011	138 (age> 75 yrs)	1 year; 87.6	Bladder perforation 0.7%; hematoma 0.7%; bleeding 0.7%.	NS	Fever 2.1%; denovo SUI 2.9%.		
ncidence of mesh	related complications		Erosion/exposure- 0-11.9	%; dyspareunia 1.4-26%;	pain 2.9-24.4%		

Table 10 : Review of retrospective single centre studies using synthetic mesh for transvaginal pelvic reconstructive surgery published in last 3 years.

Author/	Study	Number Patients/	Cure rate		Complications	
Year of publication/ Study type	type	Procedure or mesh type	(%) / follow-up.	Intraoperative (surgeon related)	Mesh related	Others
Attempt to decre	ease total a	mount of synthetic mesh by	using composite mes	h instead of Type 1 poly	propylene mesh.	
Milani AL ^[80] 2011*	PMS	127; Prolift +M	77.4 / 1 year	Bladder perf 2.3%; blood transfusion 0.8%	Mesh exposure 10.2%; pelvic pain 3.9%; denovo Dyspareunia 2%	NS
Cervigni M ^[81] 2011	PS	97 POP; Collagen coated PPM	64.9 / 1 year	NS	Mesh exposure- 21.6%; denovo Dyspareunia 11.3%	<i>Denovo</i> SUI 19.5%
Araco F ^[82] 2009	RS	36; anterior prolapse with Composite Bovine pericardium & Polypropylene	35 month; 91.7	No bladder perforation, hematoma, infection & BOOVaginal perforation- 5.6%	Vaginal erosion 8.3%	<i>Denovo</i> SUI 10%
Karp DR ^[83] 2011	RS	65; (35- no midline fascial plication 30- plication) with Perigee & intexen (biological graft)	6.2 month; 66- no placation; 73- plication	No intraoperative complication	Erosion -0; denovo dyspareunia 9.2%	NS
Culligan PJ ^[84] 2010	RS	120: POP with Avaulto solo	1 year; 81	No intraoperative complication	Erosion 11.7%; pain 7.3%	NS
Overall		445 patients	Mean 75.6%, 15.5 month		Erosion 0-21.6%; dyspareunia 2-11.3%	
Attempts to avoi	d use of tro	cars and possibly minimize p	pain related complicat	tions associated with sa	ame	
Alcalay M ^[85] 2011 *	PS	20; Endo Fast Reliant System# (trocarless system)	85 / 1 year	Nil	Mesh exposure 5%; Device related Dyspareunia 5%	Denovo SUI 10%
Zyczynski HM ^[86] 2010*	PMS	136; Gynecare prosima pelvic floor system# (nonanchored mesh)	76.9 / 1 year	Nil	Mesh exposure 8%	Failure to retain vaginal support device for 21 days associated with higher failure.

Table 11 : Review of studies using composite mesh & other kit modification for vaginal pelvic reconstructive surgery published in last 3 years

recurrent stone at a mean follow-up of 18 months.^[130] Some patients may need multiple TUR for complete mesh excision [Table 15]. ^[131] The possible complications of this approach include extraperitoneal bladder rupture and vesicovaginal fistula formation.^[130] This technique is not recommended for urethral erosion, due to higher possibility of incomplete removal and urethral perforation. To avoid complications associated with monopolar cautery, Bekker *et al.*, recently described bipolar TUR for excision of intravesical mesh.^[141]

Transurethral endoscopic excision using Holmium laser (TEEH)- It has been described as an alternative to electric current at a setting ranging from 2.5 to 10 W. Of the nine patients described since 2005, six developed recurrence over a short follow-up of slightly above one year.^[132,133]

It is not uncommon to have strands remaining when endoscopic small shears or laser is used to remove the mesh, these can continue to pose a problem, thus we find the open or intravesical laparoscopic approach the most efficient for the bladder and endoscopic best for urethral erosion.

Erosion in bowel

Although rare, enterovaginal fistula or colovaginal fistula with or without local abscess have been reported in the literature. The possible mechanisms are intraoperative injury, mechanical injury by mesh alone or in conjuction with local sepsis.^[151,152]

MESH INFECTION

This may be associated with or without vaginal mesh exposure. Various pathogens have been implicated, including Gram-positive and Gram-negative aerobic and anaerobic bacteria. They are usually linked to the type of mesh material and are now a rarity since the generalized use of knitted polypropylene monofilament implants.^[153]

Author/Year of	Number Patients/	Follow-up;		Complications	
publication	study type/ Prolapse type	Cure rate (%)	Intraoperative (surgeon related)	Mesh related	Others
Maher C ^[93] 2010	3773; Cocharane metaanalysis on surgical mgt of POP.40 RCT included	Not applicable	Not specified	NS	Concomitant SUI surgery during POP surgery does not reduce rate of post- operative SUI.
Costantini E ^[94] 2011	66; RCT- concomitant Bursh with POP repair in continent patient; Bursh (34), No Bursh (32)	OP repair POP;97 patient; months		NS	SUI- 29% (Bursh), 16% (no Bursh). No advantage of concomitant Bursh in continent patients
Moon YJ ^[95] 2010	RS- 109; abdominal sacrocolpopexy with Bursh (49) vs. TOT (60)	81.6	Retention 53.1% (Bursh), 11.7% (TOT);	NS	<i>Denovo</i> urgency 18.4% (Bursh), 3.3% (TOT)
Lau HY ^[64] 2011 RS	115; perigee + TVT-O (68), colporapphy + TVT-O (47)urodynamic SUI with cystocele	orapphy + (perigee),)urodynamic 86.9%		Erosion – 4.5% (perigee), 2.2% (colporapphy); pain 2.9% (perigee), 2.2% (colporapphy); Dyspareunia 4.5% (perigee), 4.3% (colporapphy).	UTI 2.9% (perigee), 4.3% (colporapphy)
Eboue C ^[68] 2010 RS	/ Surgipro- 57 87.7% - SUI 0.8%; Uret patients associated injury 1.6%		Bladder injury 0.8%; Urethral injury 1.6%; hematoma 3.25%;	Erosion 6.5%; Dyspareunia 11.1%	<i>Denovo</i> SUI- 24%; <i>Denovo</i> urgency 17.5%
Park HK ^[96] 2010 RS	10; anterior prolapse + SUI/ Prolift + TVT	7.1 month; 50%- prolapse 100%- SUI	2- retention	nil	1- <i>denovo</i> urgency
Groutz A ^[97] 2010/ cohort	117 (POP with UDS confirmed occult SUI); TVT-O	86 / 1 year	No bladder injury, blood loss, hematoma; Retention- 5.1%	Erosion-0%; Thigh pain- 6.4%	UTI- 6.4% <i>Denovo</i> urgency 6.9%

Table 12 : Review of literature on concomitant sling with POP repair published in last 3 years

Incidence

Incidence ranges from 0–8%.^[18]

Risk factors

Factors related to the development of mesh infection include types of mesh material, procedure, preventive measures taken, age and underlying comorbidity of the subject. Type II, III and IV meshes due to their inherent property are predisposed to develop mesh infection. Clave et al., on analyzing 100 explants, noted that multifilament polypropylene, nonknitted, non-woven polypropylene and composite implants were more frequently associated with infection than monofilament polypropylene implants (70% vs. 39%).^[154] Limited dissection with gentle tissue handling, meticulous attention to hemostasis, would help to minimize hematoma formation and bacterial colonization. Peri-operative antibiotic, thorough antisepsis of the perineum, vulva and vagina and covering the anus at surgery are important infection prevention strategies. There is no conclusive evidence that embedding the mesh in antiseptic solution may play a crucial role.^[155] It is also important to avoid performing a diagnostic paracentesis of mesh-related seromas, when there are no symptoms and/ or signs of inflammation. Such a procedure could transform an aseptic reaction into an infectious process.

Effect of infection of mesh material

Contrary to the prevailing understanding of polypropylene as an inert material when used in vaginal surgeries, Clave et al., in their study of 100 explants noted that all polypropylene implants showed evidence of degradation on scanning electron microscopy after three months.^[154] Mesh damage included superficial degradation, which appeared as peeling of the fiber surface, transverse cracks in the implant threads, significant cracks with disintegrated surfaces and partially detached material, and superficial and deep flaking. Fractures were variable in number and depth. Authors described several hypotheses concerning the degradation of the polypropylene including direct oxidation, fatty acid diffusion and oxidation due to free radical attack. It was noted that polypropylene implants degraded more in the presence of an acute infection or chronic inflammation. However, none of the poly(ethylene terephthalate) was

Author/ Publication	Type of	Number Patients/ Procedure or mesh type	Cure rate (%)/follow-up.		Complicatio	ns
year	study			Intraoperative (surgeon related)	Mesh related	Others
Geller EJ ^[100] 2011	PS	28/ robotic sacrocolpopexy	100 / 14.8 month	Nil	Exposure 7.14%	Nil
Morano SJ ^[101] 2011	PS	31/ robotic sacrocolpopexy 100 / 24.5 month		Conversion 3.2%	Nil	Myocardial infarct, reoperation for tension, wound infection & ileus 3.2% each
Maher CF ^[102] 2011	RCT	108/ laparoscopic sacrocolpopexy vs. total vaginal mesh (Lap- 53, Vaginal- 55)	77- lap, 43- vaginal / 2 year	1cystotomy & bowel injury each (lap); 1 BT in each group	Erosion- 2% (lap), 13% (vaginal); contracture 7% (vaginal);	Trocar hernia 1 (lap); UTI- 2(lap), 3(vaginal): Lap better
Sergent F ^{103]} 2011	PS	119/ Lap sacrocolpopexy with Parietex	94.8 / 34 month	Conversion- 4%; Blood transfusion 0.8%; bladder injury 2.4%; rectal injury 1.6%; retention 8.8%; Rectovesical fistula 0.8%	Erosion 3.4%; pelvic pain 0.8%; vaginal pain 0.8%	Lumbosacral spondylodiscitis 0.8%
Xylinas EX ^[104] 2010	PS	12; robotic assisted sacrocolpopexy	100 / 19.1 month	Nil	Nil	Nil
Wong MTC 105] 2011	RCT	Lap (40) vs. robotic rectopexy (23) for rectocele	NS	Conversion- 7.9%	Nil	UTI 4.7%; lleus 3.2%; outcom similar in both group
Onol FF ^[106] 2011	RS	36; extraperitoneal sacrocolpopexy with titanium coated mesh.	91 / 29 month	Bladder injury 17%; ureteric injury 3%	Erosion/ exposure- nil	Hernia 3%; DVT 3%.
Wang Y ^[107] 2011	RS	93; POP/ Lap sacrospinous ligament fixation	93.5 / 18 month	Bladder injury 4.3%, blood transfusion nil.	Erosion- nil; pain 1.1%; Dyspareunia-0	Denovo urgency 6.5%
Overall		376 patients	77 to 100% at 18 to 34 month follow-up	Bladder injury 0-17%; conversion 0-7.9%.	Erosion 0-7.14%, pain/ dyspareunia 0-1.1%	

Table 13 : Review of studies on laparoscopic &/or robotic approach for pelvic reconstructive surgery published in last 3 years

found to be altered or degraded. Hence authors expressed a need for clinical trials to comparatively investigate the performance of new type of monofilament meshes, such as poly(ethylene terephthalate).

Clinical presentation

Non-specific pelvic pain, persistent vaginal discharge or bleeding, dyspareunia, and urinary or fecal incontinence are the most common manifestations of vaginal mesh-related infection. Clinical examination may reveal induration of the vaginal incision, vaginal granulation tissue, draining sinus tracts and prosthesis erosion or rejection. A meshrelated infection may sometimes present as a pelvic abscess, urogenital or other fistulas, discharging sinus or osteomyelitis. Mesh-related infection in the form of thigh abscess has also been reported to manifest even five years after initial surgery.^[156]

Treatment

Mesh infection requires removal of the whole mesh either transvaginally or abdominally. This is accompanied with drainage of abscess cavities and administration of intravenous or oral antibiotics. Additionally, microbiological studies of removed meshes are recommended to guide appropriate antimicrobial management postoperatively.^[18] Use of copious local irrigation with antimicrobials is recommended in such a scenario.

MESH RETRACTION

Retraction of tissues surrounding the mesh is usual with a reduction in the size of the mesh. The average shrinkage is 25–30% in experimental surgery on the rat's abdominal wall; it may reach 40% of the initial surface of the implant in the patients after surgery. Therefore, many surgeons use large implants to cover defects, and anticipate scarring, shrinkage and puckering. Lo *et al.*, found 19.6% reduction in the length of mesh on ultrasonography at one month postoperatively.^[157] However, contrary to these findings, Dietz *et al.*, found no evidence of mesh contraction in their patients.^[158] The authors performed four-dimensional

Author/ N Year	Previous surgery	Indication of mesh removal *	Duration to removal	Previous	Previous Failed attempt Approach for mesh removal [†]	Followup	Complications
Kobashi KC 4 [108] 2003	Midurethral sling All erosions	All erosions	6 weeks	Nil	Abstinence from sexual activity	6 weeks	Nii; 100% success
Diffleux X 27 [109] 2005	TOT	All erosions	variable	Nil	52%- conservative treatment since asymptomatic; NS 48% partial excision	NS	2 patients (7% overall) needed complete excision.
Collinet P 34 [110] 2005	РОР	All erosions	Most within 2 months	Nil	Conservative mgt 26.4% (healed); partial excision 73.6%		8%- second surgery needed; 4% postop VVF needing surgery.
Lo TS ^[111] 1 2007	TVT	Mesh protrusion with SUI	7 months	Nil	Partial resection of protruded mesh + placement of second intermediate piece of mesh at mid-urethra	6 month	nil
South MMT 31 [112] 2007	Abdominal sacrocolpopexy				Endoscopic assisted vaginal- 54.9%; vaginal 45.1%; abdominal 22.6%	14 month	9.7% patient needed 3 attempts for symptom resolution. Bowel injury- 6.4%; fever- 3.2%; wound infection- 3.2%.
Deng DY 26	Midurethral sling	Midurethral sling Voiding dysfunction with most patients having mesh in bladder &/or urethra.	Immediate to Nil 6 weeks	Ĩ	Mesh excision, urethrolysis and urethral reconstruction 38.5%; abdominal mesh + surrounding bladder excision 27%; partial cystectomy 3.8%, excision with martius flap 15.4%	NS	NS
Margulies 13 RV ^[98] 2008	POP- apogee or perigee	Exposure 76.7%; abscess + exposure 7.7%; pain 15.4%		38.5%		6.5 month	Recurrent SUI-23%; Recurrent POP- 15%; repeat exposure- 23%; dyspareunia- 60%
Ordorica R 38 [114] 2008	SUI	BOO 53%; erosion 34%; SUI 8%; severe urgency 5%			Incision 52.7%; excision 34.2%; other 7.9% (pubovaginal sling); conservative 5.3% (urgency)		Urethral injury -2.7%; osteitis pubis- 2.7%; Recurrent SUI- 5.2%; urgency - 5.2%
Velemir L 8 [115] 2008	Mid urethral & retropubic sling	All urethral erosion	13.1 month	37.5%	2- vaginal excision & urethral repair; 4- endoscopic excision; both- 1; no treatment-1	9 month	4- SUI needing treatment
Blandon RE 21 [116] 2009		Erosion 57.1%; dyspareunia 47.6%; recurrent prolapse 42.8%		52%	Conservative - 24%; mesh excision 33.3% (vaginal 28.6%; abdominal 4.8%)		
Kuhn A ^[117] 21 2009	Midurethral sling All erosions	All erosions	4 month		Local oestrogen- 14.3% (healed); trimming and closure of vaginal wall over mesh (85.7%)	6 month	5.6% patient failed conservative approach and needed partial mesh removal
Araco F [^{118]} 1 2009	TOT	Exposed mesh with Obturator & thigh abscess	3 year	Nil	Vaginal drainage of abscess and tape remoal.	1 year	Serous vaginal discharge needing intravenous antibiotic.
Shaker D 3 [119] 2010	РОР	All erosions	3 year	Nil	Vulval pad graft over exposed mesh	5 month	Nil
Firoozi F 1 [120] 2010	POP-prolift	Mesh extrusion with VVF + retained sponge in bladder	1 month	Nil	Transvaginal removal of mesh, retained sponge and repair of VVF	4 month	nil
Khong SY 9 [121] 2010	РОР	All mesh protrusion	3 month	Nil	Partial resection + Surgisis cover of vaginal defect 4.4 month	4.4 month	33.3%- minor erosion; 11.1% second surgery needed.
Costantini 12 E ^[122] 2011	Abdominal POP repair	All erosions (1- bladder)	22.9 month	lin	10- vaginal repair; 2- abdominal repair and mesh removal.	57 month	1- patient developed VVF after endoscopic attempt and needed abdominal approach
Total / 250	0	Mostly erosion	Immediate to	0- 52%	variable	0-57 month variable	variable

English literature					
Author/ year	Ν	Original surgery & time interval there after	Endoscopic technique	Follow-up	Complications
Mechanical removal w	vith (endoscopic or Metzenba	um scissors		
Irer B [123] 2005	1	TVT (3 year);	Endoscopic resection with scissors	NS	Nil
Quiroz LH ^[124] 2009	1	TVT (6 year)	Transurethral excision under tactile traction (cystoscopic scissor failed)	1.5 month	Nil
Wijffels SAM ^[125] 2009	3	TVT-2, TOT-1 (7 month)	Excision with endoscopic scissor	2.5 month	1- Repeat excision.
Arrabal-polo MA ^[126] 2010	1	TVT (8 years)	Resection with endoscopic scissors & Holmium laser coagulation of resulting lesion.	1 month	Nil
Mendonca TM ^[127] 2011	2	Obtape (2.5 year)	Cut tape under direct eye vision with Metzenbaum scissors or push the tape with forceps	3 month	Nil
Transurethral resectio	n wi	th monopolar cautery			
Mustafa M [128] 2007	1	TVT (1 year)	TUR of mesh	2 month	Nil
Huwyler M [129] 2008	5	TVT (17 month)	TUR of mesh	10 month	Nil
Oh TH [130] 2009	14	TVT-11; TOT-3 (symptomatic for 18 month)	TUR of mesh	18 month	1-stone recurrence; 1-hematoma; 1-denovo mixed incontinence; 1- VVF.
Foley C [131] 2010	9	TVT-8; TOT-1 (2-18 month)	TUR of mesh	NS	1-redo TUR; 2- open surgery; recurrent SUI- 100%.
Transurethral excision	wit	h holmium laser			
Giri SK ^[132] 2005	3	TVT, Bursh, Stamey- 1 each. (4 year)	Holmium laser excision at 10 W	7 month	1- Recurrent SUI
Doumouchtsis SK ^[133] 2011	6	TVT-4; SPARC +TOT- 1; colposuspension-1 (5.7 yrs)	Holmium laser excision at 2.5 W	1.5 years	2- Hematuria; 5- recurrent erosion;3- repeat procedure; 1- SUI; 1-voiding difficulty.
Combination of differe	ent r	nodalities			
Frenkl TL [134] 2008	11	Variety of procedure	Holmium laser excision 4, scissor 4. TUR 2.	NS	4 -failure needing other surgery.
Feiner B [135] 2009	1	TVT (9month)	Combination of TUR & scissor excision	1 year	Nil
Combination of transu	ireth	nral and suprapubic (tran	svesical) laparoscopic approach		
Al-Badr A ^[136] 2005	1	TVT (4 month)	Excision with suprapubic laparoscopic scissor under cystoscopic guidance & tension	1.5 month	Nil
Cornel EB ^[137] 2005	1	TVT (2 month)	Lap excision with scissor (2 ports) under cystoscopic vision	4.5 month	Needed TVT-O for SUI
Baracat F ^[138] 2005	11	TVT (not specified)	Endoscopic excision with transurethrally placed nephroscope and laparoscopic scissors; lap assistance in vesical mesh (6)	6 month	2-repeat excision;
Rosenblatt P ^[139] 2005	2	TVT (7.5 month)	Excision with suprapubic laparoscopic scissor under cystoscopic guidance & tension	1.5 month	Nil
Parekh MH ^[140] 2006	1	TVT-O (6 month)	Mesh cut with a Metzenbaum scissors introduced through the urethra along the cystoscope with traction via the laparoscopic grasper	6 month	Recurrence needing vaginal removal.
Bekker MD [141] 2010	1	POP Prolift (3 week)	Bipolar TUR with accessory lap suprapubic port	1.5 month	Nil
Overall	75	SUI (74)/ TOT (1)	Various Endoscopic methods	Mean=1.6 month	17- recurrent tape erosion (22.7%)

 Table 15 : Review of reports on endoscopic management of mesh erosion into bladder or urethra from Jan 2005 to March 2011 in

 English literature

ultrasound at 3-53 months in 40 women, at least twice in each to measure mesh dimensions at two time points after implantation. However, objective recurrence of cystocele was seen in 16 patients in this study.

Clinical presentation

Normal urinary, sexual and defecatory functions require a vagina that is compliant and whose walls can easily and painlessly change conformation. With excessive stiffness of

Author/ Year	N	Initial surgery	Indication of mesh removal *	duration to removal	previous failed attempt	Approach for mesh removal [†]	Follow- up	Complications
Pikaart DP ^[142] 2005	5	TVT	60%- erosion; 40%- pain	1.3 year	20%	Laparoscopy- all	NS	None; persistent voiding symptoms in 80%.
Baessler K ^[143] 2005	17 mesh	POP	Infection 37.5%; abscess 4.1%; VVF 4.1%; pain 4.1%; BOO 8.3%; dyspareunia 41.6%	24 month		Vaginal 16.7%; vaginal + lap- 70.9%; abdominal- 12.5%	6 weeks to 6 month	No intraoperative complication; recurrent SUI- 52.6%; dyspareunia -29%; shortened vagina- 5.3%.
Stepanian AA [144] 2008 ^{‡§}	5 (total 10)	Lap sacroco Ipopexy	Exposure- 55.6%; abscess 11.1%; pelvic pain 44.5%.	1 year	Nil	5- vaginal excision; 5- laparoscopy	NS	NS
Misrai V ^[145] 2009§	31 (total 75)	TVT-77.3%; TOT- 22.7%	BOO-45%; extrusion 24%; erosion 16%; chronic pain 21%; deno SUI or urgency 12%	33 + 22 months	21.3%	Vaginal-57.3%; lap- 40%; both- 1.3%	38.4 month	Recurrent SUI- 52% at mean 0.8 months; rest- none.
Ingber MS [146] 2009	2	MUS	Bladder erosion both	5.2 years	Nil	Single port lap. surgery-both	3 month	1 pt- foreign body in bladder.
Braun NM ^[147] 2009 [§]	5 (total 83)	SUI or POP	Erosion -53%; infection- 36.1%; granulation 12%; pain 10.84%; malposition 4.8%; BOO 20.5%	58 pts > 2 years	NS	Vaginal- complete removal 73.5%; partial removal 16.9%; section 18.1%; lap- 6%; other- 10.9%	NS	Recurrent SUI- 38%; recurrent cystocele- 19% bladder injury- 1.2%; bleeding- 2.4%; VVF- 1.2%; hematoma- 6%; fever- 3.6%
Roupret M ^[148] 2010	38	TVT	Erosion 23.7%; extrusion 18.5%; BOO 18.5%; chronic pain 39.5%	2.1 year	100%	All - Iaparoscopic	NS	Recurrent incontinence 65.7%.
Total /range	103 (ove	rall 185)	Mostly erosion or exposure	1 to 5.2 year	0 to 100%	Total lap = 102 patients	Variable	Variable

Table 16 : Literature on laparoscopic mesh removal reported from Jan 2005 to March 2011. (N = 102)

*-few patients had > 1 indication; †- few patient needed multiple procedures; ‡- total 19 pt, 24 mesh; § also include patient managed by other approach; laplaparoscopy

the vaginal walls, secondary to the mesh that has undergone shrinkage, it is possible that dyspareunia, defecatory, and urinary dysfunction could result.^[98] Mesh shrinkage can expose a patient to recurrence of previous prolapse or SUI since the defect is no longer better covered. Patients may have pain of varying frequency and various natures including "tenderness" at palpation of the mesh, painful intercourse or pain when doing physical exercise. It is important to assess the impact of this pain on the quality of life using validated questionnaire scales. The exact responsibility of the retraction may be difficult to assert, but it seems likely if palpation of the retracted implant arises a pain similar to the patient's description. Retraction may also be appreciated on palpation. In a series of 17 women described by Feiner B and Maher C recently, clinical presentation included severe vaginal pain aggravated by movements and focal tenderness over contracted portions of mesh on vaginal examination in all patients.^[159] Additionally, dyspareunia was seen in all sexually active patients. Associated clinical findings were mesh erosion (9 of 17), vaginal tightness (7 of 17) and shortening (5 of 17).

Treatment

Initially, medical management must be tried including painkillers, local hormonal therapy and local antiinflammatory drug injections. If symptoms persist surgery might be required. The goal of surgical management is to relieve the tension by dividing the central graft from the arms and excising all areas of mesh contraction after mobilizing it from underlying tissues.^[159] In a case series of 17 patients who presented with mesh contraction after repair of pelvic prolapse using synthetic mesh, Feiner et al., reported that postoperatively 88% women experienced substantial reduction in vaginal pain and 64% experienced substantial reduction in dyspareunia. In the author's experience, repeat excision of entire accessible mesh was required in 17.7% patients because of persisting symptoms. Since these patients are challenging to manage surgically, they should be referred to an expert centre where a limited or a large excision, rarely a total removal may be done effectively.^[153]

DYSPAREUNIA

Dyspareunia may be caused by mesh erosion, mesh infection, mesh shrinkage or extensive fibrosis. A recent meta-analysis reported an overall incidence of 9.1% in 70 studies analyzed. ^[91] On reviewing the literature on the management of SUI over a period of the last three years

Table 17: The incidence of complications reported under
various search criteria till March 2011 in MAUDE database-

Search criteria	Number of records		
Overall			
Vaginal mesh	>2310 *		
Mesh erosion	1160		
Vaginal sling complication	550		
Vaginal mesh complication	340		
Vaginal tape complication	253		
Product specific (for SUI)			
Tension free vaginal tape	1353		
Transobturator tape	226		
TVT-O	56		
Product specific (for POP)			
Prolift pelvic floor repair	457		
Apogee / perigee	157		
Gynecare Gynemesh	147		

*There were more then 500 complications reported in 2010 with search criteria "vaginal mesh"; specific number above 500 is not displayed on the MAUDE web-site

we noted that the incidence of dyspareunia was noted in up to 6.2% patients [Table 5]. However, the incidence was reported significantly higher after POP surgery, approaching up to 24.4% [Table 10].

Interestingly, there was no difference in the rates of dyspareunia while using absorbable and non-absorbable mesh at one year.^[160] Similarly, in a recently published study the use of mesh was not associated with an increase in dyspareunia as compared with anterior colporapphy alone. ^[1,4] A concurrent procedure combined with mid- urethral sling can increase the possibility of postoperative dyspareunia. Cholhan et al., noted that postoperative de novo dyspareunia after TOT was associated with a phenomenon they call "Para-urethral banding", which are palpable bands in the urethral folds.^[161] These bands were only observed in patients undergoing TOT procedure and contributed to a substantial rate of dyspareunia (24%). Similarly, new-onset dyspareunia after transobturator tape TVT-O procedure was attributable to posterior migration of the tape, which could be palpated close to the anterior vaginal fornix.^[162] In the authors' experience cutting the tape in the midline successfully treated all four patients. However, it may become an indication for mesh removal.^[143]

In an interesting study by Mohr *et al.*, male dyspareunia (hispareunia) was evaluated in male partners of 32 patients who underwent surgery for mesh extrusion.^[163] They noted that visual analogue scale VAS score as a measurement of hispareunia significantly improved from median score of 8 to 1 after intervention of their female partners for mesh extrusion.

PAIN

Chronic pelvic pain often presents as a serious and challenging problem after use of synthetic mesh for pelvic floor reconstruction.^[164] Groin and thigh pain is a potential problem of mid-urethral sling placement, especially transobturator slings. It has been reported in up to 40% patients after transobturator sling placement.^[28] A recent meta-analysis revealed that it was more common in insideto-outside transobturator approach.^[13] Its incidence can be decreased by newly introduced mini-slings, which reported a lower incidence of pain ranging from 0-3.3% only [Table 7]. In POP surgery, the incidence of pain reported in various publications over the last three years is 1.9-24.4% [Table 8-10]. If initial conservative management with anti-inflammatory medications fails to relieve pain, a few patients may need removal of mesh with its attendant risk of recurrence of pelvic floor defect.

United States Food and Drug Administration, manufacturer and user facility device experience (MAUDE) on use of vaginal mesh in female pelvic floor reconstruction

MAUDE data represents reports of adverse events involving medical devices. The data consists of all voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996 and is updated on a monthly basis.^[15] There are more than 2310 complications reported with the search criteria of "vaginal mesh" till March 2011. The incidence of complications reported under various search criteria till March 2011 is given in Table 17. A steep increase in the incidence of reported complications with search criteria "vaginal mesh" and "mesh erosion" is noted in the MAUDE database [Figure 5].

In October 2008, the US Food and Drug Administration's (FDA's) Centre for Devices and Radiological Health, issued a warning on higher-than-expected complications reported for use of mesh in transvaginal surgeries.^[165] The FDA warning states: "Over the past three years, the FDA has received over 1,000 reports from nine surgical mesh manufacturers of complications that were associated with surgical mesh devices used to repair POP and SUI...The most frequent complications included erosions through vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence. There were also reports of bowel, bladder, and blood vessel perforation during insertion. In some cases, vaginal scarring and mesh erosion led to a significant decrease in patient quality of life due to discomfort and pain, including dyspareunia.

On July 13, 2011, the FDA stated in a news release, "There are clear risks associated with the transvaginal placement of mesh to treat POP." It further stated "The FDA issued a safety communication in 2008 due to increasing concerns about adverse events associated with the transvaginal

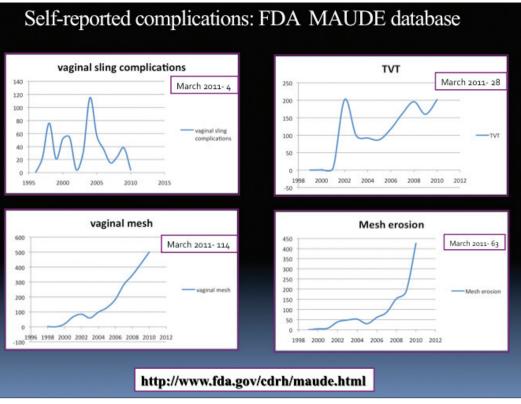


Figure 5: Incidence of complications reported under various search criteria till March 2011 in the MAUDE database. The incidence till the year 2010 is plotted in the graph; while the number of cases reported in the present year till March 2011 is reflected with in number on right upper quadrant of each graph

placement of mesh. Since then, the number of adverse events has continued to climb. From 2008 to 2010, the FDA received 1503 adverse event reports associated with mesh used for POP repair, five times as many as the agency received from 2005 to 2007." This safety communication was "limited to the transvaginal placement of mesh to repair POP. It does not address the safety and effectiveness of mesh used to treat SUI or mesh implanted abdominally.^[166]"

CONCLUSIONS

Sub-urethral sling procedures using synthetic meshes are now considered the gold standard for the surgical management of stress urinary incontinence with estimated cure/dry rates ranging from 81-84%. [167] It is also now increasingly used in the management of pelvic floor prolapse. It is imperative that we understand the complications associated with these surgeries. Awareness of these complications should help us in proper patient counseling as well as stimulate further investigations of the underlying mechanisms. Decreasing complications should be considered an important outcome in future clinical studies. The incidence of extrusion and erosion with mid-urethral sling is low, the extrusion with prolapse is higher and use in the posterior compartment remains controversial. When used through the abdomen the extrusion and erosion rates are lower. There is an FDA warning about the use of mesh in pelvic organ prolapse.

^[166] However, with appropriate counseling these may still be indicated after the surgeon and the patient take into account the benefits and complications thereof. In spite of certain perceived problems with the use of mesh in incontinence procedures, it seems to be safe and beneficial to the patient.

What is needed in future?

Surgical management of SUI continues to evolve. The rapid expansion of the market does not await results of the RCTs, a newer and more competitive product could be on the market. This might be the reason why only a few companies and centers are interested in setting up RCTs. Still it is important not to fall prey to industry-driven treatment options, but to follow evidence-based medicine in managing our patients. Ou et al., stressed the impact of attrition rate of follow-up with time that directly affects the strength of Level 1 and 2 studies regarding surgical treatment of female SUI. [168] The incidence of patients lost to follow-up was 8.1% at 12 months, 28% at 24 months, 36% at 36 months and 32.4% at 60 months or greater. Hence it is important to cautiously analyze results of various published studies in the literature. It is also of paramount importance that national societies should establish a registry for complications. There should be a protocol of recording all complications in this registry so as to know the true incidence of morbidities associated with different surgical procedures. Need of proper surgical training and experience in placing vaginal meshes need not be under

emphasized. ^[169,170] In order to record the denominator, the industry should consider a form with each kit to record and follow its use.

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