Perspective Article

Mesh In Prolapse Surgery – Is It A Mess?

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Introduction

Pelvic Organ Prolapse (POP) is a worldwide problem, affecting women of all race and creed. The life time risk of requiring surgery for POP is around 11 %. More importantly, the need for a repeat surgery following primary prolapse repair is quoted around 29%[1]. With increase in life expectancy, the need for techniques which provide long-term anatomical and functional success is important in prolapse surgery.

A better understanding of the pelvic anatomy and the supports of the pelvic organs paved the way for new techniques in POP surgery. Apart from the bony and muscular supports, the fascial supports contribute significantly in maintaining the position of pelvic organs. The primary fascial supports as described by Delancey revealed, the support of the apical compartment - cervix and vault, were suspension supports provided by the utero-sacral ligaments. The anterior and posterior compartment supports were primarily through pubo-cervical fascia and recto-vaginal fascia respectively, through their attachments to bony structures[2]. Addressing these fascial support deficiencies and weakness was the logical way to move forward with POP surgeries.

Traditional prolapse surgeries use the native fascial tissue, for repair of the anterior, apical and posterior compartment. In a patient with POP, there is the possibility of native supports to be inherently weak, leading to prolapse in the first place[3]. In addition, fascial repairs are usually carried out vaginally and address midline defects mainly, as lateral defects are relatively inaccessible via this route. Evaluating the anterior fascial repair in a study by Weber et al, following a "standard anterior repair" the recurrence risk was 70% within 2 years of follow-up[4]. The recurrence rate following posterior colporraphy with fascial tissue is quoted around 12-20%. The need for a more robust technique, to provide a durable prolapse repair lead to the use of mesh in POP surgeries.

In recent years, the use of mesh in prolapse repair has become a controversial issue. The characteristics of mesh use, its surgical outcomes and complication profile will help us to understand the controversies.

Mesh in POP surgery

Historically the use of mesh in POP repair was first published in 1955 using tantalum mesh[5]. This has been followed by use of different types of meshes in different periods, with some complications reported inherent to the material used. The first step hence in mesh surgery, is the choice of mesh type. Use of biomaterials (autografts, allografts, xenografts) and absorbable synthetic mesh showed a high recurrence risk in follow-ups and were not considered ideal for POP surgery[6,7]. Use of non-absorbable synthetic polypropylene mesh, was heralded as the answer to mesh use in prolapse. The widespread use of synthetic mesh in mid-urethral sling and its success provided an impetus to mesh use in POP surgeries.

The synthetic non-absorbable mesh is classified into 4 different types (Amid Classification) based on their pore size and filament number[8] (Table 1). The Type I mesh, macroporous (>75 μm), monofilament fibers, in a woven architecture has been identified as the suitable type for prolapse mesh repair, as their structure and design promotes better integration into host tissue[9].

Mesh can be used in POP repair either as a replacement for weakened tissue (total mesh/ mesh overlay) or as an augmentation of fascial repair (mesh augmentation). The first generation mesh kits use the obturator foramen for introduction of trocars to place a hammock type mesh, to mimic the pubocervical fascia anteriorly. For the posterior segment, the trocars are passed through the buttocks, below the anus, through the ischio rectal fossa to access the sacrospinous ligament and the mesh is used to support the rectovaginal fascia. (Fig 1 & 2).

The armed mesh types has the advantage of addressing both lateral and central fascial defects. The PerigeeTM and Apogee™ (American Medical systems, MN), Anterior and Posterior ProliftTM (Johnson and Johnson, NJ) were all designed using this principle to address anterior and posterior compartment POP. The total ProliftTM addressed the apical compartment as well[10]. Though several different types of meshes have been in market, only about 10 different types of polypropylene meshes have been in regular use.

Surgical outcomes with Mesh Surgery

The efficacy of the prolapse repair with synthetic prosthetic material was very promising at the preliminary initial studies. Several prospective and retrospective studies quoted high success rates of 80-100% over a variable follow up period of 3 to 24 months. Success rates were defined by anatomical success i.e no recurrence of prolapse during the follow-up period[11,12,13,14].

Following the cohort studies, randomized controlled trials (RCT), started comparing mesh with fascial repairs. In the RCT by Altman et al, the success rate on subjective and objective assessment was 60.8% in the mesh group versus 34.5% in the anterior colporraphy group[15]. In another RCT comparing polypropylene mesh with traditional anterior colporraphy[16], the mesh procedure reduced the risk of anatomical failure at 12 months follow-up from 59% to 9%.

The primary outcome of anatomical success favoured the mesh repair over the fascial repair, to a large extent. It was the analysis of the secondary outcomes, which started to highlight the complication rates with mesh. Both immediate intra -operative and late complications started to emerge with increase in cohort samples and long term follow-ups. This prompted the need to re-evaluate the role of mesh in prolapse surgery.

Complications of Mesh Surgery

The Food and Drug Administration (FDA) cleared the first surgical mesh product designed for the surgical treatment of POP in 2001. The use of vaginal mesh in gynecologic surgery thereafter gradually increased, at one point going up to nearly 100 different types of mesh devices. With increasing use, the adverse events also seemed to increase. Complications profile included those related to the mesh component or to the trocar needles. The immediate intra-operative complications were more commonly related to the trocar insertion and the post operative complications due to the mesh. The incidence of intra operative and early postoperative complications was reported in around 12.9% of mesh surgeries [17].

Early Complications

Intra-operative complications included bleeding, vaginal tears, urinary tract and rectal injuries. Use of transobturator space through the obturator foramen and trans gluteal insertion through ischioanal foassa were deemed to be safe anatomical spaces for insertion of trocars. However, for most surgeons these were uncharted waters and many gynecologic surgeons have not had extensive experience in sacrospinous ligament suspension and vaginal paravaginal defect repairs, which are prerequisites for the kit procedures. In addition, each of the needle kits that enter market, have different curvature and need different technique of insertion. The intra-operative complications mostly occurred from failing to appreciate these factors.

Bleeding: Severe intra-operative blood loss of > 500 ml has been reported in around 2-3%[18]. Brisk bleeding can occur during dissection to access sacrospinous ligament or during insertion of the trocars. It is usually venous bleeding and sustained pressure usually helps, with occasional need to use a haemostatic agent. In case of lacerations, a more intensive approach is needed – laparotomy along with a vascular surgeon or selective arterial embolisation to control the bleeding. The blood vessels at risk include obturator, pudendal, inferior gluteal and iliac vessels both at dissection and trocar insertion. An unrecognised bleed can lead to life threatening retroperitoneal haemorrhages, haematomas and subsequent infection[19]. Post-operative fever, significant drop in haemoglobin, urinary retention and gluteal pain should raise the suspicion of pelvic haemotomas.

Urinary tract injury: The second common intra-op complication reported with mesh includes urinary tract injuries, with reports of bladder, uretheral and occasional ureteric injuries. Both midline and lateral cystotomies have been reported with vaginal dissection and trocar insertion. During lateral dissection of vagina, bladder is at risk, especially in patients with previous pelvic surgery. These are likely to be missed if not vigilant and also difficult to repair via the vaginal route. Midline cystotomies on the other hand are more easily recognized and easier to repair. Urethral injury can happen during trocar insertions through the anterior portion of the obturator space. Problems with unrecognized urethral and bladder injury include recurrent UTI, haematuria, overactive bladder symptoms and a late diagnosis of mesh extrusion. There have been reports of unrecognized ureteric injuries needing ureteric reimplantation in the post-operative period[17]. In case of a ureteric injury, a stormy post-operative period should alert the surgeon and appropriate imaging used to rule out unrecognized injury. An intra-operative cysto-urethroscopy at the end of the mesh repair is essential in identifying urinary tract injuries.

Rectal Injury : Rectal injury during dissection or trocar insertion, necessitates immediate repair and it has been reported with POP mesh surgery[20]. In most cases it happens with previously scarred tissue. An unrecognized or incomplete repair of rectal injury can lead to fistulae. In case of any visceral injury it would be prudent to abandon mesh repair and resort to a fascial repair.

Fornix Tear: Fornix tears can occur during trocar passage through the lateral tunnels or during the initial dissection. Inspection of the fornix during and after trocar insertion helps in its identification and reduces mesh erosion risk. If the fornix tear is identified after the mesh insertion, the vaginal edges can be undermined and the vaginal mucosa approximated over the mesh[10].

Delayed Complications

Infection: Clinically patients with mesh related infection present with vaginal discharge, bleeding and mesh exposure. Apart from the patient characteristics such as diabetes and untreated preoperative bacterial vaginitis which increase the risk of infection, the characteristics of the mesh, play an important role. Use of non type 1 meshes increases the risk of infection. The type I macroporous monofilament mesh with pores over 75 μm, facilitate entry of leukocytes and

macrophages to counteract bacterial colonization and hence infection risk is reduced. Microporous and multi-filament type II & III meshes allowing the infective organism to gain access into the mesh interstitial spaces do not allow the passage of leukocytes[21].

The incidence of mesh related infective complications such as abscess, cellulitis, spondylodiscitis is quoted to be around < 1% [22]. Life threatening necrotizing fasciitis has also been reported with mesh surgery[17].In the presence of an infection, antimicrobial therapy should include those against gram-positive, gram-negative and anaerobic bacteria. The definitive treatment usually involves removal of the infected mesh.

Mesh exposure and extrusions: Mesh exposure is used to denote erosion of the mesh externally resulting in vaginal exposure whereas extrusion is used to define mesh erosion into the viscera – such as the bladder and rectum. Vaginal mesh exposure is known to occur in 13-15% of cases of vaginal POP mesh surgeries, while with abdominal sacrocolpopexy (ASC) it is quoted in around 3%. The mean timing of exposure is found to be around 234 days (range of 45-1040 days)[22,23,24]. Vaginal mesh exposure is usually a healing abnormality when it occurs early, along the suture line and with no signs of infection and sometimes can also be detected in the fornices. In a proportion of patients where it is small (<0.5 cm) and asymptomatic, can be managed with vaginal estrogen +/- excsion of mesh as an outpatient procedure. The vast majority need to be treated with excision of mesh and fascial repair over the defect. Reoperation rate for mesh exposure is between 8% -36%[25].

Bladder, urethral and rectal mesh extrusion have been reported after both vaginal mesh surgery and ASC. Bladder extrusion can present with hematuria, recurrent UTI, pain or fistula. Patients who present with urinary or fecal incontinence following the surgery should be evaluated for fistulous communication. Management is aimed at removing the mesh from the viscus, usually though an abdominal approach. Endoscopic and vaginal routes of removal have also been reported. Mesh removal is followed by visceral repair and closure of the vaginal defect. In case of urethral extrusions, urethrolysis with mesh removal and closure of the defect in 2 or 3 layers with Mauritius flap reinforcement may be needed.

Mesh shrinkage and Pain: From the patient's perspective, the most troublesome complication of mesh is the pain resulting from contraction and/or hardening of mesh leading to dyspareunia and chronic pelvic pain. The best way to mange this problem is also the surgeons dilemma. The US Food and Drug Administration (FDA) report (2011) stated that vaginal pain and dyspareunia were the most common adverse events reported[26]. Interestingly, the commonest reason for re-operation following transvaginal mesh was vaginal pain and dyspareunia (77%)[27]. This is in contrast to the common perception that vaginal mesh extrusion is the commonest delayed complication.

Feiner et al. defined mesh contraction as an adverse outcome following armed polypropylene mesh repair in which patients experience vaginal pain with movement and dyspareunia[28]. Hardening and contraction typically occur along the fixation arms of the mesh, rarely does the entire implanted mesh contract. On examination patient can have localised areas of prominent, tense and tender mesh under the vaginal epithelium. The reported rate of polypropylene mesh related pain ranges between 4 and 11 %.

The surgeon should aim not to attribute every pain in mesh implanted patient to the mesh itself and hasten to remove the mesh. The first step should be a meticulous history to identify the duration of pain and if it had been present pre-operatively. The history should also focus on the nature of pain whether it is diffuse or localized. Diffuse vaginal pain after mesh implantation is unusual and these patients are more likely to have an underlying pelvic pain syndrome. Next step, on examination is to try to map the pain sites with accurate charting of the trigger points. Following this a therapeutic trial with trigger-point injection of a local anaesthetic with steroid is useful to identify if the pain decreases. Surgical removal of the involved mesh segment is likely to ameliorate symptoms only if dyspareunia diminishes after injection. This can be helpful in counseling the patient prior to mesh excision.

Mesh removal for contracture should be managed by a surgeon who is experienced in extensive deep pelvic dissection, which is necessary to remove the mesh arms. Patients usually report symptomatic relief in over 90% following mesh removal but a few patients may never be cured completely. Several risk factors have shown to be associated with mesh related complications. Obesity (BMI>30) and smoking are independent risk factors for mesh exposure. Other risk factors include age < 55 years, concomitant hysterectomy at the time of procedure and use of mesh in prolapse of POPQ Staging of less than 3.

Current Role of Mesh in Prolapse Surgery

The primary indicated role of mesh in POP is the quoted lower recurrence risk. If surgical therapeutic index is used to assess any surgery, both its efficacy and complication can be determined. This is a risk benefit ratio of median percentage of cure rate to the median percentage of complication rate. Analysing the role of mesh in each compartment, provides the information needed for surgeons intending to use mesh in POP surgeries.

In the posterior compartment, the traditional posterior repair has stood the test of time. The Fifth International Collaboration of Incontinence review concluded that, both Level 1 and Level 2 evidence suggest that midline fascial plication without levatorplasty has superior subjective outcomes and neither mesh overlay nor mesh augmentation has shown any benefit in terms of recurrence in posterior compartment[29].

In the apical compartment, comparing the Abdominal sacrocolpopexy (ASC) with vaginal mesh repair, Maher et al., showed a higher objective success rate at 2 years with sacrocolpopexy, 77% vs. 43%. The re-operation rate was higher with vaginal mesh repair 22% compared to 5% with laparoscopic sacrocolpopexy[30].Comparing the traditional native

tissue vaginal vault repairs, sacrospinous fixation or uterosacral suspension in apical compartment with vaginal mesh, the recurrence of POP at operated site was 45% in native tissue and 10% in mesh group at the end of 12 months. However, mesh exposure was detected in 17%[31]. In the apex ASC has superior outcomes compared to a variety of vaginal procedures including sacrospinous colpopexy, uterosacral colpopexy and transvaginal mesh, with an acceptable risk - benefit ratio[32].

In the anterior compartment, where the traditional anterior repair has a high recurrence rate, the role of mesh is of considerable interest. The review at the fifth International Consultation of Incontinence stated that "Consistent level 1 evidence demonstrates superior subjective and objective outcomes following anterior transvaginal polypropylene mesh compared to anterior colporrhaphy (grade A recommendation)". However, these outcomes did not translate into improved functional outcomes or lower re-operation rates. Mesh surgery was also noted to have longer operating time, greater blood loss and a mesh extrusion rate of 10.4% requiring surgical correction. The conclusion based on this was that polypropylene anterior compartment mesh offers improved objective and subjective outcomes; however, these benefits must be considered in the context of increased morbidity[33].

Type	Pore size & filament no.	Component
Type I	Macroporous, monofilament	Polypropylene
Type II	Microporous, mulitfilament	Polypropylene / Polyglactin 910
Type III	Multifilamentous with Macroporous or microporous components	Expanded PTFE
Type IV	Polypropylene sheet	Not used in gyna-ecologic surgery

Table 1 - AMID classification - Types of pore size and filament number

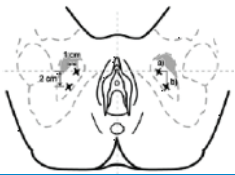

Fig 1 - Anterior trocar insertion points (marked with x) - Obturator Foramen

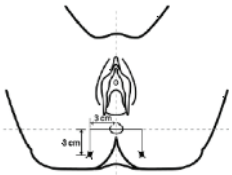

Fig 2 - Posterior trocar insertion points (marked with x) – Gluteal region

Conclusion

The role of mesh in POP surgery is specific and not all pelvic organ prolapse surgeries need a mesh. The first principle in mesh repair is therefore the recognition that in most cases, POP can be treated successfully without mesh, thus avoiding the risk of mesh-related complications. Mesh surgery is chosen only after weighing the risks and benefits of surgery with mesh versus all other surgical and non-surgical alternatives. It is important to avoid mesh surgery in primary prolapse, age < 50 years, prolapse with POPQ grade 2 or less, in women with chronic pelvic pain, poorly controlled diabetics, those on long term steroid or immune suppressants and following a previous pelvic radiation therapy.

The major issue with mesh repair is its adoption without adequate training. Proper training in the use of mesh devices is a three staged process: Didatic and cadaveric workshops to fully appreciate the less dealt anatomy in the 3 dimensional view, followed by preceptor training and finally hands-on with supervision. Assuming these as minimally invasive surgeries, undertaken with minimal or no training, passing trocar blindly in less used anatomical spaces, was one of the reasons for uncommon and serious complications.

Apart from the patient and surgeon factors, it is important to understand the dynamics of the mesh kit being used. This applies not only to the biocompatibility of the mesh, but also the trocar needles. Owing to the wide variety of devices available it is important to appreciate that every 'needle' in every 'kit' is different and an appreciation of the course of the needles in the pelvis, is crucial to the surgical safety. It is also important that replacement mesh surgery be performed as per protocol established by the manufacturer as any deviations from the accepted technique can cause complications.

Future of mesh in POP surgery is dependent on the use of safer alternatives, such as trocar-less mesh kits (avoiding blind needle pass), use of single vaginal incision for both prolapse dissection and mesh introduction and use of lighter mesh types. Currently, some of these are undergoing clinical trials and the next step will be to restrict the use of mesh only in specific indications, the recommendations based on robust evidence.

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