Complications of polypropylene mesh in prolapse surgery: an update

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Abstract

Over the last five years, there has been a considerable increase in the use of synthetic mesh to correct uterovaginal prolapse. More recently there has been an increased reporting of complications resulting in a health warning notification by the Food and Drug Administration Agency, for clinicians and the public. Evidence from recent systematic reviews supports the use of synthetic mesh for central and recurrent anterior compartment prolapse. Trials show a higher incidence of mesh related complications that can present with debilitating pain requiring reoperations and significant impact on quality of life. The lack of strict premarketing approval and post marketing surveillance along with the acceptance of the mesh without robust evidence remains an issue. It is the joint responsibility of manufacturers, clinicians and organizations to ensure that synthetic mesh is used appropriately using evidence-based data for mesh selection, usage along with post treatment surveillance.

Keywords complications; graft; mesh; mesh exposure; pelvic organ prolapse

Introduction

Native tissue repair of prolapse often provides suboptimal long-term outcome, with 13% risk of reoperation in the initial 5 years and 29% lifetime risk for pelvic organ prolapse. Mesh use in pelvic organ prolapse surgery was approved by the Food and Drug Administration (FDA) in the United States in 2002. Since this time, a multitude of meshes and mesh kits have been developed, marketed and used around the world. By 2011, every third case of prolapse repair in the US included some form of mesh, with 75% of all mesh insertions being vaginal. With a paucity of post marketing surveillance, voluntary reporting of complications increased. This led to an FDA notification for the public in July 2011, regarding the possibility of serious complications and the insufficient evidence on the superiority of mesh repairs over native tissue repairs. This review discusses the current concerns and recommendations with the use of polypropylene mesh in prolapse surgery.

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Mesh use in the United Kingdom

In the UK, mesh is commonly used in women with recurrent prolapse or congenital connective tissue disorders such as Ehlers–Danlos or Marfan's syndromes. A 2010 national prolapse survey by Jha and Moran, showed an increasing trend in the use of synthetic mesh in both primary and recurrent prolapse. Most interesting data was that for primary prolapse, though the overall increase in use of mesh was only 1%, the use of synthetic mesh increased by 38% for anterior and 5% for posterior compartments. British Society of Urogynaecology Database (BSUG) data show that the commonest mesh used was *Gynaecare Prolift*® in both anterior and posterior compartments. The other meshes used include *Pinnacle*® (Boston Scientific Corporation, USA), *Perigee*® and *Apogee*® (American Medical Systems Ltd., USA) and Avaulta® (CR Bard Inc., USA). Meshes were unspecified in approximately one third of cases.

Recent concerns with mesh

The FDA initially issued a public health notification in 2008 after receiving around 1000 reports from nine surgical mesh manufacturers. This was followed by a further notification in July 2011 "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse". This update was prompted by the five-fold increased reporting of serious complications on the Manufactures And User Device Experience (MAUDE) database during 2005–2010, particularly the last 3 years. The most frequent complications reported included mesh exposure, pain including dyspareunia, infection, urinary problems, bleeding and organ perforation. Seven deaths were reported with three out of the seven directly attributed to mesh placement including two cases of bowel perforation and one of haemorrhage.

In the United Kingdom the Medicines and Healthcare Products Regulatory Agency (MHRA) has received increasing reports on complications following mesh procedures. Following a workshop involving various professional bodies and leading manufactures, MHRA has now issued several recommendations for safe vaginal mesh use. There are also several on-going lawsuits especially in the US, which are currently awaiting trials against the various mesh manufacturers. *Scott v. Kannappan* is the first case where the $5.5 million was awarded in damages due to complications from *Avaulta*®(C R Bard Inc.) vaginal mesh in July 2012. Several transvaginal meshes have now been withdrawn from clinical use including *Prolift*®, *Prolift + M*®, *Prosima*® (Ethicon Inc.) and *Avaulta*® (C R Bard Inc.), mainly due to the financial implications of continued use since the change in regulations.

Efficacy of mesh and mesh kits

Efficacy of prolapse surgery is often measured in terms of anatomical measurements such as the Pelvic Organ Quantification System (POPQ). However, this is poorly correlated with subjective assessment as well as re-operation rates. Symptom relief is the main outcome most strongly correlated with quality of life improvement and satisfaction. It is also important to note that *recurrences* may be in a different compartment, which do not

classify as 'technical failures' and reoperation rates may vary depending on patient choice. These factors should be remembered while interpreting the results of surgical trials and consequently, many recent trials use patient reported outcomes as the primary outcome. A summary of the efficacy and safety of synthetic meshes from systematic review is given in Box 1.

Anterior compartment

Greater than 80% of prolapse repairs are done in the anterior compartment. Native tissue repairs also have the highest recurrence rates with 30–60% of cases requiring reoperation. Systematic reviews by Jia et al and Maher et al found that mesh reinforcement of the anterior compartment appears to provide higher anatomical cure rates compared with native tissue or non-synthetic mesh repairs.

Central compartment

Systematic review by Jia et al found sacrocolpopexy to be associated with recurrence rates of 0–6%, in patients with vault prolapse. A recent Cochrane review incorporating three Randomized Controlled Trials (RCTs) also found a high anatomical cure rate and low recurrence of vault prolapse for sacrocolpopexy compared with sacrospinous fixation. Maher et al, in a randomized trial for vault prolapse comparing laparoscopic sacrocolpopexy ($n = 53$) with total vaginal Prolift mesh kit ($n = 55$) found a higher objective cure rate of 77% versus 43% ($P < 0.001$) and higher patient satisfaction in the laparoscopy arm at two years. In comparing trials of uterine preserving procedures, there was limited evidence to draw reliable conclusions.

Posterior compartment

There are no RCTs comparing synthetic mesh in posterior compartment with native tissue repair on its own. Randomized trials that have used synthetic mesh for posterior as well as additional anterior or central compartments show improved anatomical outcomes that did not correlate with symptoms and quality of life. These findings did not support the use of synthetic mesh over native tissue repair.

Summary of efficacy and safety of synthetic mesh use in various compartments Maher et al (2013)

Anterior compartment

- Synthetic mesh use improves objective and subjective outcome.
- Mesh exposure rates of 11.4% and 6.8% reoperation rates.
- Evidence to support clinical use based on risk benefit analysis and informed patient choice.

Central compartment

- Sacrocolpopexy is superior to sacrospinous fixation and total vaginal mesh for vault prolapse in objective and subjective outcomes.
- Sacrocolpopexy has longer recovery with mesh exposure rates varying from 0% to 12%.
- Evidence to support clinical use based on risk benefit analysis and informed patient choice.
- Limited evidence available for uterine suspension to allow reliable conclusions to be drawn.

Posterior compartment

- Synthetic mesh repairs show better anatomical outcomes that do not correlate with symptoms and quality of life.
- Mesh exposure rates of 18% with 11% total reoperation rates.
- Insufficient evidence to support clinical use.

Box 1

Complications

The previous review highlights the difficulties in evaluating evidence relating to complications. The, International Urogynaecological Association (IUGA) and International Continence Society (ICS) have jointly developed a terminology and classification system to standardize the reporting of complications of mesh repair. This complex empirically derived system uses "Category, Time and Site" parameters for description of complications (Table 1). Though comprehensive and specific to mesh complications, a recent study by Tunitsky et al reports poor interrater reliability ($k = 0.15–0.78$) and inability to categorize some complications (e.g. granulation tissue, defecatory dysfunction). A symptom and intervention system may be simpler to use and provide useful clinical data to assess severity and management of complications.

Specific complications

Unlike the abdominal wall which has multiple layers, vaginal epithelium is single layered and vaginal incisions may be regarded as clean contaminated wounds. This potentially increases the risk of complications when mesh is placed vaginally. Specific mesh related complications include mesh exposure, infection and contraction. Other complications like dyspareunia, pain syndromes, denovo bladder symptoms and recurrent prolapse can also occur with native tissue repair, though the incidence, severity and aetiologies may be different.

Mesh exposure

Exposure is one of the main concerns with synthetic mesh use. The recent seventeen-year follow-up data on Tension free Vaginal Tape by Nilsson et al shows negligible tape exposure rates (1.1%). However, vaginal meshes used in prolapse repair include a larger amount of mesh and tissue response is directly proportional to the surface area of contact (Norris et al).

Exposure rates using synthetic mesh reported in various trials vary from 0% to 21.6%. A recent Cochrane review showed a mesh exposure rate of 11.4% in the anterior compartment with reoperation rates for exposure of 6.8%. Jia et al in a systematic review of sacrocolpopexy, found an exposure rate of 0–12%. This is contradictory to previously thought lower rate of mesh exposure in sacrocolpopexy. The only RCT to date that compares total vaginal mesh with sacrocolpopexy, showed a 2% exposure rate with sacrocolpopexy compared with 13% ($P < 0.07$) total vaginal mesh. However, the reoperation rates for mesh exposure were 2% and 9% (P 0.11) respectively. The combined mesh

Joint IUGA/ICS classification system for mesh related complications. (Reproduced by kind permission from Haylen et al (2011) Joint IUGA/ICS joint terminology and classification of complications related directly to the insertion of prostheses and grafts in female pelvic floor surgery.)

	CATEGORY				
	General Description	**A (Asymptomatic)**	**B (Symptomatic)**	**C (Infection)**	**D (Abscess)**
1	**Vaginal**: no epithelial separation Include prominence (e.g. due to wrinkling or folding), mesh fibre palpation or contraction (shrinkage)	**1A**: Abnormal prosthesis or graft finding on clinical examination	**1B**: Symptomatic e.g. unusual discomfort / pain; dyspareunia (either partner); bleeding	**1C**: Infection (suspected or actual)	**1D** = Abscess
2	**Vaginal**: smaller ≤ 1cm exposure	**2A**: Asymptomatic	**2B**: Symptomatic	**2C**: Infection	**2D** = Abscess
3	**Vaginal**: larger >1cm exposure, or any extrusion	**3A**: Asymptomatic 1-3A*a* if no prosthesis or graft related pain	**3B**: Symptomatic 1-3B (*b-e*) if prosthesis or graft related pain	**3C**: Infection 1-3C /1-3D (*b-e*) if prosthesis or graft related pain	**3D** = Abscess
4	**Urinary Tract**: compromise or perforation Including prosthesis (graft) perforation, fistula and calculus	**4A**: Small intraoperative defect e.g. bladder perforation	**4B**: Other lower urinary tract complication or urinary retention	**4C**: Ureteric or upper urinary tract complication	
5	**Rectal or Bowel**: compromise or perforation including prosthesis (graft) perforation and fistula	**5A**: Small intraoperative defect (rectal or bowel)	**5B**: Rectal injury or compromise	**5C**: Small or Large bowel injury or compromise	**5D** = Abscess
6	**Skin and / or musculoskeletal**: complications including discharge pain lump or sinus tract formation	**6A**: Asymptomatic, abnormal finding on clinical examination	**6B**: Symptomatic e.g. discharge, pain or lump	**6C**: Infection e.g. sinus tract formation	**6D** = Abscess
7	**Patient**: compromise including hematoma or systemic compromise	**7A**: Bleeding complication including haematoma	**7B**: Major degree of resuscitation or intensive care*	**7C**: Mortality * *(additional complication - no site applicable - **S 0**)	

TIME (clinically diagnosed)			
T1: Intraoperative to 48 hours	**T2**: 48 hours to 2 months	**T3**: 2 months to 12 months	**T4**: over 12 months

SITE				
S1: Vaginal: area of suture line	**S2**: Vaginal: away from from area of suture line	**S3**: Trocar passage Exception: Intra-abdominal (**S5**)	**S4**: other skin or musculoskeletal site	**S5**: Intra-abdominal

N.B.
1. **Multiple complications may occur in the same patient. There may be early and late complications in the same patient. i.e. All complications to be listed. Tables of complications may often be procedure specific.**
2. **The highest final category for any single complication should be used if there is a change over time. (patient 888)**
3. **Urinary tract infections and functional issues (apart from 4B) have not been included.**

CODE ☐☐☐- **T** ☐- **S** ☐

Table 1

exposure rate for transvaginal mesh in posterior, anterior and apical compartment was found to be 18% with a reoperation rate of 9%. The clinical presentation of mesh exposure has been described in the previous review.

Published level 1 studies (RCTs) have been under-powered to test the causation of most risk factors and conclusions are hence based on level 3 (good quality case control) and level 4 (poor quality cohort and case control) evidence. Systematic review of mesh complications by Deffieux et al found level 3 evidence for smoking, sexual activity and obesity (BMI >30 kg/m^2) as risk factors. There was insufficient evidence to establish age as a factor for mesh exposure, but concomitant prolapse surgery in other compartments and excision of excess vaginal skin increases risk (level 4). There is conflicting evidence for concomitant hysterectomy (level 1), but level 3 evidence of increased mesh exposure with vaginal hysterectomy. Genital atrophy, previous scarring, diabetes, immunosuppression or pelvic irradiation was not found to be risk factors. Type II mesh were found to be associated with four times mesh exposure compared with type 1 by Cundiff et al Murray et al on comparison of mesh kits with non-mesh kits found similar (11% versus 13%) incidence of mesh exposure, with non-mesh kits being more cost effective. Studies by Achtari et al and Deffieux et al, did not find composite mesh or light weight (50 g/m^2) mesh to reduce exposure rates. Deffieux et al also found no difference in mesh exposure rates in abdominal or laparoscopic sacrocolpopexy unless a "mixed route" i.e. vaginal and abdominal, is used. There are no comparative studies looking at reperitonization of mesh versus no peritonization during sacrocolpopexy, however majority of the studies recommend reperitonization to minimize risk of adhesions.

The term "mesh exposure" was considered non-specific, lacking clarity and not always suitable for clinical scenarios by the joint IUGA/ICS committee. New definitions including *mesh exposure* (when the mesh is displayed/revealed through the vaginal epithelium), *mesh extrusion* (when part of the mesh is extruding out of the vagina or skin) and *perforation* (if there is an abnormal opening into a hollow cavity) are now recommended. These definitions are based on the hypothesized different pathophysiological mechanisms underlying the complication and hence preferred over "mesh exposure". Historically, these terms have been used interchangeably in the past limiting retrospective interpretation.

Mesh infection

Mesh infection may present together with exposure. Jacquetin et al of the French TVM group quote a reduced incidence of mesh infection associated with the use of type 1 macroporous, monofilament knitted meshes. Mesh infection may present with non-specific pelvic pain, dyspareunia, persistent vaginal discharge, bleeding and pelvic abscess.

Mesh contraction

Mesh contraction can be appreciated on clinical examination as a reduction in size of the implanted mesh. The main symptom is pain which may be intermittent, regular or in extreme cases constant with significant impact on quality of life. Animal studies have shown 25–30% contraction of mesh which may increase to 40% after implantation. Hence larger pieces of mesh have been used in anticipation of shrinkage. Maher et al in RCT comparing sacrocolpopexy with transvaginal mesh found a mesh contraction rate of 0% versus 7% respectively (P 0.05). Ultrasound studies by Velemir et al and Letouzey et al suggest mesh shrinkage based on the appearance at post-operative follow-up. However, serial ultrasound by Dietz et al, at 3 months and an average of 18 months did not find any evidence of mesh shrinkage.

Treatment of specific complications primarily depends on symptoms and the presence of infection. Investigations should be undertaken to exclude mesh perforation into various neighbouring organs depending upon symptoms. This may include evaluation under anaesthesia, imaging to identify other causes for pain, cystourethroscopy and sigmoidoscopy. 50–60% of exposures reported in trials were asymptomatic and successfully managed conservatively.

Smith and Davila describe a simplified management algorithm for mesh exposure (Box 2). Small (≤0.5 cm) asymptomatic exposure can be managed conservatively by abstinence for 6 weeks, topical oestrogen therapy and antibiotics, with or without office mesh trimming in the first or subsequent visits. Though there is limited data on the long-term expectant management of this group, Deffieux et al reports no increase in size of mesh exposure or symptoms in a small series of nine sexually inactive

Management of mesh exposure (Smith and Davila 2011)

Small lesions (<0.5 cm) asymptomatic/symptomatic
- Inform patient especially if sexually active and advice abstinence for 6 weeks
- Vaginal oestrogen twice weekly
- Antibiotics if vaginal discharge
- Mesh trimming in office or monitor 3–6 m if asymptomatic
- Repeat trimming if required

Larger lesions (>0.5–4 cm)
- Conservative management as above
- If no response in 2 months or symptomatic, for surgical excision
- Mobilization of vaginal wall epithelium, mesh excision and tension free closure
- Surgical excision by experienced surgeons with urological and colorectal support

Largest >4 cm
- Surgical excision of mesh with biological graft to bridge the defect
- Surgical excision by experienced surgeons with urological and colorectal support

Perforation into adjacent organs
- Surgical excision in tertiary centres with urological and colorectal support

Box 2

women over 10 years. Surgical management is recommended for larger exposures up to 4 cm, not responding to conservative management.

Surgeons should have sufficient expertise and have access to urological and colorectal support, preferably in a tertiary centre. Lee et al found a significant association between size of the lesion and symptoms, with lesions >1 cm more likely to result in pelvic pain, though not necessarily dyspareunia. A study by Skala et al showed 64% resolution of pain and 55% reduction in dyspareunia following surgical resection. Surgical excision is recommended for lesions >4 cm along with biological grafts to bridge defects. The main risk of surgical excision is vaginal stricture, infection and visceral injury. If there is recurrence of symptoms, the algorithm can be repeated. Perforation into viscera invariably requires surgical excision. There is a significant risk of development of fistula and residual symptoms in this group.

Pain and dyspareunia

Pelvic pain and dyspareunia can occur after prolapse repair irrespective of mesh use. This is a debilitating and serious complication with significant impact on quality of life. Though the precise pathophysiology is unknown, mesh contraction is thought to be strongly linked to this symptom. In a case series of 17 patients, Feiner et al describes vaginal pain classically deteriorating with movement and dyspareunia. Trigger points are often found at the junction of mesh arms with the body of the mesh but also can be found elsewhere. Lee et al, in their review of 58 patients who required mesh removal found pain in 100% with 72% having dyspareunia and 45% pelvic pain and or buttock pain. 74% of these patients also had mesh exposure and 9% had infection showing the multiple aetiology of the symptom.

Cochrane review found no difference in the denovo dyspareunia rates between native anterior repair (4%) and transvaginal mesh repair (7%). Dyspareunia was less frequent following sacrocolpopexy (16%) compared with sacrospinous fixation (36%). Treatment involves simple analgesics, oestrogen replacement and local anaesthetic or steroid injection. Smith and Davila found that patients who responded to topical local anaesthetic injection were more likely to have resolution of pain following mesh excision. Diffuse pain is difficult to treat and is often associated with levator spasm and pelvic floor hypertonia. Pelvic floor physiotherapy with a specialist physiotherapist with injection and massage of trigger points along with smooth muscle relaxants may be of benefit before surgical excision.

Denovo urinary and faecal incontinence

Cochrane review found de novo stress urinary incontinence to be lower in native anterior repair (8%) compared with 13% in the transvaginal mesh group. Sacrocolpopexy was found to have a lower incidence of stress urinary incontinence compared with sacrospinous fixation. However, these results may have been influenced by concomitant stress incontinence operations carried out within these trials.

Visceral injury

Bladder injury rates were 0.3% after native anterior repair compared with 2.4% after transobturator mesh in the Cochrane review. Jia et al found that visceral damage ranged from 0 to 8% with an average incidence of 2.1% in sacrocolpopexy. These rates are higher than native tissue repair.

Perioperative haemorrhage

A recent Cochrane review by Maher et al found that blood loss was significantly less with native anterior repair compared with transobturator mesh group, measured as blood loss or change in haemoglobin. Jia et al report blood transfusion rates in sacrocolpopexy ranging from 0% to 17% with a mean rate of 1.7%.

Reoperation rates

The overall reoperation rates, including surgery for recurrent prolapse, incontinence, pain and mesh complications, were lower for native tissue anterior repair (5%) compared with transvaginal mesh repair (10%). The total reoperation rates for combined apical, anterior and posterior compartment mesh surgery are 11% compared with 3.5% for native tissue repair. Sacrocolpopexy had lower reoperation rates compared with sacrospinous fixation and transvaginal mesh repair.

Prolapse of other compartments

Anterior repair using synthetic mesh kits have shown to have a higher denovo apical or posterior compartment prolapse (18%) compared with native tissue repair (10%). Both sacrocolpopexy and sacrospinous fixation do not appear to increase this risk.

How to minimize complications

The main concern with the use of vaginal mesh has been the lack of evidence from robust RCTs. In the UK, National Institute of Clinical Excellence (NICE) acknowledges specific risks with mesh and its guidelines include recommendations for clinical practice with special arrangement of governance, consent, audit and research. Following the FDA notification, IUGA also has developed several consensus documents on various aspects of mesh use intended to increase the safety of mesh use in prolapse surgery (Box 3).

Selecting the right mesh

In the US, the 510k premarket notification process allowed the introduction of various modifications of vaginal meshes on the basis of equivalence, without the need of clinical trials. A review by Nygaard observed that the majority of meshes used in stress incontinence surgery as well as prolapse have been based on the ProteGen (Boston scientific) sling in 1996, even though it was subsequently recalled due to complications. The IUGA consensus document aims to provide minimum standards that should be implemented by the manufacturers before a mesh is launched for clinical use. This is recommended to be implemented by regulatory authorities in the premarket approval as well as by clinicians to ensure the efficacy and safety. Slack et al recommend, 'When selecting a mesh, comprehensive and exact data on physical properties, data from animal studies and cadaver studies and a well conducted cohort study should be considered as minimum standards prior to launch and marketing. This should be followed by maintaining a registry of 1000 consecutive

Recommended steps for introduction of mesh in prolapse surgery based on 2nd IUGA Grafts Roundtable consensus

For premarket approval
- Ensure data available on physical properties, animal studies and cadaver studies along with a well conducted cohort study.
- Post market surveillance using registry of initial consecutive 1000 cases.

Surgical training
- Undertake surgery only if adequate surgical expertise in vaginal prolapse surgery with specific training in mesh placement.
- Undertake educational courses to enhance knowledge and competency.

Patient selection
- Informed consent after discussing other treatment options, lack of long-term data, risk of significant complications.
- Provide written information leaflet.
- MDT discussion of appropriateness of use of mesh.
- Reduce smoking, encourage weight loss.

At surgery
- Use only type I polypropylene mesh.
- Deep dissection, limit trimming of vaginal epithelium, avoid tension.

Post treatment surveillance
- Use patient reported outcome measures.
- Maintain post marketing registers.
- Report adverse events to MHRA.
- Enter data on national database like BSUG and audit outcomes.

Box 3

patients after marketing clearance by the appropriate regulatory body'

The Medicines and Healthcare products Regulatory Agency (MHRA), which is responsible for approving medical devices in the UK, advises the notified bodies to check the appropriateness of the CE marking and also involve specialist medical personnel or professional bodies if there are doubts on the equivalence of the device. With the current evidence, Royal College of Obstetrics and Gynaecologists recommend the use of mesh in trial settings only or as a part of registry. Prior to clinical use, clinical governance leads of the trust should be notified as per NICE and MHRA recommendations.

Selecting the right surgeon: who should perform mesh surgery?

NICE recommends that mesh surgery should only be carried out by gynaecologists with "special expertise in the surgical management of prolapse". Though "special expertise" was not defined, it may be dictated on training recommended by professional bodies such as the British Society of Urogynaecologists (BSUG) in the UK. MHRA recommends sufficient workload and ability to work in a multidisciplinary setting with provision of conservative therapy, physiotherapy as well as surgical management essential for the prolapse. An audit of the outcomes including complications is recommended. IUGA consensus also recommends specific knowledge of mesh properties, safety and complications as well as pelvic anatomy. Additional assessment of technique and technical competency should be attained using cadaver labs, educational programmes or preceptors and a "post-test" certification is recommended for satisfying the various aspects of training for mesh placement, ensuring competency. MHRA recommends including manufacturer's educational programmes in the procurement of mesh kits as a criterion for purchase.

Patient selection

Smoking cessation and weight loss are recommended, though not proven to reduce risk. Optimum control of diabetes is recommended as it minimises the incidence of post-operative infection. The use of mesh in patients with connective tissue disorders may be justified due to the higher risk of recurrence. Based on current evidence, recurrent anterior compartment and apical prolapse (rather than posterior compartment prolapse) may be an indication for mesh use. Withagen et al found patients with pre-existing pelvic pain and dyspareunia at higher risk for worsening or persistence of symptoms. Based on lack of evidence, patients considering future pregnancy should not receive vaginal mesh. MHRA recommends multidisciplinary team discussion of all cases of recurrent prolapse in the same compartment. The majority of tertiary units in the UK have multidisciplinary team meetings where approval of cases requiring mesh amongst the team members as standard.

Informed consent

NICE recommends that it is the responsibility of the clinician to ensure that patients are aware of the uncertainty of long-term data and the risk of complications including sexual dysfunction, mesh exposure with need for reoperation. Additional written information using leaflets is also recommended clarifying the risks and benefits of treatment.

Selecting the right technique

There are no studies comparing specific antibiotic protocols in this context. Standard antibiotic policy for gynaecology surgery is recommended. French guidelines on mesh use advice strict asepsis with antiseptic cleansing double gloving, using clean gloves during handling of mesh with removal of mesh from packaging immediately prior to implantation. Most evidence has been gathered from retrospective analysis and hence unproven in reducing or preventing the complications. These include tension free placement of mesh, minimal trimming of excess vaginal tissue, deep implantation and haemostasis. MHRA recommends the entry of the details of implanted material including the model, batch number and the device unique identifier for future identification of the product.

Post procedural follow-up

There is increasing evidence that patient centred outcome measures using questionnaires are more relevant in patients with

pelvic floor dysfunction than objective or anatomical cure. MHRA recommends all institutions to ensure that NICE guidance is followed so that all products are included in registries and is subject to audit. It also recommends that accident and emergency units are aware of mesh complications to ensure appropriate referral. If an adverse event is detected, it should be reported to the MHRA as well as the manufacturer. NICE also recommends the entry of data into BSUG database to facilitate national audit and research.

Conclusions

Mesh use in prolapse surgery has been largely industry driven in the absence of an evidence based strict premarket approval process, and also supported by the eagerness of clinicians to adopt these devices to improve outcomes. Evidence from systematic reviews support the use of type I polypropylene meshes in recurrent anterior compartment and vault prolapse. However, the incidence of complications appears to be higher than native tissue repair. Given the considerable risks associated with synthetic mesh, it may not be justifiable to introduce new products for clinical use without robust evidence. Stricter regulations for premarket approval, along with use of mesh in dedicated centres with surgical expertise and multidisciplinary set up will ensure the safe use of polypropylene mesh. Post treatment surveillance by registries as well as audit will provide data on the true incidence of complications which can be used for further research. ◆

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