Management of complications of mesh surgery

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Abstract

Polypropylene mesh (PPM) has been used in abdominal sacrocolpopexies since the 1990's however following a patient led campaign controversy surrounds its use incontinence procedures, midurethral slings (MUS) and vaginal mesh prolapse repairs. The complication rates following mesh surgery may be as high as 10%. NHS England paused the vaginal insertion of polypropylene mesh in July 2018 pending a review by Baroness Cumberledge. This review will outline the assessment and basic management of complications of polypropylene mesh. This is a relatively new area of urogynaecological practice which non-specialist obstetric and gynaecology clinicians and GPs need to be aware of. Symptoms which could be due to mesh complications are vaginal discharge or bleeding, recurrent urinary tract infection, haematuria, dyspareunia and pelvic pain. Women presenting with any of the above symptoms should be asked if they have had previous surgery for stress incontinence or prolapse. The women may not recall having mesh inserted and may use different terms "sling" "net" or "tape". They should be examined to both look and feel for PPM. Mesh complications should be managed by the designated mesh centres which are listed on the BAUS and BSUG websites. All mesh complications should be reported to the Medicines & Healthcare products Regulatory Agency (MHRA) by the yellow card system. All mesh complications requiring further surgical intervention should be recorded on the British Society of Urogynaecology (BSUG) national database.

Keywords mesh complication; mesh exposure; pain after mesh; SCP; SUI; TVM for POP

Introduction

Polypropylene mesh is synthetic non-absorbable mesh. According to the Amid classification, there are four types of permanent synthetic mesh. In gynaecology, type 1 monofilament polypropylene mesh is used.

PPM was first used for abdominal hernia repairs and then in abdominal sacrocolpopexy (SCP). It replaced other materials developed in the 1960s, such as gortex and polyester. In the early 1990s Ulmsten developed the tension free mid-urethral slings for Stress urinary incontinence (SUI) using PPM which was a day case continence procedure and could be performed under local anaesthetic. In large randomized controlled trials it was shown to be as effective as colposuspension.

The mid-urethral sling (MUS) became the most common surgical procedure performed to treat SUI in women. Between 2005 and 2013 about 3.7 million continence meshes were sold worldwide.

Mesh was introduced for pelvic reconstructive surgery to address significantly high failure rates with native tissue repair (29%). Compared to native tissue repair the use of mesh in POP repair reduces the risk of anatomical failure however but it adds the risk of potential mesh related complications, The Cochrane review of prolapse surgery in 2016 found that transvaginal mesh for POP compared to native tissue repair has lower rates of awareness of prolapse (10–15% vs. 19%), lower rates of repeat surgery for prolapse (5% vs 7–18%), and lower rates of recurrent prolapse on examination (11–20% vs. 38%). However, eight per cent of women in the mesh groups required repeat surgery for mesh related complications.

Public concern was raised about uncommon but severe complications related to use of mesh for SUI and vaginal POP surgery. A public petition (2014) to the Scottish Parliament about these concerns led the Scottish government to commission an independent review of the safety, use and efficacy of vaginal mesh implants.

The report acknowledged the lack of long term follow up and patient related qualitative outcome data following mesh UI and POP surgery. It also recommended the use of a national database to record mesh related complications and the need to improve the awareness amongst both primary and secondary care of possible symptoms and complications following mesh surgeries.

Incidence of mesh complications

There is a lack of good quality data about the incidence of mesh complication especially in the long term. The PROSPECT study (2017), a large RCT in 38 centres in the UK found 12% of women needed treatment for mesh complications. The Kieltie paper found a mesh complication rate of 10%.

Mesh complication vary depending on, the pore size of the mesh, its weight and the volume of mesh used. Also, the anatomical location of mesh effects the risk of complications. The reported rate of mesh complication with MUS is 5%, TVM for POP 17 % and abdominal SCP 2–5 %. Other factors, such as surgical skill and individual patient characteristics, for example diabetes, smoking, age and previous prolapse surgery may affect the incidence of mesh complication.

Presenting symptoms

All surgical procedures can be associated with intraoperative, anaesthetic and surgical complications for example bleeding, infection and pain. For the purpose of this article we have focussed on complications related specifically to use of mesh for SUI and POP.

Patient can present with a variety of symptoms which might date to their index surgery or develop after some time.

1. Pain or sensory change in the back, abdomen, vagina, pelvis, leg, groin or perineum that is either unprovoked, or

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provoked by movement or sexual activity or either generalized, or in the distribution of a specific nerve, such as the obturator nerve.
2. Vaginal symptoms including discharge, bleeding, painful sexual intercourse, penile trauma or pain
3. Urinary problems including recurrent infection, incontinence, retention, or difficulty or pain during voiding
4. Bowel problems including difficulty or pain on defaecation, faecal incontinence, rectal bleeding or passage of mucus
5. Symptoms of infection, either alone or in combination with any of the symptoms outlined above.

Patients may not remember or associate their symptoms with mesh. They may use other terms such as "net" "hammock" "gauze" or "tape"

The International Urogynecological Association (IUGA) (2010) and the International Continence Society (ICS) developed a mesh complication classification to facilitate international comparison and to improve our understanding of complications (Figure 1). This code is applied to surgical cases for the analysis of complications after mesh insertion. The classification allows comprehensive coverage of both ***insertion complications*** and ***healing abnormalities***. The latter is a CTS system incorporating (a) Category, (b) Time and (c) Site divisions into a six (or seven) digit code for any conceivable complication https://www.ics.org/complication.

Evaluation of symptoms

A detailed history and thorough clinical examination is key in patients' assessment. Clinical examination should include general, abdominal and vaginal examination. Assessment for tenderness in abdomen, suprapubic area, groins and vagina, for vaginal mesh exposure or extrusion, placement of the graft and any graft abnormality like contraction, splinting and localized tenderness over graft is essential. Patient should also be examined for any residual/recurrent SUI/POP. PR examination should be carried out if rectal perforation/fistula suspected. Neurological examination should be included depending on patients' symptomatology.

Investigations needs to be tailored depending on patient presenting symptoms, clinical and examination findings (Table 1). Several tests are available and can be utilized to help guide the patient's management.

IUGA/ICS terminology of complications

CATEGORY

	General Description	A (Asymptomatic)	B (Symptomatic)	C (Infection)	D (Abscess)
1	**Vaginal**: no epithelial separation Include prominence or excessive scarring. Vaginal invagination. Grades of pain from table 3 incorporated	**1A**: Abnormal 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 epithelial separation or ulcer ≤1 cm	**2A**: Asymptomatic	**2B**: Symptomatic	**2C**: Infection	**2D** = Abscess
3	**Vaginal**: larger >1 cm epithelial separtion or ulcer or suture extrusion	**3A**: Asymptomatic 1–3A*a* if no surgery related pain	**3B**: Symptomatic 1–3B (*b–e*) if surgery related pain	**3C**: Infection 1–3C/1-3D (*b–e*) if surgery related pain	**3D** = Abscess
4	**Urinary Tract**: compromise or perforation include 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 include 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 hematoma	**7B**: Major degree of resuscitation or intensive care* including septic hematoma	**7C**: Mortality* *(additional complication) – if no site is 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 area of suture line | **S3**: Adjoining viscus e.g. bladder or bowel | **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** ☐

Exposure: A condition of displaying, revealing, exhibiting or making accessible (e.g. vaginal mesh exposure)
Extrusion: Passage gradually out of a body structure or tissue
Perforation: Abnormal opening into hollow organ or viscus

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Figure 1 IUGA/ICS terminology of complications.

Common investigations

Investigation	Type of mesh	Indication
Examination under anaesthesia	All types of mesh	Pain Organ perforation Infection
Cystourethroscopy — telescopic examination of bladder and urethra	MUS, anterior TVM and abdominal mesh	Suspected: a) Urethral perforation b) Bladder perforation c) Fistula
Sigmoidoscopy	Posterior TVM and abdominal mesh	Suspected bowel perforation
Diagnostic Laparoscopy	Abdominal mesh	a) Pain b) Suspected bowel entrapment around mesh c) Suspected adhesions secondary to mesh placement
MRI pelvis	All types of mesh	a) Suspected mesh infection b) Pelvic and groin pain c) Identification of discitis or osteomyelitis
Ultrasound scan (transperineal, transvaginal or translabial, or 3D), performed and reported by a clinician with experience in interpreting mesh complications	MUS and TVM	a) Pain b) Suspected infection c) Suspected urethral mesh perforation d) Previous partial excision

Table 1

It is important to have the details of index procedure, the kind of mesh used, any previous treatment including conservative treatment and prior attempts to revise or remove mesh.

Management of mesh complications

Women with mesh related complications should be referred to specialist urogynaeclogist or urologist or colorectal surgeon with experience in managing mesh complications.

There are 18 trusts in UK that have self-assessed themselves against standards produced by BSUG/BAUS demonstrating the have the multi-disciplinary teams and experience to provide advice and treatment or onward referral for women with mesh complications.

Mesh or suspected mesh complication should be managed as part of MDT under umbrella of clinical governance. Management is based on various factors like the type of mesh, the index operation, symptom of the complication itself, the cure rate expected after treatment and patient wishes.

Mesh exposure

'**Presentation**: mesh exposure (Figure 2) can present as an isolated symptom or associated with other symptoms such as bleeding, pain, vaginal discharge, dyspareunia, penile laceration or sexual dysfunction. It can sometimes be an incidental finding during a routine examination, for example at a smear test.

Incidence: the reported rate of mesh exposure following MUS is lower (3–5%) compared to TVM. The rate is similar with transobturator and retropubic approach. One year after prolapse surgery the incidence of mesh exposure is higher for transvaginal mesh (TVM) (8–20%) than for abdominal sacrocolpopexy (3–4%). Incidence of mesh exposure is higher if SCP is performed with total hysterectomy and post total hysterectomy due to increased risk of exposure at the suture line across the vaginal vault.

Investigations: most mesh exposures can be seen or more commonly felt on vaginal examination.

Examination under anaesthesia can help in mapping the exposure and in planning the subsequent surgical management. This is usually combined with cystoscopy, urethroscopy and/or sigmoidoscopy to exclude organ perforation.

The type of imaging performed will vary depending on the index procedure and should be considered if underlying infection or other pathology suspected. Magnetic resonance imaging (MRI) is more useful in the evaluation of abdominal mesh compared to vaginal mesh. Ultrasound scan (transperineal, transvaginal or translabial) is probably better to evaluate MUS and TVM.

Treatment: this will depend on the symptoms and severity of the exposure, the index procedure and the comorbities and the wishes of the patient.

MUS and TVM exposures

(1) Conservative management

Asymptomatic mesh exposure and small exposures =< 1 cm can be managed conservatively, with or without a trial of vaginal estrogens and with regular annual patient follow up.

(2) Simple excision of exposed mesh and closure

The first episode of exposure may be treated with excision of only the exposed mesh and then epithelial closure. However,

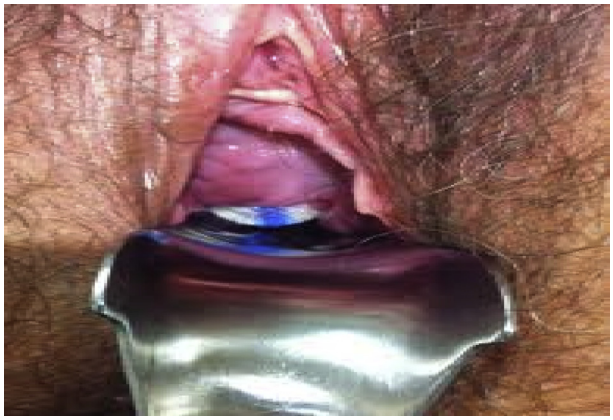

Figure 2 Mesh exposure.

women should be counselled about the risk of further mesh exposure requiring more surgery, the potential risk of infection and in the case of MUS the risk of recurrent incontinence in up to 50% especially with removal of suburethral portion of mesh.

(3) Removal of the vaginal portion

In cases of repeated mesh exposure, multiple sites of exposure or large areas of exposure then total removal of vaginal portion should be considered.

Women should be advised that if the vaginal section of a TOT is removed then it will not be possible to remove the groin sections at a later date.

(4) Complete removal of mesh

Complete removal is considered a better way to prevent recurrent exposure.

There is uncertainty about the risks and benefits of total removal of TVT and TOT versus excision of only the vaginal portion.

In cases of vaginal mesh kits for prolapse patient should be aware that total removal of the arms of mesh is not usually advisable except in the presence of severe infection.

Vaginal exposure of abdominal mesh

Vaginal exposure of abdominal mesh can occur following sacrohysteropexy, rectopexy or sacrocolpopexy. These exposures carry a theoretical risk of sinus formation and intra abdominal sepsis. An MRI scan can help to evaluate infection associated with the mesh.

Resection of these types of exposure by the vaginal route alone could result in injury to bladder or bowel which might be adhered to the mesh in pelvis. Hence, it is safer to perform such resection via the laparoscopic route with direct visualization of the intra-abdominal mesh and bowel.

Patient should be informed of risks associated with surgery including worsening of associated pain, new onset pain, scarring, visceral injury and recurrence of preoperative symptoms of SUI and/or POP depending on the site or extent of exposure.

Pain

Most surgical procedures can cause chronic pain which usually starts at the time of surgery. However, the pain patients develop following a mesh procedure can have a delayed onset, even after several years.

Incidence

The incidence of thigh or leg pain is higher after a transobturator tape (TOT) (15%) compared to a retropubic tape (RP) (3%). However suprapubic pain can occur after a RP tape and is very uncommon after a TOT.

Pooled data from seven RCTs with 1015 patient showed that the incidence of non-sexual pain after pelvic floor repair procedures is higher after transvaginal mesh compared with native tissue repair.

Aetiology

Pelvic pain related to previous mesh procedures can be complex and multifactorial and is not fully understood. It can result from tethering of mesh to the adductor muscles of the thighs, following mesh contracture, spasm of pelvic floor muscles, and entrapment of obturator nerve or as a result of a chronic inflammatory response.

Presentation: following MUS or TVM women may experience pain in the pelvis, leg, groin or perineum. Their pain can be unprovoked or provoked by movement or sexual activity. Pain could be generalized, or in the distribution of a specific nerve, such as the obturator nerve. Patients can present with pain in their back, abdomen, pelvis or vagina following intra-abdominal procedures but the incidence is unknown. Vaginal pain after SCP in absence of exposure is rare.

In the elderly a rupture of diverticula abscess can lead to delayed onset infection of intra abdominal mesh.

Assessment and Investigations: it is useful to quantify pain using a standardized pain questionnaire for example Pain Dtect or simple VAS (visual analogue score) to quantify pain.

The site of pain should be mapped anatomically, the onset and nature of the pain should be recorded.

Investigations: This would depend on the clinical history, examination and location of the mesh implant (see Table 1). MRI scan can be particularly helpful to rule out any other pathology which could explain patient symptoms.

Treatment

A. Conservative management

1. Vaginal oestrogen cream
2. Pelvic floor physiotherapy with trigger point treatment, myofascial relaxation with or without biofeedback
3. Local anaesthetic and steroid injections to localized tender area which if effective can be repeated
4. Referral to pain management team to optimize patient symptoms using medications designed to disrupt or alter peripheral or central pain transmission and mindfulness.

B. Surgical management

Surgical removal should only be considered once conservative treatment has failed. Women should have detailed counselling about the risks of specific removal of that type of mesh.

Women should be aware that they can develop new onset pain or worsening of the existing pain due to formation of new scar tissue and nerve injury. Other risks are of organ damage with fistula formation and recurrence of SUI symptoms and POP should also be discussed.

There is very limited data about the benefit of mesh removal for pain. One retrospective study by Goodall et al., of laparoscopic removal of retropubic MUS for chronic pain (n = 56), found that 88% of patients reported in improvement in their symptom of pain however 46% had worsening of their SUI symptoms at 3 months' follow up visit.

Sexual dysfunction

Dyspareunia can result from loss of vaginal tissue, scarring, contracture of mesh and exposure of the mesh. It can also be due to pelvic floor muscle hypertonia. Male partners can also experience pain "hispareunia" or penile laceration from exposed mesh.

The incidence of sexual dysfunction is poorly understood following both native tissue and mesh surgery for prolapse and incontinence. Rates of dyspareunia vary considerably due to use of different definitions and questionnaires used.

Following SCP most women report improvements in sexual function due to anatomical correction of prolapse which was often very severe, stage 3 or 4.

Hispareunia is usually due to mesh exposure and can be managed as described above.

Dyspareunia in absence of mesh exposure can be managed as for pain post mesh insertion.

Organ perforation-bladder/urethra/bowel

The type of perforation invloved is usually specific to the type of procedure. Urethral perforation (Figure 3) is usually due to MUS. Bladder perforation (Figure 4) more commonly is due to either a retropubic MUS or an anterior vaginal mesh or rarely abdominal SCP mesh. Bowel perforation can be associated with any abdominal mesh or a posterior TVM. There have been some rare cases of ureteric injury reported following TVM.

Presentation: With urinary tract perforation clinical presentation can be with recurrent UTI, cystitis, pain, constant urinary incontinence due to the presence of a fistula, pain from bladder or urethral calculi. Patients with mesh perforation of the bowel can present with dyschezia, blood in stools, increased discharge per rectum or unexplained rectal pain.

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 or due to local sepsis.

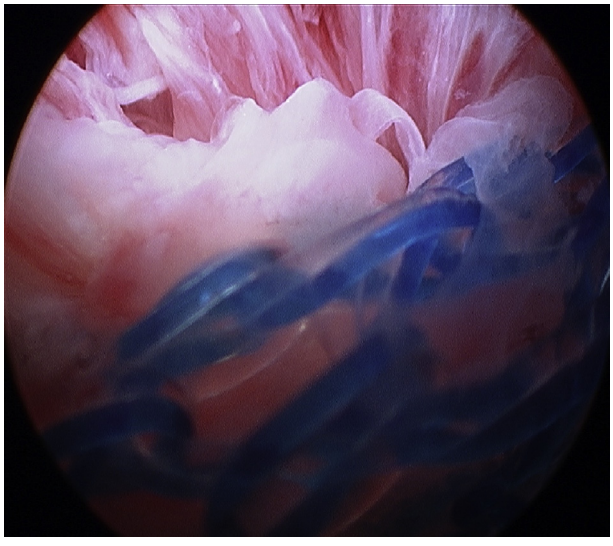

Figure 3 Urethral perforation.

Investigations: further tests will help to locate the position and extent of mesh perforation. EUA, Cystoscopy, MRI and ultrasound can be performed. If rectal perforation is suspected the patient will require proctosigmoidoscopy.

Management

The recommended management is removal of the mesh from the organ. For vaginally placed mesh vaginal approach is favoured. For SCP mesh laparotomy would be required to achieve removal of the mesh.

In a recent study done in our tertiary centre by Dalia et al. on outcomes after surgical removal of MUS as a treatment for lower urinary tract perforation, 50% of the cohort had postoperative recurrence of SUI, 15% were cured and 54% felt significant improvement in their symptoms.

A detailed counselling about risks with surgery especially fistula formation and new onset symptoms especially pain should be discussed with the patient.

Infection

Incidence: the available evidence suggests that mesh-related infections following pelvic reconstructive surgery occurs rarely but can seriously compromise the patient's health and quality of life. The incidence depends on the type of mesh, the anatomical location and comorbidities of individual patients.

The incidence of infection after a TVM is reported to range from 0 to 8%. Clinically evident infection is frequently associated with exposure of the mesh. Patients can present with retropubic abscess with cutaneous sinus, vesical-vaginal fistula, rectovaginal fistula, pelvic abscess, perineal necrotizing infection, and vertebral osteomyelitis.

Clinical presentation

Non-specific pelvic pain, persistent vaginal discharge or bleeding, dyspareunia, and urinary or faecal incontinence. Severe low back pain may occur years after abdominal sacral colpopexy as an unusual complication due to sacral abscess.

Clinical examination can reveal induration of the vaginal incision, vaginal granulation tissue, draining sinus tracts, and mesh erosion or extrusion.

Investigations: MRI scan can help to rule out any deep seated collection and can help in planning treatment. Cystoscopy and/or sigmoidoscopy may be required to rule out any organ perforation.

Treatment

Complete removal of the mesh, wherever possible, is the treatment of choice for infected mesh. Detailed counselling of patient regarding associated risks with surgery especially organ injury and fistula formation and new onset symptoms with pain and recurrence of USI/POP symptoms should be undertaken.

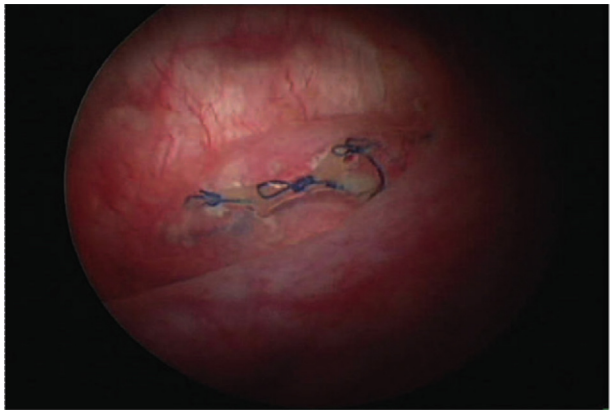

Figure 4 Mesh perforation in bladder.

Sacral osteomyelitis or Discitis

This is a complication specific to SCP and can present as back pain. Patient can present remote from surgery and is associated with high morbidity.

Investigation: there are no specific findings on clinical examination unless the patient develops sinus tract with or without mesh exposure. Non-contrast MRI is the investigation of choice, which might show evidence of osteomyelitis or infection at the site of suture placement.

Treatment: a multidisciplinary approach involving specialists in female pelvic reconstructive surgery, orthopaedics, infectious disease physiotherapy is required in the management.

The first line of treatment is prolonged antibiotics directed against staphylococcus and streptococcus which are the causative organisms in 50% of cases. Actinomycosis is another frequently reported organism and should be managed with consultation with infectious diseases.

In case of failure to respond to conservative treatment with antibiotics drainage of abscess, removing the graft with or without debridement and reconstruction of vertebrae or disc spaces may be required. ◆

Practice points

- There is currently a pause on the use of MUS and TVM in England and in Scotland awaiting review by Baroness Cumberledge
- Clinician should be highly vigilant to suspect complications of PPM. Persistent vaginal bleeding, pain, recurrent UTI, microscopic haematuria in women who have had PPM warrants a specialist referral to investigate mesh complications.
- Pelvic pain and groin pain may have a delayed onset and may be due to PPM
- Women with pain in association with PPM with no other obvious cause should be assessed by a pain specialist before considering surgical removal of the PPM.
- Women require detailed counselling explaining risks and benefits of removal/revision of mesh surgery prior to embarking on surgical intervention.

FURTHER READING

Scottish independent review of the use, safety and efficacy of transvaginal mesh implants in the treatment of stress urinary incontinence and pelvic organ prolapse in women: final report. 2017. Edinburgh: Scottish Government, http://www.gov.scot/Resource/0051/00515856.pdf.

Medicines and Healthcare Products Regulatory Agency. A summary of the evidence on the benefits and risks of vaginal mesh implants. 2014. London: MHRA, http://thepelvicfloorsociety.co.uk/budcms/includes/kcfinder/upload/files/MHRS%20evidence%20on%20Mesh.pdf.

NHS England. Mesh oversight group report. 2017. Leeds: NHS England, https://www.england.nhs.uk/wp-content/uploads/2017/07/mesh-oversight-group-report.pdf.

Cundiff GW, Quinla DJ, van Rensburg JA, Slack M. Foundation for an evidence-informed algorithm for treating pelvic floor mesh complications: a review. *BJOG* 31 January 2018, https://www.nice.org.uk/guidance/NG123.

NICE guidelines on urinary incontinence and pelvic organ prolapse in women: management (NG123), April 2019.