Consensus statement

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Position statement by the Pelvic Floor Society on behalf of the Association of Coloproctology of Great Britain and Ireland on the use of mesh in ventral mesh rectopexy

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Abstract

The following position statement forms part of a response to the current concerns regarding use of mesh to perform rectal prolapse surgery. It highlights the actions being pursued by the Pelvic Floor Society (TPFS) regarding clinical governance in relation to ventral mesh rectopexy (VMR). The following are summary recommendations.

1 Available evidence suggests that mesh morbidity for VMR is far lower than that seen in transvaginal procedures (the main subject of current concern) and lower than that observed following other abdominopelvic procedures for urogenital prolapse, e.g. laparoscopic sacrocolpopexy.

2 VMR should be performed by adequately trained surgeons who work within a multidisciplinary team (MDT) framework. Within this, it is mandatory to discuss all patients considered for surgery at an MDT meeting.

3 Clinical outcomes of surgery and any complications resulting from surgery should be recorded in the TPFS-hosted national database (registry) available for this purpose; in addition, all patients should be considered for entry into ongoing and planned UK/European randomized studies where this is feasible.

4 A move towards accreditation of UK units performing VMR will improve performance and outcomes in the long term.

5 An enhanced programme of training including staged porcine, cadaveric and preceptorship sessions will ensure the competence of surgeons undertaking VMR.

6 Enhanced consent forms and patient information booklets are being developed, and these will help both surgeons and patients.

7 There is weak observational evidence that technical aspects of the procedure can be optimized to reduce morbidity rates. Suture material choice may contribute towards morbidity. The available evidence is insufficient to support the use of one mesh over another (biologic *vs* synthetic); however, the use of polyester mesh is associated with increased morbidity.

The Pelvic Floor Society

The Pelvic Floor Society (TPFS) is an affiliate of the Association of Coloproctology of Great Britain and Ireland (ACPGBI) and was formed to set and raise standards in pelvic floor surgery and to update members on the advances of the specialty. TPFS has a diverse membership including colorectal surgeons, urogynaecologists, urologists, radiologists, gastroenterologists, chronic pain practitioners, specialist nurses, physiotherapists and gastrointestinal physiologists. The society collaborates with other pelvic floor organizations including the UK Continence Society and the British Society of Urogynaecology.

As a responsible society, and in the light of ongoing concerns by the media and public groups surrounding the use of mesh in patients with pelvic organ prolapse (POP) and female stress urinary incontinence (SUI), this statement aims to address the use of mesh (synthetic and biologic) in ventral mesh rectopexy (VMR) using current available evidence. Further impetus for writing this statement is in response to an ACPGBI Delphi process which ranked VMR outcomes and mesh choice as number 8 in the list of important non-cancer-related questions [1]. In particular, the subjects of patient selection, mesh morbidity, efficacy, clinical governance, and research and development will be examined. This is not intended to be an exhaustive

systematic review, nor is it a formal Delphi or RAND style consensus. It is expert opinion heavily informed by the available evidence.

Background

Ventral mesh rectopexy using an autologous graft and then synthetic mesh was first reported in 1972 by Orr-Loygue *et al.* [2] for the treatment of external rectal prolapse (ERP). Unlike posterior rectopexy where simple sutures may be employed to suspend the dissected rectum, VMR requires a mesh that is fixed to the rectum and then suspended from the sacral promontory. A laparoscopic ventral approach (termed laparoscopic VMR or LVMR) was adopted and supported by D'Hoore *et al.* [3] for ERP citing reduced risk for postoperative constipation compared with the posterior approach and the ability to address coexistent middle compartment prolapse in a minimally invasive fashion. Improved knowledge and insight into the pathophysiology of obstructed defaecation syndrome (ODS) and the role of internal rectal prolapse (IRP) (usually combined with rectocele) has made LVMR a procedure of choice for this condition. Surgical take-up was rapid especially within Europe for LVMR for ERP and ODS despite a lack of high-level evidence for safety or efficacy [15].

In the USA in 2008, the US Food and Drug Administration issued a public health notification on serious complications caused by the transvaginal placement of mesh in women treated for POP and SUI [4]. In 2016, the Food and Drug Administration issued a final order to mesh manufacturers and the public to reclassify these devices from Class II (moderate risk) to Class III (high risk). The use of transvaginal mesh in the USA has fallen by 40–60% since [5]. In Scotland in 2014, a group of women affected by mesh-related complications (Mesh Survivors Campaign) gave evidence to the Holyrood Petitions Committee. As a result, the Scottish Minister for Health wrote to Scottish health boards requesting a suspension of the use of mesh for POP and SUI pending an official enquiry. In 2017, the Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of POP and SUI in Women was published [6]. In the conclusions, the Chairman stated the following.

1 There should be patient-centred care with adequate patient choice and shared decision making supported by robust clinical governance arrangements involving a multidisciplinary team (MDT) approach.
2 Evidence of working in an MDT together with audit and the mandatory recording and reporting of adverse events should be a necessary part of a consultant's appraisal and revalidation.
3 There should be informed consent.
4 Recording databases should be improved to a national level with the creation of new data codes that would allow better National Health Service (NHS) capture.
5 Transvaginal meshes should not be offered routinely.

In the UK in 2014, the Medicines and Healthcare Products Regulatory Agency (MHRA) also published its conclusions on the evidence of the benefits and safety of vaginal mesh implants [7]. These concluded that for the majority of women, vaginal mesh implants were safe and effective, and when used correctly they could help alleviate POP and SUI. In addition, the benefits of mesh outweighed the risks. Contrary to these conclusions, the European Commission published a report led by its Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) in 2015 [7]. It stated that the implantation of any mesh via the vaginal route should only be considered in complex cases, in particular after a failed primary repair. Furthermore, SCENIHR opined that mesh use in SUI was acceptable if performed for moderate/severe SUI by experienced surgeons. A recent Cochrane Review in 2016 [8] on transvaginal mesh concurred with the SCENIHR conclusions.

The use of mesh in VMR is not analogous to transvaginally placed mesh. It does have similarities, however, with mesh use in trans-abdominal sacrocolpopexy performed for vaginal vault prolapse. Indeed, VMR is quite correctly combined with sacrocolpopexy by some colorectal surgeons for single-stage correction of multicompartment prolapse. The safety and efficacy of mesh use for sacrocolpopexy was not called into question in recent enquiries; however, long-term mesh/suture erosion rates of 10.5% have been estimated [9]. Current National Institute for Health and Care Excellence (NICE) evidence on the safety and efficacy of sacrocolpopexy using mesh appears adequate provided that normal arrangements are in place for clinical governance and audit (IPG283). There are no NICE guidelines for VMR.

In 2014, TPFS Chairman wrote to Society members suggesting that all VMR interventions should be the subject of ongoing, continuous audit and that decision making should be part of an MDT process. In addition, device-related adverse events should be reported to the MHRA.

Patient selection for VMR

Since VMR is performed almost exclusively by a laparoscopic approach (LVMR), the following text is principally focused on this variant of the procedure.

In 2014, a consensus report on LVMR was published from a panel of international experts [10]. Definitive recommendations were for ERP in patients deemed fit for general anaesthesia. Relative indications were symptomatic high-grade IRP and patients with solitary rectal ulcer syndrome, all of whom had failed maximal conservative management. Relative contraindications included male patients with IRP, morbid obesity, previous pelvic radiotherapy, high-grade endometriosis and previous sigmoid peri-diverticulitis. Absolute contraindications were pregnancy, no demonstrable pelvic anatomical problem, a hostile abdomen, severe proctitis, psychological instability and anismus resistant to conventional treatment. It was suggested that patients with multicompartment prolapse and those with ODS/IRP be discussed at an MDT meeting.

In 2016, the results of a nationwide pelvic floor census were published based upon research undertaken by TPFS in 2014 [11]. One of the notable conclusions was that complex pelvic floor surgery (including VMR) was being undertaken in some units that did not profess an interest in pelvic floor surgery and that some units did not have access to an MDT meeting. The main value of the MDT meeting is not only in the avoidance of missing any factors relevant to the decision-making process and defining the most appropriate treatment for an individual patient but also in preventing clinicians with an over-enthusiastic belief in their own favoured treatment modality, e.g. VMR, pursuing an inappropriate course of treatment. It also allows a robust audit process to be developed with adequate data collection.

The monitoring of standards and quality of MDT meetings and of data collection will in future form part of a UK pelvic floor unit's accreditation. This initially voluntary process is being driven by TPFS to define and monitor standards of care, organization and quality and should reassure patients, commissioners and providers that selection, efficacy and safety are paramount in delivering care for patients undergoing VMR.

LVMR: technical considerations

Since VMR is performed almost exclusively by a laparoscopic approach (LVMR), the following text is principally focused on this variant of the procedure.

Mesh

Meshes currently used for LVMR are either synthetic or biologic. Synthetic meshes are non-absorbable, partially absorbable or absorbable. Biologic meshes are porcine derived and either crosslinked or non-crosslinked.

The use of absorbable and semi-absorbable synthetic meshes is not advised because of concerns over recurrence rates [10]. The commonest non-absorbable synthetic meshes in use are polypropylene and polyester. Polypropylene can be light or heavy weight, and coated or uncoated.

The data regarding mesh complications and recurrence rates are summarized below for the interested reader. Critical to the interpretation of these data is a prior understanding that all current data are observational and nearly all derive from low-quality studies (level IV case series or poor quality cohort studies) or syntheses thereof. Thus, while the data have been provided, it is TPFS view that no current evidence-based recommendation can be made regarding mesh selection (in particular, the biologic *vs* synthetic mesh argument).

The largest study examining outcome after LVMR (for a mix of internal and ERP) was an observation study conducted in the Netherlands and Belgium [12]. Synthetic mesh (polyethylene or polypropylene) was used in 919 patients with a mix of internal and ERP. Median follow-up was 33.9 months (0.4–143.6). Estimated mesh-related complications assessed by survival curves and analysis (Kaplan–Meier) at 3, 5 and 10 years were 1.5%, 2.9% and 4.6%. However, this estimation included detachment of mesh from the sacral promontory (2.7%). A multicentre collaboration to assess the safety of laparoscopic ventral rectopexy examined mesh type and complication rates for various synthetic ($n = 1764$) and biologic ($n = 439$) meshes implanted in over 2200 patients [13]. The synthetic meshes compared were polypropylene (0–85 g/m^2), polyester and titanium-coated polypropylene (35 g/m^2); biologics were either crosslinked porcine dermis or uncrosslinked porcine intestinal submucosa. The synthetic erosion rate was 2.4% (mean follow-up 38 months [0–162]) and the biologic erosion rate was 0.7% (mean follow-up 26 months [0–68]). Kaplan–Meier estimates of erosion probability at 1, 2 and 5 years for synthetic mesh were 0.4%, 1.1% and 2.3%. For biologic, they were 0.5%, 0.7% and 0.7%. There was no statistical difference between synthetics or biologics. However, no patients with a biologic complication required major surgical intervention compared with 40% of synthetic mesh complications. Polyester mesh was associated with a statistically significant increased risk of erosion compared to the other mesh types.

These low rates of complications are similar to a recent systematic review comparing synthetic and biologic meshes [14]. In this study, the synthetic mesh erosion rate was 1.87% (66/3517) and the biologic rate was 0.22% (1/439).

As part of the National Institute of Health Research (NIHR) funded (£2 million) Constipation Treatment

Pathway programme of studies (CapaCITY), a systematic review of surgical treatments for constipation has recently been conducted for five main procedure approaches. One of these five methodologically robust reviews addressed outcomes of forms of rectal suspension procedures (rectopexy) with LVMR being one of the main procedures considered (predominant available data). Following data synthesis of 18 eligible studies, mesh-related complications were 0.5% (0–3.9%) [15] at a median follow-up of 25 months.

The above data compare highly favourably with erosion rates following sacrocolpopexy. In a systematic review, these were 0–21% [16], and in the CARE trial [9] the Kaplan–Meier estimate at 7 years was 10.5% (95% CI: 6.8–16.1). Published evidence suggests that LVMR has far less mesh-related morbidity compared with sacrocolpopexy.

Sutures

It has been postulated that some mesh-related morbidity is related to suture type. A historical cohort study compared suture type in sacrocolpopexy and mesh/suture complications [17]. Patients all had polypropylene mesh implanted. Erosion rates were 3.7% for polyester (Ethibond) sutures (6/161) and 0% for polydioxanone sulfate (PDS) sutures (0/254). A consensus statement expressed a view that vaginal sutures for LVMR should be PDS (for any mesh type) and that rectal sutures should be PDS if synthetic mesh is used [10]. In an effort to avoid sutures altogether, two centres have promoted the use of synthetic mesh with tissue glue (cyanoacrylate or synthetic hydrogel) to secure mesh to the rectum [18,19]. Results appear encouraging and these warrant further research.

Consent

Regarding consent for LVMR, it is imperative that the operating surgeon explains that a mesh will be used and warns the patient of potential complications. Ideally, risk should be based upon the surgeon's own data (a further argument for unit data submission); however, registry and systematic review data are also acceptable. On the basis of the latter (and uncertainty due to poor data quality and study design), it is reasonable to quote an overall mesh complication rate of 2.5% based on worst-case scenario. These figures will potentially be higher for re-do surgery. Patients should also be warned of the rare risks of discitis from fixation to the sacral promontory. TPFS is producing an enhanced LVMR consent form together with patient information documentation. This will also integrate patients' views on language based on a national meeting (Birmingham, June 2017).

Efficacy of LVMR

Evidence for efficacy for LVMR either for ERP or ODS/IRP is of poor quality. Except for one study, there are no randomized trials examining the outcome for LVMR. This small randomized clinical trial was a double-blind, randomized, single-centre study comparing laparoscopic posterior suture rectopexy ($n = 37$) with LVMR using polypropylene mesh ($n = 38$) for patients with ERP [20]. The primary outcome was a change in the ODS score at 12 months. Both procedures resulted in significant reductions in the ODS score (mean 2.18 [95% CI: −0.14 to 4.49]) with no significant difference in effect size between groups. There was no significant difference in recurrence rates (suture 5%, LVMR 0%) and no mesh-related morbidity. A further trial is seeking NIHR funding to address which is the superior procedure with validated patient-reported outcome measures and scoring systems, and longer follow-up (for recurrence and mesh morbidity).

Observational data include a variety of cohort designs of varying quality (mostly level IV evidence). The study with the longest follow-up by Consten *et al.* [12] included 919 patients with ODS ($n = 677$) (with IRP and/or symptomatic rectocele) and patients with ERP ($n = 242$). Improvement in faecal incontinence was seen in 80% of all patients, and improvement in ODS scores in 74% of those with ODS and 61% of those with ERP. Estimated overall prolapse recurrence rates estimated by Kaplan–Meier at 3, 5 and 10 years were 7%, 10.7% and 14.3%. The recently conducted systematic review conducted as part of the NIHR CapaCITY programme provides the following synthesized data estimates and graded practice recommendations.

1 For rectal suspension procedures performed for ODS (the majority being LVMR), global satisfaction was 83% (74–91%) (level of evidence IV, graded practice recommendation C) [15]. For LVMR, there was an 86% improvement in constipation (level of evidence IV, graded practice recommendation C). Data were predominately derived from level IV observational studies and it is known that observational bias can affect results.
2 There were no data comparing the efficacy of biologic *vs* synthetic mesh use in LVMR, and any outcome data for biologic mesh are short term only.

Proficiency

There is no doubt that LVMR can be challenging technically. If done incorrectly, there is not only a risk to

efficacy but also potential for harm. There is undoubtedly a learning curve to achieve proficiency. Although this is difficult to estimate, the adoption of CUSUM curve methodology suggests in terms of operating time that this learning curve takes approximately 54 cases before stability is achieved [21]. Such numbers are difficult to achieve even in a high volume centre. However, it is possible to reduce the learning curve with robust mentorship and training [22]. If a rigorous training programme is undertaken (including theory assessment and simulation), estimates of the learning curve using the same methodology suggest proficiency can be achieved after around 25–30 cases.

In order to provide this rigorous training, TPFS has been engaged in devising a specific curriculum, developing hands-on training courses, providing mentorship and organizing regular education events where issues can be discussed in an open forum with experienced surgeons. TPFS website [23] contains various teaching aids including operative videos. Specific pelvic floor fellowships are encouraged and advertised through this website.

Accreditation

It is essential to identify UK units that have the necessary expertise and infrastructure to deliver high quality including surgical expertise. A recent census identified 67 centres that provide a pelvic floor service [24]. In 39% of these centres, there was significant infrastructure and support for pelvic floor services and the volume of LVMR procedures was high (median 20 per annum). These units were often tertiary referral centres for their region. Other centres had less support but still delivered a median of 12 cases per year. In 13%, there was little specific pelvic floor interest but nevertheless a median of three procedures occurred per year. Whilst volume does not necessarily equate to optimal outcome [25], it is essential that there is a process to assess all centres whatever their volume of work. Accreditation is one method of assessment. If carried out correctly, accreditation not only allows identification of units providing high quality care but introduces a mindset of high performance bringing up below standard units and improving further those who meet the set standards [26]. This benefits the patient first and foremost in terms of confidence, choice and influence. However, there are also benefits to health professionals in terms of recognition and leverage, to trusts in terms of quality assurance and to regulators and commissioners in terms of risk reduction and value for money. A part of the accreditation process will be the assessment of a pelvic floor unit's MDT approach. TPFS robustly endorses the MDT approach. As in the Scottish Independent Review [6] on recommendations for urogynaecology units performing vaginal prolapse surgery, for pelvic floor units performing VMR there should be patient-centred care with adequate patient choice and shared decision making supported by robust clinical governance arrangements involving an MDT approach. In addition, evidence of working in an MDT together with audit and the mandatory recording and reporting of adverse events should be a necessary part of a consultant's appraisal and revalidation.

TPFS is in the process of developing a voluntary accreditation process along the lines of that already in practice in urogynaecology [27].

The need for expertise is nowhere more acute than in the care of patients who have had mesh-related complications. Such patients may require very complex surgery with a significant incidence of morbidity. This is also true for surgery for recurrent prolapse. There is evidence that suggests that timely and appropriate intervention in these groups can reduce the potential morbidity and allow restoration of normal function [28]. TPFS has identified UK units that profess to have this expertise [23] and surgeons are encouraged to refer to these teams early if complications occur.

Research and development

Many surgeons are convinced by the perceived benefits of an LVMR in terms of reduced symptom recurrence and improved functional outcome compared with alternative therapies. The procedure is now the most commonly performed abdominal procedure in the UK for full-thickness rectal prolapse [29]. Nevertheless, the evidence base remains weak [30–32]. There is a desperate need for high-quality UK audit data and research in this area. TPFS has developed and introduced a carefully designed database (https://npfs.herokuapp.com/users/sign_in) that will allow assessment of current practice. Data entry, however, is voluntary, but all surgeons that carry out this procedure are encouraged to enter their cases into the database. In addition, any adverse incident involving a mesh should be reported to the MHRA (https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency).

Regarding research, two relevant UK initiatives merit mention. The first, CapaCiTY 3 [15], is an NIHR funded randomized trial that will evaluate efficacy for LVMR in patients with ODS using a stepped-wedge design. This study is currently recruiting in eight UK centres. Further research into full-thickness rectal prolapse is planned with a grant application submitted based on recent quality evidence from Denmark comparing posterior suture rectopexy with LVMR [20].

Given the current concerns regarding mesh-related harm all surgeons that utilize this procedure should be encouraged to offer each and every patient the opportunity to be part of such a trial.

Patient commentary

Whilst all surgery is not without risk of complications, a small number of patients have reported distressing symptoms following pelvic surgery where mesh implants have been used. In addition, various international regulatory bodies have disagreed with regard to the risk status of using such implants, and there is a lack of clarity with regard to the extent of risk for each of the different types of operation where mesh is used to treat prolapse of the various different organs which make up the pelvic floor.

Patients should know that, where surgery is used to correct ERP or troublesome internal prolapse, there is a lower risk of mesh failure than with surgery to correct the weakness of the other pelvic organs where mesh is used. This is because the mesh for the VMR operation is inserted between the rectum and the vagina rather than directly into the vagina.

Patients should be aware that VMR, with which this Statement is concerned, is the best available treatment in the UK to restore normal rectal function. This remains the case until any fresh evidence may arise.

Patients present and future can be reassured that all measures are under way to ensure that all aspects of delivering a safer service are being explored and recorded in order to understand why a small number of patients are affected, and what can be done to make this procedure as safe as possible in the future. In this way, it is hoped that an eventual 'gold standard' service in VMR will be achieved for patients.

New guidelines have been provided to surgeons with greater attention to further training and a database is already under way, which will give information on patient outcomes. The various surgical specialists who deal with pelvic floor problems are working together to pool their expertise to try to understand this complex area of surgery, and to refine surgical techniques. All patients should now benefit from the combined opinions of a range of experts in the pelvic floor when their clinical case is discussed before treatment. Hospital units which deliver this operation are to be examined and accredited to ensure the highest standards of care. However, the implementation and ongoing research will take some time, but every effort is being made to achieve greater understanding of this area of surgery and therefore how to minimize complications.

Importantly, measures are now being taken to prepare improved patient information to help patients in the discussions they have with their surgeon with regard to weighing up the risks of treatment against the benefits of a potential return to improved rectal function, where other treatments have failed. Patients may wish to explore with their surgeon their individual risk profile, with an understanding of the type and extent of the prolapse for which treatment is sought and to ensure that they are also fully prepared for the slim chance of complications.

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Conflicts of interest

CHK is a paid consultant and speaker for Medtronic in relation to sacral neuromodulation (no involvement with mesh or rectopexy instrumentation). MMJ is a preceptor for Medtronic in relation to LVMR. ABW is a non-paid consultant for Cook Medical and Medtronic in relation to pelvic floor surgery and anal fistula surgery.

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