

Revised Use of Mesh in Vaginal Pelvic Organ Prolapse Surgery—an overview

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The use of macroporous monofilament lightweight mesh in cases of vaginal prolapse surgery repair has been in practice for several years now. The type 1 monofilament, macroporous polypropylene should be used because it has been suggested to have the lowest incidence of infection and erosion among the non absorbable prostheses Synthetic meshes have been used with increasing frequency in gynecological surgery, both vaginally and abdominally, over the last 30 years [1].

The use of mesh to augment pubocervical and rectovaginal fascia in cases of cystocele and rectocele, respectively is based on the belief that conventional repair is inadequate and incomplete, resulting in recurrence and poor patient satisfaction. An argument is made that conventional colporrhaphy and perineorrhaphy results in a shortened vaginal length often due to excess excision of healthy vaginal tissue. Mesh use has been advocated to prevent this occurrence. The issue of nulliparous prolapse is also addressed by the procedure of intravaginal slingplasty which is a procedure to help create 'neo' uterosacrals in conservative uterine prolapse surgery as well as restore the apex of the vagina in vaginal vault prolapse repair.

The introduction of these procedures have thrown up issues of the necessity, safety, efficacy, complications and desirability of such mesh use in vaginal prolapse surgery. Questions have also been raised whether this methodology

of mesh use is market driven what with multiple surgical kits being made available at exorbitant cost. The issue before us therefore is—whether mesh use should be routine in vaginal prolapse surgical repair. Paradoxically the use of tensionfree vaginal tape or trans obturator tape for stress urinary incompetence is considered routine, is widely performed and accepted and has good evidence supporting its use [2].

A survey of urogynecologists attending the 34th annual scientific meeting of the Society of Gynecologists 2008 suggested that the majority of them used vaginal mesh for prolapse repair, more commonly in the anterior as compared to the posterior compartment [3].

In a prospective clinical assessment of the transvaginal mesh technique for treatment of pelvic organ prolapse documenting 5-year results Miller et al. [4] demonstrated that women who enrolled with Pelvic Organ Prolapse Quantification (POPQ) stage II–IV, who underwent vaginal prolapse surgery showed an anatomic success rate of 67% (95% CI, 56–76%), an improvement of quality of life and prolapse specific symptoms. The POPQ system provides a validated, precise method of assessing pelvic organ prolapse and has been formally accepted by the International Continence Society, the American Urogynecologic Society and the Society of Gynecologic Surgeons. However, it is still used in fewer than 50% of clinical studies [5]. In India

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there is no contemporary detail informing the acceptance and routine use of the POPQ methodology in research articles on vaginal prolapse repair.

A prospective observational study reported by Carey et al. [6] showed 95 women with International Continence Society POPQ stage II or more pelvic organ prolapse who underwent vaginal surgery using mesh augmentation had an objective success rate of 92 and 85% at 6 and 12 months, respectively and a subjective success rate of 91 and 87% at 6 and 12 months, respectively. Vaginal prolapse surgery has to address correction of anatomical deficits primarily, however debilitating symptoms of bulge, bladder dysfunction, bowel problems and sexual dysfunction need redressal as well. In 2004 Maher and Baessler [7] performed a literature review for the Cochrane Database, looking at the surgical management of pelvic organ prolapse. They concluded that there was evidence, although limited, to suggest that polyglactin (absorbable) mesh can reduce the risk of recurrent cystocele. They followed with a review article in 2006 [8] on surgical management of anterior vaginal wall prolapse. They ultimately concluded that there was level 1 and 2 evidence to support the use of absorbable mesh for anterior vaginal wall prolapse in terms of decreasing recurrent prolapse but, again, the evidence was limited and longer term adverse effects were not considered.

There could be many who doubt the need for mesh use in vaginal prolapse surgery, who cite their long years of experience in performing conventional surgery for prolapse with good results. The argument often put forward is that the use of synthetic mesh placement adjacent to the bladder and rectum involves extensive paravesical and pararectal dissection, includes the passage of needles blindly through the obturator foramen or the ischiorectal fossa which in turn increase the potential for immediate complications like excessive bleeding, perforation of the bladder, rectum and blood vessels. Delayed complications including mesh erosion, severe mesh infections and deep fascial necrosis, fistulae, dyspareunia are additional factors that make them treat this methodology with skepticism. In the second half of 2008, the Society of Gynecologic Surgeons Systematic Review Group published a comprehensive review of literature regarding graft use in transvaginal pelvic organ prolapse repair. The aim of the study was to estimate the efficacy of graft (synthetic and biological) use in transvaginal prolapse repair, as well as describe the severity, type and prevalence of adverse events associated with its use. The authors found 16 comparative studies, including six randomized trials, 37 noncomparative studies with at least 30 women, 11 case series with fewer than 30 women and ten case reports of adverse events. Examining the anterior compartment, one randomized trial and one prospective comparative study evaluating synthetic,

nonabsorbable graft use documented favorable subjective and objective outcomes with graft use. As for the use of graft for the posterior and apical vaginal compartments, there was insufficient information available to determine its efficacy. Similarly, there was a paucity of knowledge regarding efficiency of use of biologic absorbable graft in all vaginal compartments. The rates and spectrum of adverse events associated with graft use included bleeding (0–3%), visceral injury (1–4%), urinary infection (0–19%), graft erosion (0–30%) and fistula (1%). The authors concluded that the available data are limited to draw guidelines for vaginal mesh insertion for POP repair, and that adequately powered and well-designed randomized trials are needed to assess anatomic and subjective outcomes. A whole gamut of postoperative complication is associated with the use of vaginal mesh, some of which were never seen before the introduction of prosthetics to the vagina. In view of the increasing use and concomitant increase in complication rates related to vaginal mesh, the US FDA issued a statement and warning pertaining to the use of vaginal mesh including vaginal mesh extrusion, pain, especially during intercourse, for both partners in the presence of exposed vaginal mesh, infection, voiding dysfunction and recurrent prolapse and incontinence.

The dilemma therefore is whether a gynecological surgeon should acquire skills to perform procedures involving mesh use in prolapse repair. Should the use of mesh be propagated despite the possibility of complications that may occur during a learning curve phase or even later due to the inherent nature of the performance of these procedures, usage of the kits requires a learning curve, as well as an unavoidable blind passage of trocars or large curved needles in order to place the mesh at its destined location. In the process, perforation injury to the bowel, bladder and blood vessels are continuously reported.

The advent of new surgical procedures especially those involving the use of synthetic mesh adjacent to viscera should be met with a healthy dose of skepticism initially, followed by a relentless perusal of literature to understand the concepts and reasoning to depart from conventional techniques, viewing a wide variety of these procedures, discussing the suitability, effectiveness, cost and the duration and methodology of training, with peers and thereupon arriving at an informed decision on whether to incorporate these techniques in practice. Many questions need to be answered whether mesh use in vaginal prolapse surgery should be routine or whether its use should be wisely restricted and judicious. There could be no argument against the use of mesh in vaginal vault prolapse repair where site specific defects are large and multiple and the use of anterior compartment and apical mesh support to ensure the maintenance of adequate vaginal length. Similarly there could be an argument made in favor of mesh use

in large midline anterior vaginal wall defects or for the correction of a lateral cystocele which by its very definition almost negates a conventional vaginal repair due to its correction involving the area near the white line of the pelvis. Mesh use could also be indicated in recurrent anterior or posterior vaginal wall defects. A primary use of mesh for correction for correction of large cystoceles could prevent recurrence. A meta-analysis reviewed surgical techniques for anterior compartment repair, investigating studies comparing a standard midline cystocele plication for anterior repair versus a standard repair with additional mesh reinforcement. In a multicenter, parallel-group, randomized, controlled trial, the use of a trocar-guided, transvaginal polypropylene-mesh repair kit was compared with traditional colporrhaphy in women with cystocele. The primary outcome was a composite of the objective anatomical designation of stage 0 (no prolapse) or 1 (position of the anterior vaginal wall more than 1 cm above the hymen), according to the Pelvic Organ Prolapse Quantification system, and the subjective absence of symptoms of vaginal bulging 12 months after the surgery. There were higher short-term rates of successful treatment but also higher rates of surgical complications and post-operative adverse events [9].

Intravaginal slingplasty is a surgical procedure which helps in the creation of 'neo' uterosacral ligaments and incorporates the use of mesh anchored at the insertion of the uterosacrals. This is a daycare procedure which could be an alternative to traditional existing surgery. A study aimed to evaluate the anatomical and functional outcomes of posterior intravaginal slingplasty (P-IVS) for the treatment of a vaginal vault or uterine prolapse (VP/UP) as a 12-month prospective, multicenter, observational study was carried out by Korean researchers. Women aged over 30 years who presented with stage II or greater VP/UP underwent P-IVS by four urologists at four university hospitals. The cure and improvement rates among the 32 women were 65.6 and 34.4%, respectively. The conclusion was Trans-vaginal repair by P-IVS is an effective and safe procedure for restoring the anatomical defect and improving the associated pelvic floor symptoms in women with VP/UP [10].

The methodology for training to acquire skills to perform vaginal prolapse corrective procedures using mesh would include a thorough knowledge of pelvic anatomy, a competence to perform paravesical and pararectal dissection by means of gradual non adventurous ventures to explore these spaces during routine vaginal surgery for

prolapse, an ability to dissect the space near the ischial spine, performing 'dry runs' on a pelvis specimen with needles and studying the performance of these procedures by various techniques with different vaginal kits via videos or by apprenticeship.

Vaginal surgery for pelvic organ prolapse is dictated today by the need of individual patient problems. Though the primary endpoint could be a successful anatomic site specific correction there is no way of completely satisfying patients' expectations. The way forward would then be a detailed appraisal of each patient, identifying her unique problems, assessing the use of mesh surgery efficacy and the possibility of complications, explaining the advantages and reasons of mesh use and outlining the details of follow up. Unrealistic expectation endpoints should be deliberated and discarded at the outset.

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