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CURRENT CONTROVERSIES IN OBSTETRICS AND GYNAECOLOGY – OPINION

Transvaginal mesh: let's not repeat the mistakes of the past

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Over the last decade the premature introduction of transvaginal meshes for the surgical treatment of pelvic organ prolapse has had a negative impact on women who have experienced unexpected suffering and morbidity. The resulting litigation has seen the voluntary removal of most of these products from the market[1] and several international regulatory bodies, including the Food and Drug Administration (FDA),[2] the Medicines and Healthcare Products Regulatory Agency,[3] the Scientific Committee on Emerging and Newly Identified Health Risks, (a committee that advises the European Commission),[4] an Independent Scottish review committee[5] and the New Zealand Accident Compensation Corporation,[6] issuing cautions regarding use of transvaginal mesh for the management of pelvic organ prolapse. This has led to women not only questioning the efficacy and safety of transvaginal meshes for prolapse but also questioning the highly effective mid-urethral slings for the management of stress urinary incontinence, as well as the competence and trustworthiness of us as clinicians. It is imperative that pelvic floor surgeons take a leadership role that ensures the mistakes of the past are not revisited.

From 2003 transvaginal mesh was introduced into treatment pathways for pelvic organ prolapse without adequate evaluation of their safety or efficacy.[1] Initial confidence in these products was extrapolated from the success of synthetic mesh for hernia repair,[7] sacral colpopexy for vault prolapse[8] and mid-urethral slings for urinary stress incontinence.[9] There was no evidence from comparative trials of either the safety or the efficacy of any of the transvaginal mesh products until seven years after they were brought into treatment pathways.[10] By this time is had become evident that, due to the properties and function of the vagina, mesh had unpredicted complications when used in the vagina, specifically pain and dyspareunia due to mesh contraction and high rates of mesh exposure.[1,11]

After transvaginal mesh placement, one in ten women undergo reoperation for mesh exposure.[12] The number who undergo reoperation for, or live with, chronic pain is poorly defined. We do know that pain and/or dyspareunia were the leading causes of adverse events reported to the FDA and that in a series reporting on re-intervention after transvaginal mesh, pain and dyspareunia are the leading indicators for reoperation at a rate higher than mesh exposure.[13]

It has been argued that a proportion of the blame for this high complication rate can be assigned to the fact that transvaginal meshes were so quickly up-taken by pelvic floor surgeons regardless of their surgical experience, volume or procedure-specific training.[14] However, high-volume, experienced surgeons who sought out procedure-specific training have also reported high complication rates with transvaginal meshes. Maher *et al.*[15] reported a reoperation rate of 22% at two years and a mesh exposure rate of 25% was reported by Balakrishnan *et al.*[16] at 12 months.

Thirteen years on, there is now an emerging body of evidence beginning to articulate the limited role for transvaginal mesh in reconstructive pelvic surgery. The 2016 Cochrane review[12] on transvaginal meshes found that although synthetic mesh reduces the rates of awareness of recurrent prolapse, objective prolapse and reoperation for recurrent prolapse when compared to native tissue repairs, it results in a two-and-a-half-fold increase in overall reoperation rates for either prolapse, stress urinary incontinence or mesh exposure and a higher rate of *de novo* stress incontinence. There is higher morbidity with transvaginal

mesh and quality of life and sexual outcomes are not improved. There is limited evidence that the use of absorbable mesh may decrease recurrent prolapse on examination and there is insufficient evidence as to whether biological grafts add benefit to native tissue repairs.

The 2016 Cochrane Review on anterior compartment[17] prolapse found that synthetic mesh reduces awareness of recurrent prolapse, objective prolapse and reoperation for recurrent prolapse, but results in higher overall reoperation rates for either prolapse, stress urinary incontinence or mesh exposure and higher rates of recurrent prolapse in both the apical and posterior compartments. In retrospective studies the risk-benefit profile is similar for recurrent anterior wall prolapse but with a higher reported rate of mesh erosion for recurrent prolapse.[18] It is also known that in the posterior compartment neither mesh nor grafts improve anatomical or functional outcomes.[19]

For utero-vaginal prolapse, the data is not supportive of hysterectomy and concomitant vaginal repair with mesh, due to the high rates of mesh erosion associated with this combination of operations[20] and it remains undefined as to whether there is a role for vaginal mesh in uterine preservation surgery. We are awaiting the publication of the first randomized controlled trial (RCT) on this subject from the Pelvic Floor Disorders Network.[21]

For apical prolapse there is evidence that transvaginal mesh does not improve anatomical or functional outcomes and the mesh exposure rate is 18% with 10% requiring surgery to correct the exposure.[12]

However, all of the above information pertains to products that have been voluntarily withdrawn from the market by the industry due to costs of litigation, primarily in the USA. Two new products available in Australia are Restorelle (Coloplast, North Mankato, MN, USA) and Uphold (Boston Scientific, Marlborough, MA, USA). There is currently no peer-reviewed data on Restorelle and given the ongoing litigation and negative media attention associated with the premature approval and usage of older transvaginal mesh products, it is surprising that these products have Therapeutic Goods Administration regulatory approval for use and are being utilised by clinicians without comparative data confirming safety and efficacy.

Uphold (Boston Scientific) is a transvaginal mesh designed to provide support into the anterior and apical compartments. There is currently level three (non-comparative) evidence reporting outcomes after placement in women. Altman *et al.*[22] reported a multi-centre prospective case series evaluating 207 women with apical prolapse undergoing Uphold pelvic floor system repair and reported a subjective success rate of 90% at one year. The reoperation rate for mesh exposure was 1.3%. Vu *et al.*[23] published a retrospective case series of 53 women who had Uphold mesh placed with excellent anatomical results, a mesh erosion rate of 3% and a dyspareunia rate of 14% (9% preoperatively) at 12 months. There were no reported reoperations for any indication in this 12 month period. Letouzey *et al.*[24] performed another prospective case series of 118 women with symptomatic stage two or greater prolapse in the anterior and/or the apical compartment. At 12 months, anatomical success was reported as 93%, reoperation for mesh exposure was 3%, *de novo* dyspareunia was 8% and reoperation for reasons other than mesh exposure (pain, prolapse recurrence or urinary retention or incontinence) was 10%. Persistent pain at 6 weeks was 6%.

These newer meshes are lighter (<30 g/m^2) than those they have replaced and the hope is that there will be lower rates of mesh exposures and less pain.[22–25] Early-phase biomechanical and *in vitro* research into the properties of mesh that determine its favourability for use in the vagina is in full swing. Apart from mesh weight, pore size, porosity, pore geometry and stiffness may be critical in the type of immunological response a mesh incites.[26] As yet, there is no comparative clinical data confirming that any of the new meshes result in a reduced risk of mesh contraction causing pain, or mesh exposures. Women should be aware that the newer transvaginal meshes may be better, the same or worse than native tissue repairs. Women should also be aware of alternatives to transvaginal meshes, such as adequate apical support at time of colporrhaphy or alternative approaches such as sacral colpopexy that have very significant supportive data as to both their safety and efficacy.

As a group, our collective unfounded enthusiasm for transvaginal meshes resulted in loss of trust from women. We cannot, in good faith, vouch for the safety or efficacy of any of the currently available transvaginal meshes. We have alternative procedures to offer women that are supported by robust evidence of both safety and efficacy. Until comparative data confirms the safety and efficacy of the currently available transvaginal meshes, it would be prudent if these products were utilised under the auspices of the local ethics committee. This not only protects women from risk of harm but also protect us, the surgeons, from repeating mistakes of the past. It is through this process that evidence defining the role for transvaginal mesh in reconstructive pelvic surgery will be established. If favourable new data becomes available regarding new innovations, treatment pathways can be modified to reflect the evidence.

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