

## UPDATE ON MESH USED FOR PELVIC ORGAN PROLAPSE

In the last twenty years, we have seen mesh used initially for the treatment of urinary incontinence with great efficacy and for pelvic organ prolapse, which in some women have had a negative impact and unexpected morbidity. This has resulted in issuing of warnings by regulatory authorities,<sup>1 2 3 4 5</sup> the voluntary removal of some of these products from the market, adverse publicity in the media and an impending Senate Enquiry.

The inevitable outcome of this has been the concern women have of the safety of mesh used for prolapse surgery and the unfortunate consequence of questioning the benefits of the highly effective midurethral sling products used for the treatment of stress urinary incontinence.

We were of the view that at this point of time it would be useful to bring you up to date on the current state of mesh products used of pelvic surgery.

In modern urogynaecology, the use of mesh has become popular due to the work of Ulmsten who revolutionised incontinence surgery using suburethral slings.<sup>6</sup>

In 2001, Weber et al published a randomised trial comparing three techniques for anterior vaginal repair. Using a definition of success as a reduction of prolapse of 2 cm above the hymenal remnants, success rates were significantly better in the group of patients in whom mesh was used. Based on this study, gynaecologists started to use mesh when they treated pelvic organ prolapse. It was believed that mesh use improved anatomical success rates.<sup>7</sup>

Between 2003 and 2005, several mesh products were introduced that used anchoring with mesh arms placed through the obturator foramen, the Perigee and Anterior Prolift. The first was invented in Queensland, by two local Urogynaecologists. These meshes seemed particularly effective, even in very difficult patients, and we performed several audits which seemed promising.<sup>8 9 10</sup>

By the time proper randomised controlled trials showed the efficacy of such meshes in the

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<sup>1</sup> US Food, Drug Administration (FDA), FDA Safety Communication: Urogynaecological Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse. FDA Public Health Notification available at: <http://www.fda.gov/downloads/medicaldevices/alertsandnotices/ucm262760.pdf>

<sup>2</sup> Mesh working Group. Interim Report December 2015. Available <https://www.england.nhs.uk/wp-content/uploads/2015/12/mesh-wg-interim-rep.pdf>

<sup>3</sup> Opinion on the Safety of Surgical Meshes used in Urogynaecologic Surgery 2015 available: [http://ec.europa.eu/health/scientific\\_committees/emergic/docs/scenhir\\_o\\_049.pdf](http://ec.europa.eu/health/scientific_committees/emergic/docs/scenhir_o_049.pdf)

<sup>4</sup> 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: Interim Report 2 October 2015. Available: <http://www.gov.scot/resource/0048/00486661.pdf>

<sup>5</sup> ACC Surgical Mesh Review Analysis of Treatment Injury Claims 1 July 2005 to 30 June 2004. Available from: [http://www.acc.co.nz/PRD\\_EXT\\_CSMP/group/external\\_providers/documents/referncetools/wpc138053.pdf](http://www.acc.co.nz/PRD_EXT_CSMP/group/external_providers/documents/referncetools/wpc138053.pdf)

<sup>6</sup> Ulmsten U, Henriksson L, Johnson P et al "An ambulatory surgical procedure under local anaesthesia for treatment of female urinary incontinence" In Urogynecol J 1996; 7:81-6

<sup>7</sup> Weber AM, Walters MD, Piedmonte MR, Ballard LA (2001) "Anterior colporrhaphy: a randomised trial of three surgical techniques." Am J Obstet Gynecol 185(6): 1299-1304

<sup>8</sup> Shek KL, Dietz HP, Rane A, Balakrishnan S. "Transobturator mesh repair for large and recurrent cystocele." Ultrasound Obstet Gynecol 2008; 32: 82-86

<sup>9</sup> Shek KL, Rane A, Goh J, Dietz HP. "Stress urinary incontinence after transobturator mesh for cystocele repair." Int Urogyn J 2009; 20: 421-425

<sup>10</sup> Dietz HP. "To mesh or not to mesh" Aust NZ J Obstet Gynaecol 2009; 49: 344-345

anterior compartment,<sup>11</sup> especially in women with a highly abnormal pelvic floor<sup>12</sup> the Anterior Prolift had been removed from the market due to irregularities with the original FDA application. While we were getting better at selecting patients most likely to benefit from mesh,<sup>13</sup> the accumulating information on risks associated with mesh use effectively shut down the discussion.

It has become apparent that the restoration of structural anatomy does not necessarily restore normal functional anatomy as the reaction to the mesh creates a more rigid, non-pliable vagina and does not reduce the urogenital hiatus, which is so essential in maintaining normal functional anatomy. Additionally, the restoration of normal anatomy does not necessarily result in the reestablishment of normal vaginal, urinary or bowel function and in some cases worsened the patient's quality of life.

It became evident that in 7 percent of women further surgery was needed to be undertaken to remove the eroded mesh; that 36 percent of patients who had mesh complained of dyspareunia; and that in posterior compartment 3 percent of patients sustained a rectal perforation, mesh erosion was reported to be around 14 percent and dyspareunia occurred in 16 percent.<sup>14</sup> Additionally, Injury of the bladder, urethra, rectum and pelvic nerves arose from the surgical technique used.

Furthermore, complications from mesh implant surgery which do not arise from traditional surgical treatment options are chronic and severe pain, more severe dyspareunia than after traditional prolapse surgery, dyspareunia,<sup>15</sup> mesh erosion, mesh contraction and repeat surgery because of mesh erosion or contraction.

Finally, mesh certainly does not fix all cases of prolapse, and our group has documented patterns of recurrence that in some cases raise entirely novel technical issues.<sup>16</sup>

We believe that, as always, patient selection and individualisation of treatment is the key to optimal outcomes.<sup>17</sup> Hence it makes sense to use mesh only in women at high risk of prolapse recurrence, that is, in those with previous failed surgery, levator avulsion and, possibly, severe ballooning. However, this is a moot point as long as those meshes that have been proven to be effective are no longer available. The second best documented mesh, the 'Perigee', was taken off the Australian market in 2016.

Newer products such as "*Restorelle*" and "*Uphold*" are anchored in a different (and likely

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<sup>11</sup> Altman D, Väyrynen T, Ellström Engh M, Axelsen S, Falconer C. "Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic-Organ Prolapse." *New Engl J Med*. 2011;364:1826-36

<sup>12</sup> Svabik K, Martan A, Masata J, El-Haddad R, Hubka P. "Comparison of vaginal mesh repair with sacrospinous vaginal colpopexy in the management of vaginal vault prolapse after hysterectomy in patients with levator ani avulsion: a randomized controlled trial." *Ultrasound Obstet Gynecol*. 2014;43:365-71

<sup>13</sup> Rodrigo N, Wong V, Shek K, Martin A, Dietz H. "The use of 3-dimensional ultrasound of the pelvic floor to predict recurrence risk after pelvic reconstructive surgery." *Aust NZ J Obstet Gynaecol*. 2014;54(3):206-11

<sup>14</sup> The National Institute for Clinical Excellence (NICE) report June 2008.

<sup>15</sup> The development of severe pain in the male partner during sexual intercourse, usually from the sharp fibres of eroded mesh in the vagina.

<sup>16</sup> Shek K, Wong V, Lee J, Rosamilia A, Rane A, Krause H, et al. "Anterior compartment mesh: a descriptive study of mesh anchoring failure." *Ultrasound Obstet Gynecol*. 2013;42:699-704

<sup>17</sup> Wong V, Shek K "The mesh debate: Transvaginal anterior anchored mesh should not be abandoned" *ANZ L Obstet Gynaecol* 2017; 57(1):105-107

less effective) way, and as yet there is very limited evidence on safety or efficacy.<sup>18</sup> As long as this is the case it may be reasonable to limit mesh use to clinical trials. In the meantime we are working on several alternatives to mesh. We have been re-attaching avulsed levator ani to the pubic rami<sup>19</sup> and are conducting two trials involving a reduction of the levator ani hiatus, in an attempt to reduce recurrence rates by normalizing pelvic floor functional anatomy.<sup>20</sup> All three trials are ongoing. So far we can say that both methods seem to be effective in certain patients, but neither is the 'magic bullet' that would allow us to cure all prolapse. A randomized controlled multicenter trial is nearing completion this year, and results should be available in 2018.

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<sup>18</sup> Mowat A E, Maher C. "Transvaginal Mesh: Let's not repeat the mistakes of the past." *Aust NZ J Obstet Gynaecol* 2017; 57: 109

<sup>19</sup> Dietz H, Shek K, Daly O, Korda A. "Can levator avulsion be repaired surgically?" *Int Urogynecol J*. 2013;24:1011–5

<sup>20</sup> Dietz H, Korda A, Benness C, Wong V, Shek K, Daly O. "Surgical reduction of the levator hiatus." *Neurourolog Urodyn.* 2012;31(6):872-3