The mesh debate

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The U.S. Food and Drug Administration (FDA) published a second warning to medical practitioners and patients on “Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse” in July 2011. Following this, on the advice of legal advisors the research and ethics committee of one of our hospitals (P.L.D) recommended that no further synthetic mesh be used for any incontinence or prolapse surgery. This recommendation was a case of “throwing the baby out with the bath water” and was not ratified following further discussion. However, it is an indication of the perfect storm referred to by Brubaker and Shull in this issue of the *International Urogynecology Journal* [1]. In order to give a range of opinions we are also publishing in this issue the views of other well-known gynaecologists on the usage of synthetic grafts [2, 3].

So how did we get to this? Polypropylene synthetic mesh has been used in urogynaecology since the 1960s to treat stress incontinence [4]. However, it was not until Ulmsten and Petros developed the TVT sling with its advantages of same-day surgery and less postoperative pain and morbidity that the mid-urethral sling became the commonest stress incontinence operation performed world-

wide. This success led to the development of a number of similar slings by many commercial companies. Complications did occur, frequently related to inexperienced trocar positioning and incorrect placement of tape in the bladder, small bowel or blood vessels. The incidence of polypropylene mesh-related complication was low, with a less than 1% rate of infection or mesh exposure, although this was not the case when non-polypropylene tapes were used, when infection and rejection rates were high. These were then discontinued, but not until considerable damage had been done.

The problem with transvaginal polypropylene mesh was evident from the beginning. In a prospective randomised study by Julian in 1996 of 24 patients with mesh versus non-mesh for surgical treatment of recurrent cystocele [5], there was a better anatomical result with no recurrence in the mesh group but 3 of the 12 patients had mesh exposure. When we reported our 2-year results in 2004, our mesh exposure rate was 9% [6]. It was interesting that the results of a meta-analysis of recent studies published this year by Abed et al. [7] showed an incidence of 10.3%. Therefore, little progress has been made in this critical area despite the use of softer, lighter polypropylene meshes.

These exposures are often asymptomatic, but may cause symptoms of discharge, bleeding and pain, especially during intercourse, both to the patient and her partner. Bowel and bladder perforation are rare but occur especially if these organs have been injured. These mesh exposures in most cases require excision of the exposed mesh and vaginal closure, usually under general anaesthesia as day surgery. In some cases multiple attempts at repair are required for recurring mesh exposures. As mesh exposures can occur late, long-term studies (10 years or more) may be needed to know the true mesh exposure complication rate. Vaginal exposure of

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polypropylene mesh following transabdominal colposacropexy or hysteropexy is infrequent (1–2%), but is more common if the vagina has been opened inadvertently or a hysterectomy is performed. Pain related to the polypropylene mesh is uncommon but can also occur. However, pain following native tissue surgery whether a sacrospinous suspension or fascial repair is also reported. In the present climate, in any patient who has mesh inserted and subsequently experiences pain, the mesh will frequently be blamed for the pain.

The concept of permanent reinforcement of hernia defects in the pelvic floor or elsewhere is an attractive one. The uptake of the use of synthetic mesh in commercial kits has been extensive. In recent studies in the UK and in Australia and New Zealand, gynaecologists would use a synthetic mesh repair in 75% and 56% of recurrent anterior repairs respectively [8, 9]. In the USA the FDA [10] reported that “in 2010 approximately 300,000 women underwent surgical procedures in the United States to repair POP and according to industry estimates, approximately one out of three POP surgeries used mesh, and three out of four of the mesh POP procedures were done transvaginally.” This has been driven also by the various commercial companies involved. Most educational meetings are by necessity sponsored by grants from these companies, so the programmes tend to be biased in favour of mesh presentations compared to native tissue repairs, and talks tend to be given by presenters with conflicts of interest.

The Hippocratic Oath states “primum non nocere”—first, do no harm. This is not always possible as surgical complications will always occur sometimes, but it is important that we do more good than harm. This issue in relation to the use of synthetic grafts will only be resolved by good long-term studies, so it is important that until this

is resolved we proceed slowly and carefully lest we do considerably more harm than good.

References

1. Brubaker L, Shull B (2011) A perfect storm. *Int Urogynecol J*. doi:10.1007/s00192-011-1596-8
2. Murphy M, Holzberg A, van Raalte H, Kohli N, Goldman HB, Lucente V, on behalf of the Pelvic Surgeons Network (2011) Time to rethink: an evidence-based response from pelvic surgeons to the FDA Safety Communication “Update on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse”. *Int Urogynecol J*. doi:10.1007/s00192-011-1581-2
3. Haylen BT, Sand PK, Swift SE, Maher C, Moran PA, Freeman RM (2011) Transvaginal placement of surgical mesh for pelvic organ prolapse: more FDA concerns—positive reactions are possible. *Int Urogynecol J*. doi:10.1007/s00192-011-1580-3
4. Moir JC (1968) The gauze-hammock operation (a modified Aldridge sling procedure). *J Obstet Gynaecol Br Commonw* 75 (1):1–9
5. Julian TM (1996) Efficacy of Marlex mesh in the repair of severe, recurrent vaginal prolapse of the anterior midvaginal wall. *Am J Obstet Gynecol* 175:1472–1475
6. Dwyer PL, O'Reilly BA (2004) Transvaginal repair of anterior and posterior compartment prolapse with Atrium polypropylene mesh. *Br J Obstet Gynaecol* 111(8):831–836
7. Abed H, Rahn DD, Lowenstein L, Balk EM, Clemons JL, Rogers RG (2011) Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review. *Int Urogynecol J* 22 (7):789–98
8. Jha S, Moran P (2011) The UK national prolapse survey: 5 years on. *Int Urogynecol J* 22(5):517–28
9. Vanspauwen R, Seman E, Dwyer P (2010) Survey of current management of prolapse in Australia and New Zealand. *Aust N Z J Obstet Gynaecol* 50(3):262–7
10. FDA Safety Communications: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse. (2011) <http://www.fda.gov/MedicalDevices/Safety/AlertandNotices/ucm262435.htm>