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EDITORIAL

The great mesh debate

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The introduction of mesh for pelvic floor reconstructive surgery has generated considerable debate regarding efficacy and safety. Of the few randomised controlled trials which exist, most are underpowered, and the data reported in systematic reviews are of poor quality [1, 2]. For example, in the one commissioned by the National Institute for Clinical Excellence (NICE) in the UK, the authors concluded: "The evidence for most efficacy and safety outcomes was too sparse to provide meaningful conclusions about the use of mesh/graft in anterior and/or posterior vaginal wall prolapse surgery" [2, 3]. Therefore, these procedures should be considered experimental (i.e. a protocol should be available and results published (Declaration of Helsinki) until such evidence is available that patients can be counselled accordingly [4].

The innovative French TVM group who have pioneered the 'total vaginal mesh' concept give their opinion on this important subject in this month′s edition of the IUJ [5]. Their views and recommendations are based on considerable experience with vaginal mesh procedures and backed up with audit and research data. They are to be commended for this evaluation and for stating so clearly their disclosures or conflicts of interests. However, such good reporting is not universal: for example, since the introduction of the TVM in 2005, only 4,000 (3%) of the 120,000 procedures performed worldwide have actually been reported (Ethicon Women's Health and Urology).

The use of new products implies innovative or experimental practices [6], and these should be rigorously audited. In the UK, NICE supports this and recommends that for all vaginal mesh procedures, clinicians should:

- Inform clinical governance leads
- Ensure that patients understand the uncertainty about long-term results and complications
- Provide patients with clear written information
- Audit and review clinical outcomes of all patients having mesh

In contrast to the introduction of new drug therapies, surgical procedures and devices can be marketed rapidly. In Europe, implants or devices require only CE marking, while in the USA, it is possible to market based on the so-called 510K pre-market notification when a new material is deemed "substantially equivalent".

Why there should be a difference between the introduction of new surgical devices and drugs is unclear. It could be argued that the risks of surgery are greater than those of drug therapy; yet, their "governance" is less. Until properly designed comparative studies using both subjective and objective outcomes and long-term follow-up are undertaken, uncertainty regarding efficacy and safety will remain. In the meantime, it is hoped that industry and clinicians can work together in developing national databases to which surgeons will submit all their data including complications. Only in this way can we truly understand the outcomes of new surgical procedures and be able to counsel our patients.

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While large numbers of mesh repairs are undertaken worldwide without published outcomes, the data from the inventors of the TVM are helpful and provide useful information for patients and clinicians. It is also reassuring that manufacturers of mesh 'kits' are providing training courses and helping with audit.

As with any surgical procedure, complications arise, and the French TVM group feel that these are often: "over-estimated, overemphasised, poorly described and inappropriately managed". They make an important point that it is relatively easy to publish a case report of a severe complication but that this can paint a falsely pessimistic picture. These reports might be interesting and important if there are lessons to be learnt from the case. However, it would be better if complications were properly classified (as the authors recommend) and reported to national databases so that the true incidence can be identified. This is unlikely to happen while voluntary reporting is the norm. In time, it is likely that government health departments will insist on all data being reviewed; it might be better if surgeons pre-empted this by collecting and reporting their own data rather than it being done by someone else.

What is the evidence?

The rationale for the use of mesh relates to the poor outcomes of traditional prolapse surgery especially for the anterior compartment. Te Linde stated over 40 years ago that: "every honest surgeon of extensive and long experience will have to admit that he/she is not entirely and absolutely satisfied with his/her long-term results of his/her operations for prolapse and allied conditions" [7]. It could be argued that not much has changed with 40% failure rates being quoted for anterior repair [8]. However, unlike surgery for urodynamic stress incontinence, the problem with most studies of prolapse surgery has been the lack of standardisation of outcome. Most studies have relied solely on anatomical outcomes and in those which have looked at subjective ones, there is a marked discrepancy between post-operative symptoms and anatomical results, i.e. there is lower subjective than objective or anatomical failure [9, 10]. There is, therefore, a need for patient reported outcomes related to expectations and goals, e.g. EGGS [11].

The argument that most women with anatomical failure will eventually require further surgery *in the same compartment* is unproven. For example, the much-quoted study by Olsen et al. [12] suggests that 11% of women will undergo surgery for prolapse during their lifetime and 29% will require a second operation. However, these figures relate to both urinary incontinence and prolapse surgery rather than prolapse alone. From the same department, the 10-year re-operation rate is almost 20%, but when further surgery for the anterior compartment alone (i.e. the one that is most likely to recur anatomically) is analysed separately, the re-operation rate is only 4.6% [13]. This has been seen in other studies with re-operation rates for the anterior compartment of between 5% and 10% at intervals between 1 and 5 years after a primary "traditional" procedure [14–17]. While these re-operation rates are not synonymous with failure, nonetheless, one would imagine that if after "failed" primary surgery the symptoms were bothersome then patients would seek further treatment, whether that be with vaginal pessaries or surgery. Clearly, more research is needed to answer this question.

The debate regarding new surgical procedures such as mesh will continue until we have good-quality data from well-conducted randomised controlled trials of all vaginal prolapse surgery. One is due to commence shortly in the UK (Prolapse Surgery, Pragmatic Evaluation by Randomised Controlled Trial), and the results will be awaited with interest. It can be argued that data such as these should be available before mesh or any other surgical implant is marketed.

In the meantime, we must hope that national urogynaecology societies in collaboration with industry will set up databases and that all of us, as clinicians and surgeons, will submit our data, both "good" and "bad". Only then will we know the real outcomes of our surgery and be able to fully and effectively counsel our patients on the appropriate treatment for their pelvic organ prolapse.

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