Quo vadis, vaginal mesh in pelvic organ prolapse?

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The use of vaginal mesh in pelvic organ prolapse (POP) has prompted a new and unprecedented media frenzy. For example, in a highly polarising statement, an Oxford-based professor of evidence-based medicine in a *Guardian* article recently compared vaginal mesh to the devastation wreaked by thalidomide. We believe that it is now time for a less emotional and more scientific-based voice to be heard on this issue.

There is no doubt that there were major complications with vaginal mesh and that certain actions were appropriate, including recommendations for improved education, counselling and evaluation of new products. Unfortunately, there were also actions that we believe to have been unjustified, including the complete banning of vaginal mesh in Australia and the UK.

Contrary to public opinion, there are sufficient randomised controlled trials (RCTs) reporting the benefits of vaginal implants over native tissue repair [1]. An excellent example is a Scandinavian Network RCT published in the *New England Journal of Medicine*, showing better objective and subjective outcomes in women undergoing vaginal mesh versus native tissue repair. They also reported a low re-operation risk for mesh-related complications, with an incidence of 3% [1].

There is no doubt that optimising the outcomes of vaginal mesh surgery requires concentrating mesh surgery in a few high-volume centres. Education in mesh surgery also needs to be improved and coupled with this, accreditation strategies by local societies need to be addressed. In native tissue surgery, no improvements in technique are imminent. In contrast, mesh surgery has huge potential, for example, the textile of the biomaterial can be engineered, the type of biomaterial can be changed and coatings can be added. Diameters of the fibres, patterns of weaving, elasticity, interstitium size and surface characteristics can be adjusted to improve immune resistance

and biomechanical characteristics. Surgical delivery methods can also be optimised. With these improvements, the balance between the risks and benefits of mesh surgery is likely to change in such a way that in the future it may even become the standard in primary POP surgery.

The mesh industry has been criticised for selling poor products, educating the wrong physicians and not supporting sufficient studies to evaluate the outcomes of their products. However, we need to accept that these activities are all, in fact, our responsibility. It should also be remembered that most companies do not define the requirements that allow them to sell a product, they simply follow what is requested.

In the decision to abandon marketing mesh in the UK and Australia, the PROSPECT trial, published in *The Lancet*, may have played an important role [2]. In this study, after 2 years' follow-up, mesh surgery did not result in better outcomes and 1 in 10 women had a mesh-related complication. This is much higher than the 3% reported by many other studies. We believe that a more prudent response would have been to explore reasons for the higher re-operation rate, including indications, training, surgical technique, peri-operative management or organisation of care.

In vaginal prolapse surgery, about 20% of procedures are performed for recurrent prolapse. There are not many other fields in which surgical outcomes are that poor. But even more incriminating is the slow pace in improvement in that figure. We believe that there are still endless opportunities to improve the outcomes of mesh surgery. If we decide now to restrict ourselves to performing exclusively native tissue surgery, we believe that there are women who will not receive optimal treatment. European Societies have recognised this and currently recommend that mesh still be available for complex cases [3].

Unfortunately, the media are always ready to misconstrue the results of clinical studies, and coupled with its withdrawal in the UK and Australia, there was collateral damage to the reputation of mesh surgery worldwide. This action was misinterpreted, not only by gynaecologists and urologists, but also by general practitioners, nurses and other health-care providers. Many now believe that mesh surgery is bad,

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which results in scared patients, scared doctors, scared industry and no innovation as a result.

So, quo vadis? We recommend collaboration among professionals, patients and industry to improve the outcomes of mesh surgery. There are many examples demonstrating that optimal collaboration shortens the innovation cycle. We believe that this is a far more appropriate response than completely abandoning new technology.

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