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Invited Editorial

# Vaginal mesh: What lessons have we learnt?

Pelvic floor dysfunction, whilst not life threatening, is known to have a significant and important effect on Health-Related Quality of Life (HRQoL). Approximately a third of women complain of stress urinary incontinence [1] and women have a 10% lifetime risk of requiring surgery for urogenital prolapse or urinary incontinence. Of those who have surgery, a third will subsequently require a redo procedure [2] and this is supported by a more recent study from the UK reporting the risk of repeat surgery to be 15.8% [3].

It was this significant risk of recurrence with native tissue surgery and the morbidity associated with traditional continence procedures that initially prompted interest in the use of synthetic mesh to reduce complications and recurrence rates.

## Vaginal Mesh: Early Development

The use of synthetic materials in continence surgery was first described by Chassar Moir in 1968 [4] but it was not until the approval of the ProteGen (Boston Scientific) sling in 1996 that a commercial device became available. This was subsequently withdrawn due to safety concerns in 1999 [5]. It was only following the introduction of the retropubic mid-urethral Tension Free Vaginal Tape (TVT) in 1995 [6] that the use of synthetic mid-urethral polypropylene tapes became widespread and subsequently the Transobturator Tapes (TOT) were also introduced [7]. Retropubic Mid-urethral slings (MUS) remain the most commonly used surgical procedure for stress urinary incontinence and their long-term safety and efficacy have been clearly documented [8].

The success of the MUS led to the assumption that the use of vaginal mesh may reduce the risk of recurrence of urogenital prolapse when compared with native tissue repair and comparisons were made to the use of mesh during hernia repair [9]. Subsequently there was a large expansion of mesh surgery within urogynaecology using mesh kits and inlay mesh, although many products had limited efficacy data, follow-up was only short term and consequently mesh complications were often not identified or reported.

## Vaginal Mesh: Initial Concerns

In 2008 the Federal Drug Administration (FDA) in the United States issued a warning regarding the risk of complications associated with the use of mesh for SUI and urogenital prolapse, including mesh exposure, pain, infection and dyspareunia [10]. This was followed by a second safety alert in 2011, when there was a recommendation to perform post-marketing (522) surveillance studies to investigate safety and effectiveness [11]. Subsequently the FDA reclassified vaginal mesh as a class III procedure in 2014, meaning there was a requirement for more rigorous pre-registration studies [12].

In 2015 the European Scientific Committee on Emerging and Newly Identified Heath Risks (SCENIHR) [13] identified the increased risks associated with vaginal mesh whilst acknowledging the efficacy and safety of MUS. The report highlighted that vaginal mesh should be considered only for redo surgery and there was a need for further research and audit of results. These themes were echoed in the Scottish Independent Review in 2017 [14] and the report from the NHS England Mesh Oversight Group in 2018 [15]. In addition, both of these reports discussed the importance of informed consent and shared decision making. Given these largely supportive public enquiries, it was surprising that the use of mesh was 'paused' within the UK in July 2018 and an inquiry, chaired by Baroness Cumberlege, was initiated. In addition, vaginal mesh and single incision mini-slings were withdrawn in Australia and New Zealand in 2018.

## Vaginal Mesh: Current Situation

As a response to the emerging safety concerns, an international consensus statement was reported in 2018 [16] supporting the efficacy and safety of mid-urethral slings in the management of stress urinary incontinence in addition to stressing the importance of ongoing research and audit, appropriate training and informed consent. The use of mid-urethral slings for stress urinary incontinence and vaginal mesh for recurrent prolapse was also supported by the National Institute for Health and Care Excellence (NICE) Urinary Incontinence Guidelines in 2019 [17].

More recently, in July 2020 the long-awaited Independent Medicines and Medical Devices Safety (IMMDS) Review, chaired by Baroness Cumberlege, has reported [18]. The report acknowledges that there may be a place for the use of mesh procedures for stress urinary incontinence and pelvic organ prolapse, although it makes very clear recommendations regarding the governance procedures that need to be in place before the 'mesh pause' can be lifted. These include the appropriate training and accreditation of mesh surgeons, the identification and accreditation of mesh removal centres, establishing a national database to document mesh procedures and the mandatory reporting of mesh complications. These recommendations are currently being implemented within the UK.

## Vaginal Mesh: Conclusions

The initial introduction and subsequent widespread adoption of mid-urethral sling procedures preceded the use of vaginal mesh for urogenital prolapse. Whilst the former have acknowledged long-term

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efficacy and safety data, the evidence base for vaginal mesh procedures is much less robust. More recently the long-term complications associated with the use of mid-urethral slings for stress urinary incontinence and vaginal mesh for pelvic organ prolapse have been identified and we must acknowledge that a significant number of women have suffered significant harm. However, it is also important to acknowledge the long-term safety and efficacy data of mid-urethral sling surgery and recognise that the vast majority of women have benefited greatly from these procedures in terms of HRQoL improvement.

The rise and fall of vaginal mesh is perhaps best illustrated by Scott's Parabola [19], which accurately describes the introduction, widespread adoption, and subsequent demise of innovative surgical procedures before their true value is appreciated. Ultimately, the recommendations suggested by the Cumberlege report should help define the role for vaginal mesh and adoption of this governance structure will protect patients and reduce the risk of significant long-term complications.

## Contributors

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