Vaginal Mesh and its implications of current reluctance to use in surgery

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Scope of presentation

- Vaginal mesh for urological and urogynaecological indications

- Excluded
  - Abdominal mesh for prolapse
  - Hernia mesh also excluded

Areas to cover

- History of mesh
- Recommendations by governing bodies
- National reports
- Why the reluctance to use vaginal mesh
- Future options

Brief History of mesh

- 1890, Theodor Billroth - prosthetic material for hernia repair
- 1955, Dr. Francis Usher studied – Nylon, Dacron and Teflon met with: foreign body reaction, sepsis, rigidity, fragmentation, loss of tensile strength and encapsulation.
- 1958,Usher published his surgical technique using a polypropylene mesh, and 30 years later the Lichtenstein repair (known today as “tension-free” mesh technique) was popularised for hernia repair

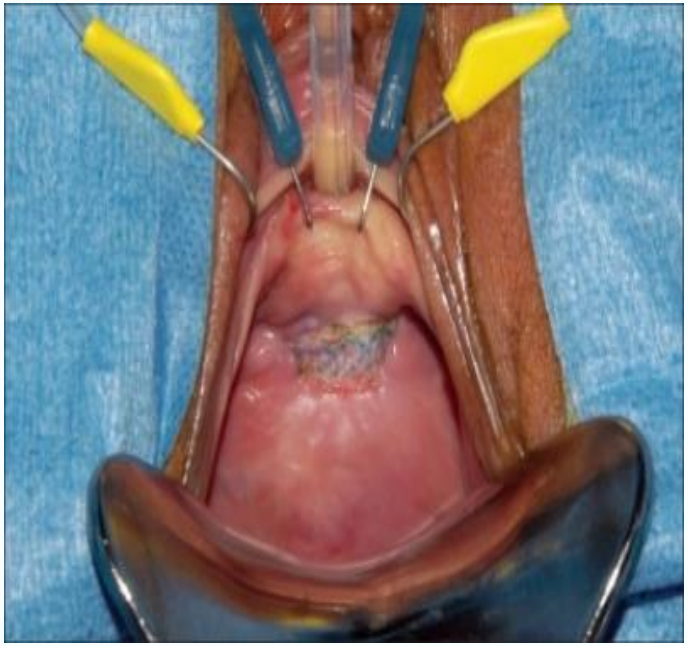
Mesh in Urogynaeology

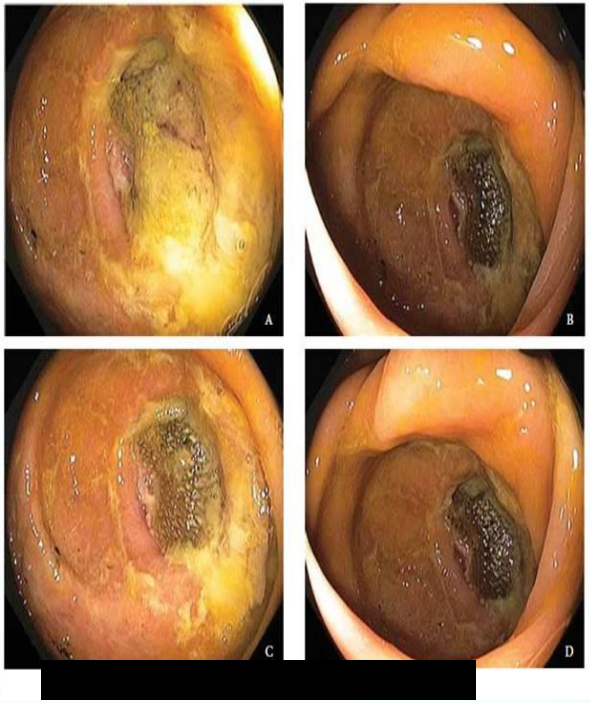
- Abdominal mesh was well established
- Late 1990's TVT developed for SUI
- The initial use of mesh in pelvic floor disorders was inspired by the
  - successful use of mesh in abdominal wall hernia repair.
  - based on the safety and efficacy demonstrated by synthetic midurethral slings

Mesh expansion

- In the mid-2000s, vaginal mesh use for POP and SUI experienced a rapid uptake trocar-based vaginal mesh POP “kits”.
- Facilitated by the US (FDA) 501(k) Premarket Notification approval system for class II medical devices, which requires manufacturers to ***demonstrate only that a new device is similar enough to an existing or predicate device to anticipate similar results,*** over 100 mesh products were introduced between 2001 and 2010.
- Coupled with:
  - unprecedented direct-to surgeon marketing and
  - lack of training or credentialing oversight for these products,
  - these procedures were quickly adopted.

What did this lead to?

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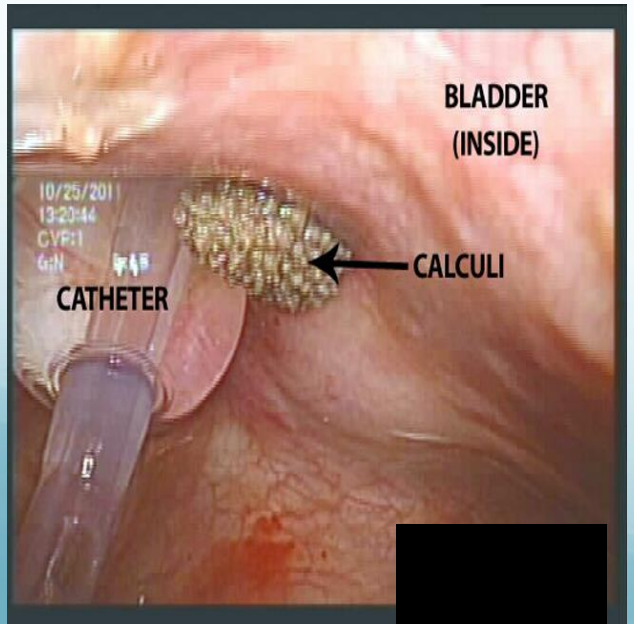
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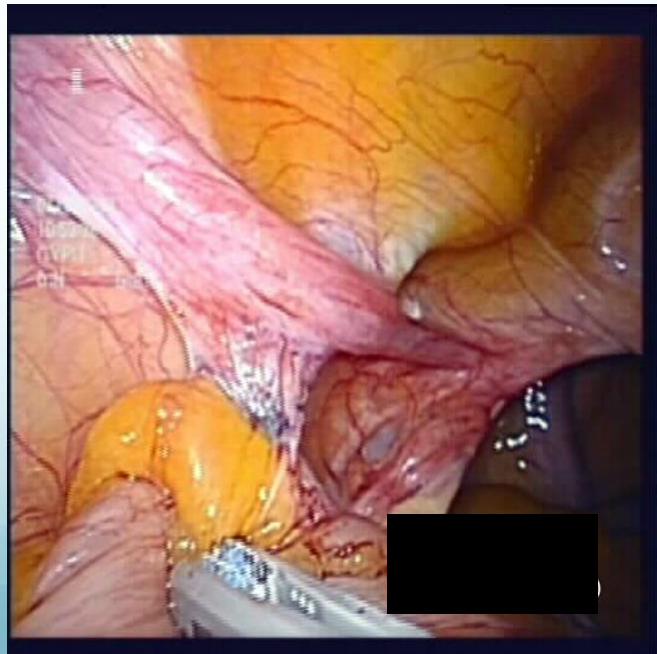


Timeline of FDA recommendations

- **2008** -FDA issued a Public Health Notification (PHN)
  - inform clinicians/patients of adverse events related to surgical mesh, and;
  - Recommendations - mitigating risks counseling patient

- 2011, released a 2nd PHN - "serious complications associated with surgical mesh for transvaginal repair of pelvic organ prolapse are not rare

- 2016 - transvaginal mesh for POP was officially reclassified as a class III device.

UK/European/International recommendations

- **NHS England review (2014-17)**
  - Working group interim report
  - Mesh Oversight group report
  - Responses to the oversight group report
- **MHRA review 2014** - safe and effective for majority. However, there is an element of risk. Compliance with NICE and other sources of guidance. Need for informed patient consent and suitable patient selection
- **European Commission review 2015**
- **Scottish Government review 2013-2017**
- **Welsh Government review 2017-18**
- **Prospect Study in 2017**
  - vaginal repair with mesh did not improve outcomes in short term, but >1:10 had mesh complication.
  - follow-up is vital to identify any longer-term potential benefits and serious adverse effects
- **International action** - number of mesh implants being/asking companies not to market mesh implants in the country until they are proved as safe
  - Australia
  - New Zealand

Summary of most of these reports

- evidence suggests a higher morbidity in (POP) than (SUI), as the former uses a much larger amount of mesh.
- Mesh must not be offered routinely for pelvic organ prolapse.
- Reporting of all procedures and adverse events to be mandatory
- Extra steps to ensure that patients can make informed choices.
- In the case of surgical treatment for SUI, all appropriate treatments should be available, subject to informed choice and assessment.
- Improved training for clinical teams involved in transvaginal mesh.
- Improved research into the safety and effectiveness of the products.

Change of practice

- Vaginal mesh for POP increased from:
  - 3,073 in 2008/09 to 3,413 in 2011/12 but has since has fallen year on year down to 2,680 in 2016/17.

- Midurethral tapes has fallen year on year from;
  - 13,990 in 2008/09 to 7,245 in 2016/17

Why the reluctance/decline

- Externally imposed by governing bodies
- Internally imposed by surgeons – fear of litigation and complaints
- Media influence
- Reluctance by patients to undergo these procedures

To: Regional Directors, Trust Medical Directors, and clinicians involved in the care of patients with stress urinary incontinence and pelvic organ prolapse
From: Professor Keith Willett and Dr Kathy McLean

On 10th July 2018, the Secretary of State HSC and the CMO announced a 'pause' in the use of synthetic mesh/tape for SUI and vaginal mesh for POP

- ✓ **Advise on high vigilance processes which must be followed by NHS and private hospitals for any mesh/tape surgery defined in (A) but deemed clinically essential during the restriction, and for the procedures defined in (B) and (C). This requires provider trust/hospital Medical Directors to be accountable for ensuring that procedures are in place to:**
  - ✓ **Ensure the necessity and appropriateness of any procedure covered by the restriction of use and high vigilance period.**
  - ✓ **Ensure that all appropriate surgical options have been offered, including where secondary referral would be required.**
  - ✓ **Ensure that appropriate information and consenting processes are in place in all cases.**
  - ✓ **Provide assurance of a surgeon's competence for any procedure offered.**
  - ✓ **Ensure there is documenting and registering of included procedures.**
- ✓ **Recommend how Trusts and GPs should support patients with advice, including patients newly referred or diagnosed, patients on the waiting list, and patients who have had previous mesh surgery who may have concerns.**

Recommendations of the Mesh Pause Clinical Advisory Group to Medical Directors and Surgical Teams

Recommendation A:

- The mesh and tape procedures to be included in the restriction of use – for SUI/POP surgery

Recommendation B:

- Mesh procedures that should be excluded from the restriction but should be subject to high vigilance scrutiny - Abdominally-inserted mesh for prolapse (such as for sacrocolpopexy, hysteropexy, and rectopexy)

Recommendation C:

- Alternative non-mesh procedures that should also be subject to increased vigilance given the change in practice that may result from the restriction of synthetic mesh and tape use. including non-tape procedures for SUI in the high vigilance scrutiny: e.g. colposuspension, fascial sling procedures, and periurethral injectable treatments.

- Biological mesh should not be used - insufficient evidence to support its routine use.

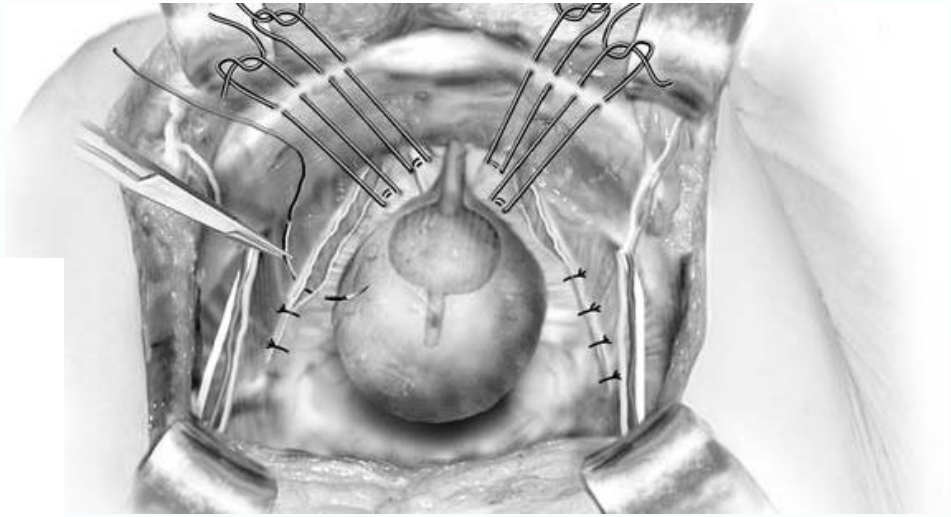
Short term implications

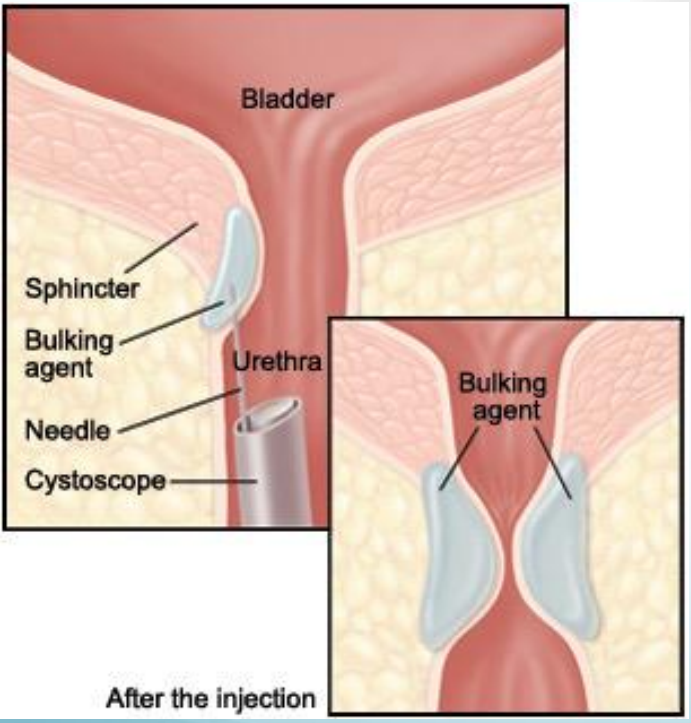
- Effect of current pause on patient choice for surgical options
- Training for junior doctors
- Need for more structured approach with use of MDT before embarking on surgery
- Mandatory reporting of surgical data and complications

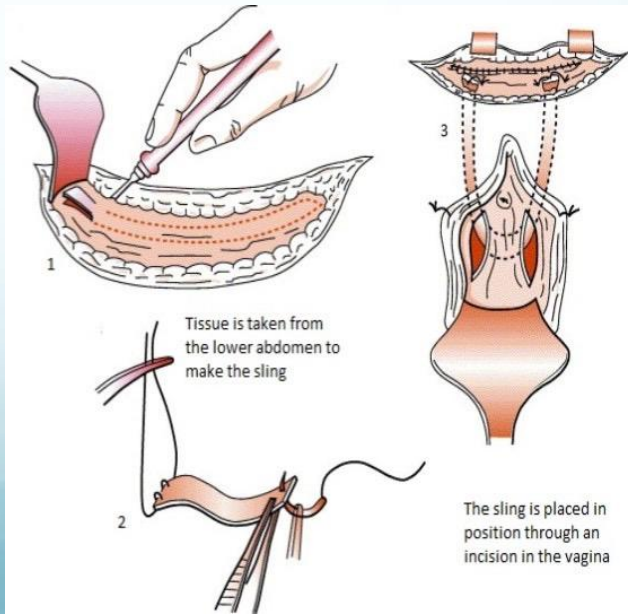
Conservative management

- Supervised pelvic floor muscle training remains the cornerstone
- Pessary type devices
- Medical treatment – Duloxetine / Oestrogen
- Lifestyle changes

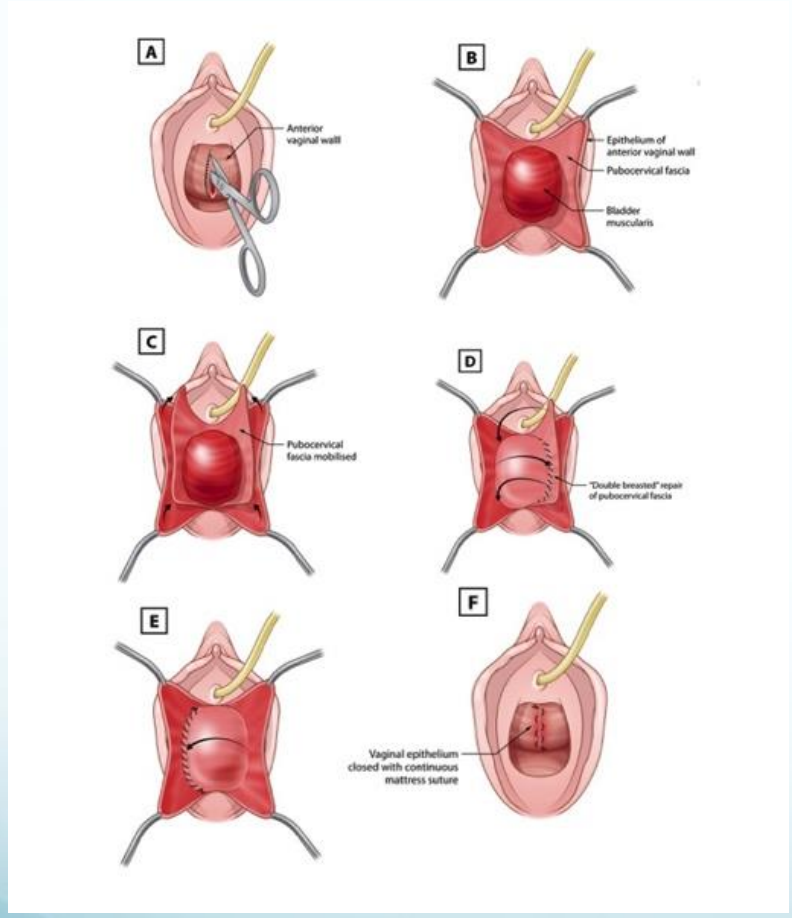
Traditional SUI Surgical Options

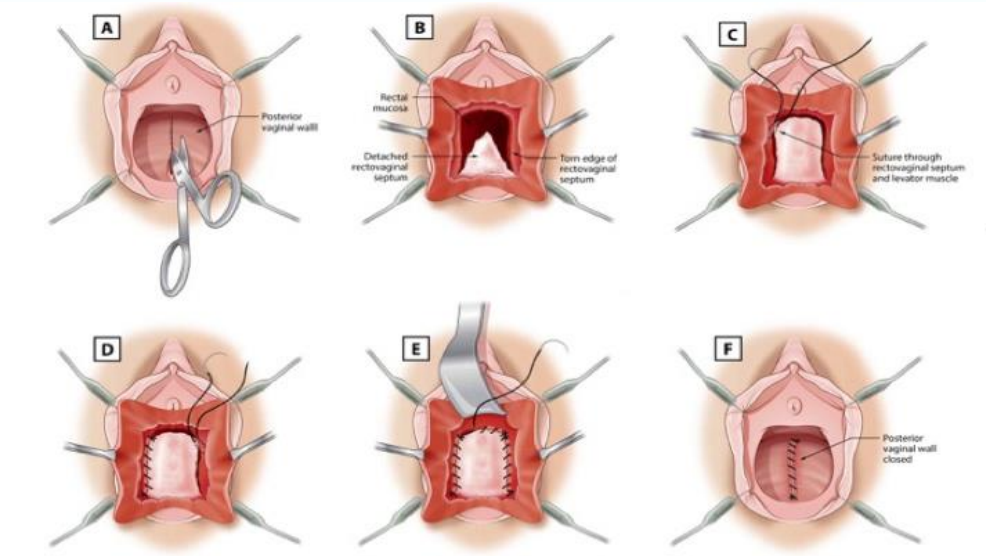






Native tissue vaginal prolapse repair





Vaginal Hysterectomy
Manchester repair
Sacrospinous Fixation
Uterosacral plication

Future Options

- An ideal treatment
  - restore the function of the underlying muscles, nerves, and connective tissues
  - without the need to implant a foreign body, which presents the risk of erosion, exposure, and lasting damage.
- For SUI, injection of autologous muscle-derived stem cells into the urethral sphincter has demonstrated efficacy in phase I/II trials and may ultimately represent a more optimal treatment.
- Autologous stem cells on growth-promoting scaffolds remain in development in pre-clinical studies as a potential treatment for POP as well.

Future Options (Cont'd)

- In addition to
  - assessing the efficacy and practicality of these methods,
  - it will be necessary to evaluate costs of using human progenitor cells for treatment of pelvic floor disorders.
- Synthetic mesh made from slowly absorbable (1 to 2 years) material such as poly-l-lactic acid may represent an effective, safer alternative to polypropylene mesh but at this point remains in pre-clinical development as well.
- Adoption of any new materials and the surgeons implanting them will be subject to much greater scrutiny going forward.

Thank you for listening