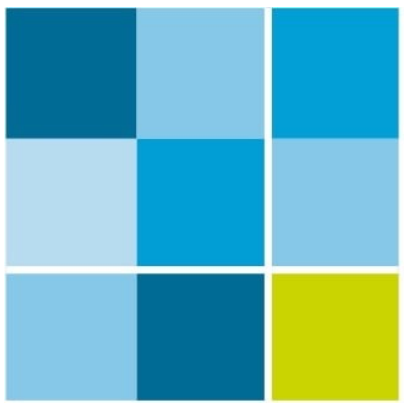

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Introduction to Pelvic Mesh: Incontinence Litigation

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In this Talk…

- Introduction to key terms
- Brief History of Mesh in UK
- Discussion practical application of *Montgomery* to mesh cases
  - Breach allegations: Reasonable Treatment Options / Risks
  - Causation

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Stress Urinary Incontinence (SUI)

What is SUI?

- *'Stress incontinence is the leakage of urine, usually caused by increase in pressure in abdomen (tummy) when there is existing weakness in the neck of the bladder'*
- *'Weakness usually caused by childbirth, which can damage pelvic floor muscles. Further weakening can occur around the menopause'* (Oxford University NHS FT)
- The sphincter that closes the urethra fails when under pressure and urine leaks out.
- Brought on by coughing, sneezing, bending, jumping, physical activities.
- 'Mixed' SUI: SUI with symptoms of overactive bladder – urge, urge frequency, urge incontinence

How severe is SUI?

- Wide range of symptoms
- Mild: Occasional leakage on exertion; to
- Severe: Leaking on non-exertion (e.g. walking); up to 12 pads daily.

Brief History
1960s-1990s: Burch Colposuspension

What is Colposuspension?

- ‘Gold Standard’ SUI operation prior to introduction of TVT in 1998
- Open operation
- Abdominal incision
- Success rates: high (80-90%)
- But required several weeks recovery

1998: Tension-Free Vaginal Tape

What is Tension-Free Vaginal Tape?

- Synthetic polypropylene mesh

How is the Tape used?

- '*Tape is inserted through a small cut just inside the vagina. It is placed around the urethra (water pipe) to form a sling, using needles, and then passed through two small cuts just above the pubic area*' (Oxford University NHS FT 2020)
- Intended to fit permanently
- Quick procedure: day case, around 45 minutes in theatre.
- Success rates comparable to colposuspension (80-90%)

Two Types of Tension-Free Transvaginal Tape

Retropubic Tension-Free Transvaginal Tape (TVT)

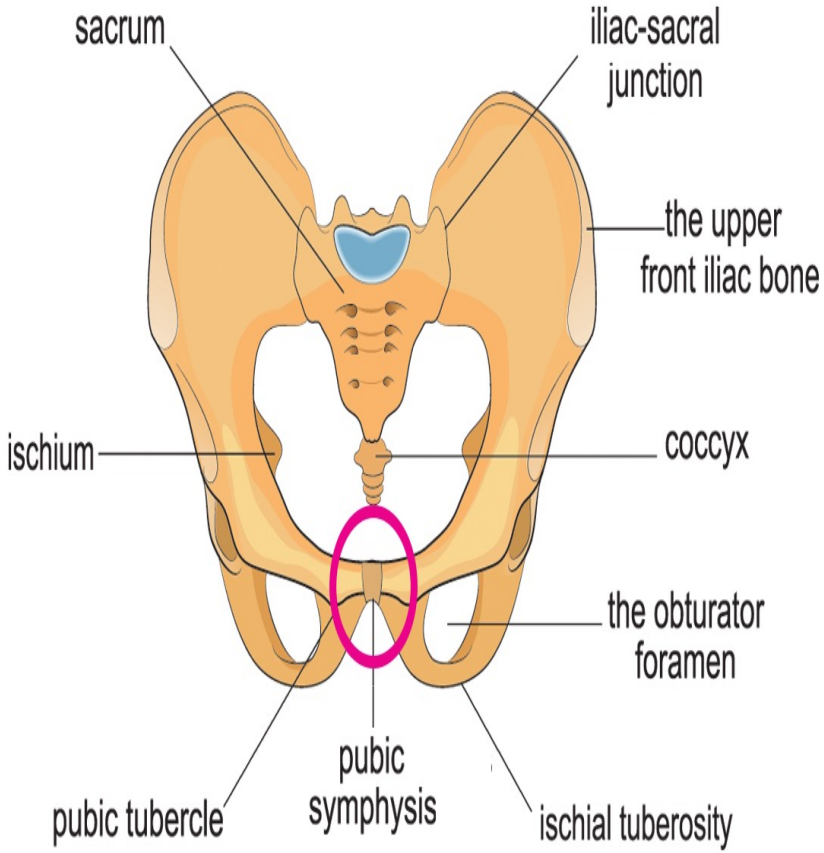
- Involves retropubic placement of tape at symphysis pubis
- Retropubic: because tape placed behind the pubis
- The ‘conventional’ or ‘classic’ tape

Transobturator Tape (TOT)

- Later development (early 2000s) with different anatomical placement of tape to TVT
- Tape placed through obturator foramen and into inner aspect of the thighs
- Success rates similar to retropubic TVT.
- This tape leads to groin and chronic pain

Practice Point

- Watch terminology: clinicians can refer to ‘TVT’ when actually carrying out ‘TOT’
- Defendants may say, no difference in procedures save for surgeon’s preference: not so, experts will say TVT & TOT different procedures with different risk profiles



The Rise of Mesh from 1998

- **1998:** TVT (i.e. retropubic TVT) first made available in UK
- **2001:** TVT the most commonly performed SUI procedure
- **2001:** TOT first used in UK
- **2003:** TVT NICE approved
- **2006:** TOT begins to be used in significant numbers

(Independent Medicine and Medical Devices Safety Review, 'First Do No Harm' – Baroness Julia Cumberlege 2020)

Rise of Mesh in Numbers

The Cumberlege Report provides figures available from 2006 for **TVT & TOTs** in UK:

- **2006-07: 7,750 (approx.)**
- **2007-08: 11,500**
- **2008-09: 11,800**
- **2009-10: 11,000**
- **2010-11: 10,800**

- About 1/3 of tapes from 2008 are **TOTs**.
- In same period, **colposuspension** declines: 4,000 in 2000-01 to less than 500 in 2005

Adverse Effects of Pelvic Mesh

- Baroness Cumberlege emphasises that for many women, TVT has been successful treatment option.
- However, her Report identifies wide variety of problems from TVT and TOT:

  - **Pain:** sometimes severe and chronic, sometimes requiring opioid painkillers
  - **Mobility Issues**. Some wheelchair bound.
  - **Erosion of Mesh.** Into vagina and/or other organs
  - **Sexual difficulties (dyspareunia).**
  - **Recurring or new incontinence / urinary frequency**
  - **Recurring or new pelvic organ prolapse**
  - **Recurrent urinary tract infections**
  - **Haemorrhage**
  - **Autoimmune issues.** Including fatigue, 'brain fog', skin complaints, hair loss, swelling.
  - **Psychological impacts.** Including depression, anxiety, PTSD, social withdrawal, suicidal feelings, attempted suicide.
  - **Death.** Mesh complications implicated in at least one patient in UK.

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The Fall of Mesh: 2010s

- **2011:** Food and Drug Administration (FDA):
  '*Serious adverse events are NOT rare*' in POP mesh repairs
- **2017:** Scottish Transvaginal Mesh Implants Independent Review
  Recommends stopping transvaginal pelvic organ prolapse mesh surgery
- **2017:** NICE guidance changes:
  Transvaginal POP mesh surgery restricted to research trials
- **7/2018:** Independent Medicines and Medical Devices Safety Review
  Recommends pause for mesh in SUI procedures
- **7/2018:** NHS England and Department of Health and Social Care
  Mesh for SUI procedures immediately paused
  Only used in prescribed exceptional circumstances
- **2020:** Cumberlege Report
  Recommends pause on mesh to continue
  Specialist centres to deal with treatment for variety adverse effects of mesh

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Fall of Mesh in Numbers

The Cumberlege Report shows sharp decrease in **TVT & TOTs** carried out 2011-2019

- **2011-12:** 10,500
- **2012-13:** 10,000
- **2013-14:** 9,800
- **2014-15:** 8,000
- **2015-16:** 7,000
- **2017-18:** 4,000
- **2018-19:** <500

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Informed Consent: '*Montgomery*' Claims

How do *Montgomery* principles apply to mesh claims in practice?

Relevant Principles

- Duty to advise claimants of reasonable treatment options.
- Duty to advise claimants of the material risks associated with treatment options: TVT and TOT in particular

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Typical Reasonable Alternative Treatment Options to TVT / TOT in SUI cases

Conservative Treatment Options

- Physiotherapy / Pelvic Floor Muscle Training

Surgical Treatment Options

- Bulking Agents (Urethral Injectables)
- Retropubic TVT as alternative to TOT

- Autologous Fascial Slings: be aware but untypical
- Colposuspension: be aware but untypical

Pelvic Floor Physiotherapy

What is Pelvic Floor Physiotherapy?

- '*Pelvic floor muscle training (PFMT) involves recruiting pelvic floor muscles for muscle strengthening and skill training*' (NICE 2013)

Scope of Duty likely to include consideration of physiotherapy before mesh:

- *'Routine digital assessment of pelvic floor muscle contraction should be undertaken before the use of supervised pelvic floor muscle training for the treatment of urinary incontinence.*
- *A trial of supervised PFMT of at least 3 months' duration should be offered as first-line treatment to women with stress or mixed urinary incontinence.*
- *If PFMT is beneficial, an exercise programme should be continued'* (NICE 2006)

Strong evidence PFMT can in general cure or manage SUI successfully:

- '*Five-year follow-up has been reported of women from a 3-month study during which the control group was offered PFMT. At 5 years in women with stress, mixed or urgency UI,* ***69%*** *reported improvement or dryness compared with pre-treatment.*' (NICE 2013)
- With no risk involved

Pelvic Floor Physiotherapy (2)

In practice:

- Potentially potent breach allegation: ‘clinician should have offered pelvic floor physiotherapy’
- Defence often argues physiotherapy not full cure. But full cure not necessarily required for PFMT to make crucial difference: it can offer opportunity to ‘*improve*’ symptoms to claimant’s satisfaction
- However, physiotherapy not ‘magic bullet’: PFMT more likely reasonable treatment option where SUI is not severe
- But where reasonable option, may be relatively easy to persuade Court claimant would have opted for physiotherapy over surgery (causation)

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Bulking Agents (Urethral Injections)

What are Bulking Agents?

- Implants (silicone, collagen, hydrogel) injected into urethra
- Aims to 'cushion' the urethra thereby preventing leakage
- Low risk: some risk retention, pain on urination

How effective are Bulking Agents?

- *'Women should be made aware that:*
- *- repeat injections may be required to achieve efficacy*
- *- efficacy diminishes with time*
- *- efficacy is inferior to that of retropubic sling'* (NICE 2006)

Bulking Agents (2)

Benefits of Bulking Agents change over time

- In 2000s experts may say only 20% chance of improvement to patient's satisfaction.
- In 2010s greater efficacy (Bulkamid): experts can assert up to 60% although NHS experts contend for no more than 50% improvement for patient's satisfaction.
- Presently being used more frequently because mesh is paused.

In practice:

- Clinicians often do not mention option of urethral injections to claimants
- Greater chance of success for urethral injections in the 2010s.
- 'Bulking Agents as reasonable treatment option' often stronger for claimants with milder SUI

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TVT: Reasonable Option to TOT (1)

- NICE 2006:
- *Retropubic mid-urethral tape procedures … with … polypropylene meshes [i.e. retropubic TVT] are recommended as treatment options for SUI if conservative management has failed. Open colposuspension and autologous rectus fascial sling are the recommended alternatives when clinically appropriate*.
- *Synthetic slings using … a transobturator foramen approach are recommended as alternative treatment options for stress UI if conservative management has failed, provided that women are made aware of the lack of long-term outcome data*.
- NICE 2013:
- 'Top Down' retropubic TVT – only in clinical trials
- emphasized lack of long-term outcome data for TOT

TVT: Reasonable Option to TOT

TVT vs TOT

- TOT higher risk of mesh erosion than TVT.
- TOT significant risk of damage to groin, including Obturator Nerve damage. Risk not associated with TVT.
- TOT involves significant risk of chronic groin pain.
- Lack of long-term outcome data for TOT as compared to TVT.
- Reduced risk of bladder trauma and urinary retention cp to TVT

In practice:

- Surgeons tend not to offer choice between TVT / TOT but simply choose TOT if they prefer that mode
- Some surgeons say they are offering 'TVT' but in fact perform TOT.
- Defendants argue just 'different risks': TVT greater risk of bladder trauma, TOT of chronic pain. But experts will say bladder trauma temporary and fixable whereas chronic pain is not.

Risks: TVT and TOT

Duty to advise of risks associated with TVT / TOT

TVT

- Risk of erosion
- Risk of dyspareunia (experts may put up to 5% to 10%)
- Risk of urinary retention / exacerbation of overactive bladder symptoms
- Small risk of chronic pain, but risk probably known only around 2013
- Risk of bladder damage during surgery

TOT

- Risk of mesh erosion higher than TVT.
- Significant risk of obturator nerve, with resulting damage to groin
- Significant risk of chronic groin pain.
- Absence of long-term outcome data.
- Knowledge of risks became greater with years

Risks associated with TOT

In Practice:

- Risks typically may be mentioned at Consultation, through Leaflet or on Day of Surgery / Consent Form.
- If claimants told of risks on day of surgery: likely to be insufficient
- Leaflets often generic, even if still available
- Specific risks of TOT often not advised by clinicians
- Scrutinise whether particular risk was material to claimant – Defendant will argue risks were low and claimant would have proceeded in any event

Causation (1)

General Principles:

- Claimant must establish she would have acted differently: *Diamond v Royal Devon & Exeter NHS FT* (2019)
- Consideration of risks - mixed objective / subjective test (*Thefaut v Johnston* (2017)) with increasing emphasis on objective element
- Cannot use hindsight (*Pepper v Royal Free Hospital NHS Trust* (2020))

In practice:

- Stronger arguments:
  - PFMT instead of TVT or TOT;
  - TVT instead of TOT (especially if pain case)
- Weaker but potentially sustainable arguments:
  - Urethral Injections instead of TVT (especially if into 2010s)
- Weak arguments:
  - Do Nothing / Colposuspension instead of TVT

Causation (2)

What injuries are caused by the negligence?

- Risk Case: trace causative link between failure to advise of the risk, the same risk eventuating and the injuries.
- Alternative Treatment Case: trace causative link between failure advise treatment option, risk particularly associated with treatment option chosen eventuating, and injuries.
- Eg: failure to advise of erosion; erosion eventuated; injuries including later treatment are relatable to erosion.

Practice Points

- Some risks may eventuate in any event: e.g. erosion from TOT could eventuate if TVT chosen
- Disentangle negligence-related injury from co-morbidities: e.g. overactive bladder symptoms or, in pain cases, non-mesh-related orthopaedic issues, or other pain issues (fibromyalgia)

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Conclusion

- Background of national criticism of mesh helpful starting point for cases.
- Negligence claims can be complex
- Causation is often the main battle-ground: witness statements must set out fully what claimant would have done and why
- Claims can be hard-fought – especially if higher value (£50K+) – but NHS so far reluctant to take cases to trial.
- Conference with Expert and Claimant pre-pleading essential, ideally pre-issue.
- Pleadings need to be comprehensive, dealing with full narrative of events, all breaches, and causation.
- Once the argument is properly set up, persevere and the cases should prove rewarding.