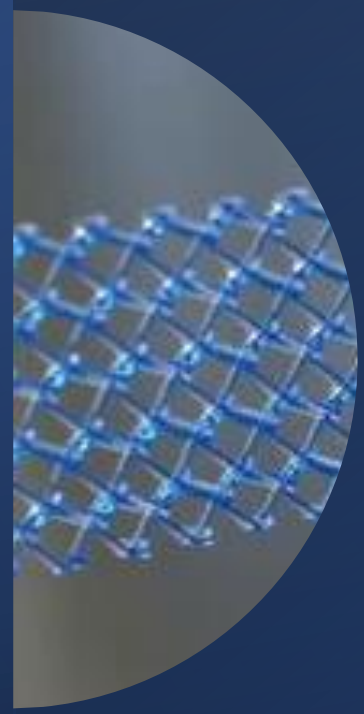
New Zealand Female Pelvic Mesh Service

Susan Rae & Sara Behrooze

Clinical Nurse Specialists

Northern Centre

Te Whatu Ora Waitemata



CAVEAT! Not all female pelvic mesh is bad!

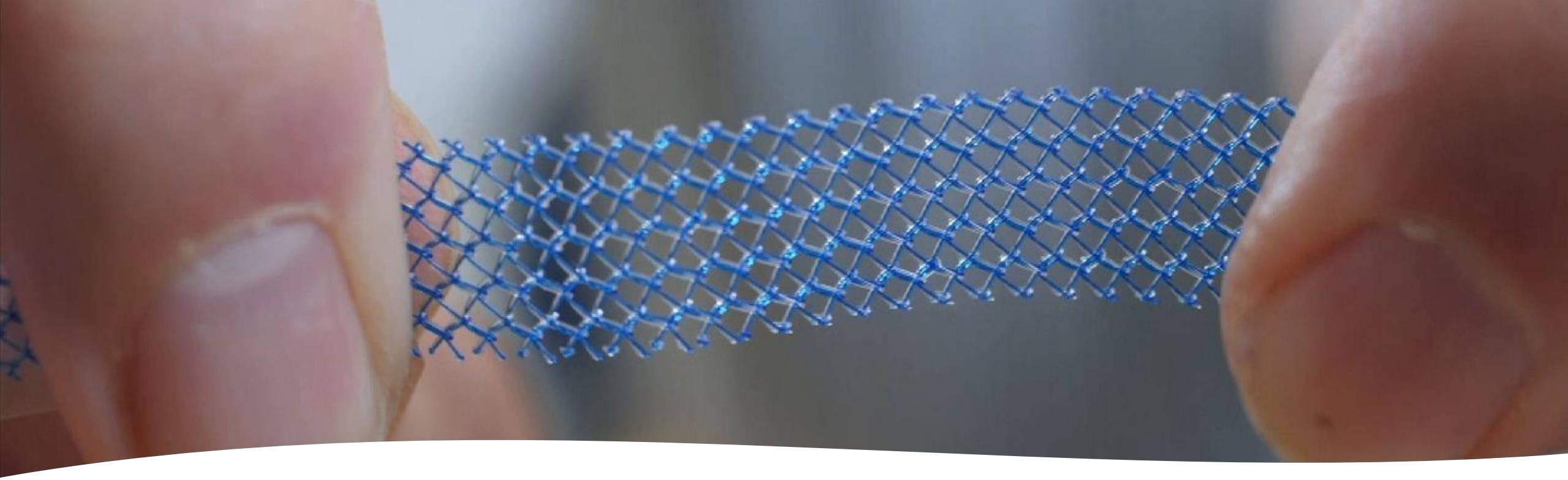
For the vast majority of women pelvic mesh can be life-changing

BUT for those who have experienced complications

- It can be catastrophic
- Can present years after the mesh was inserted

Quote from a woman referred to the service:

“I haven’t been able to have intercourse with my husband since my operation”



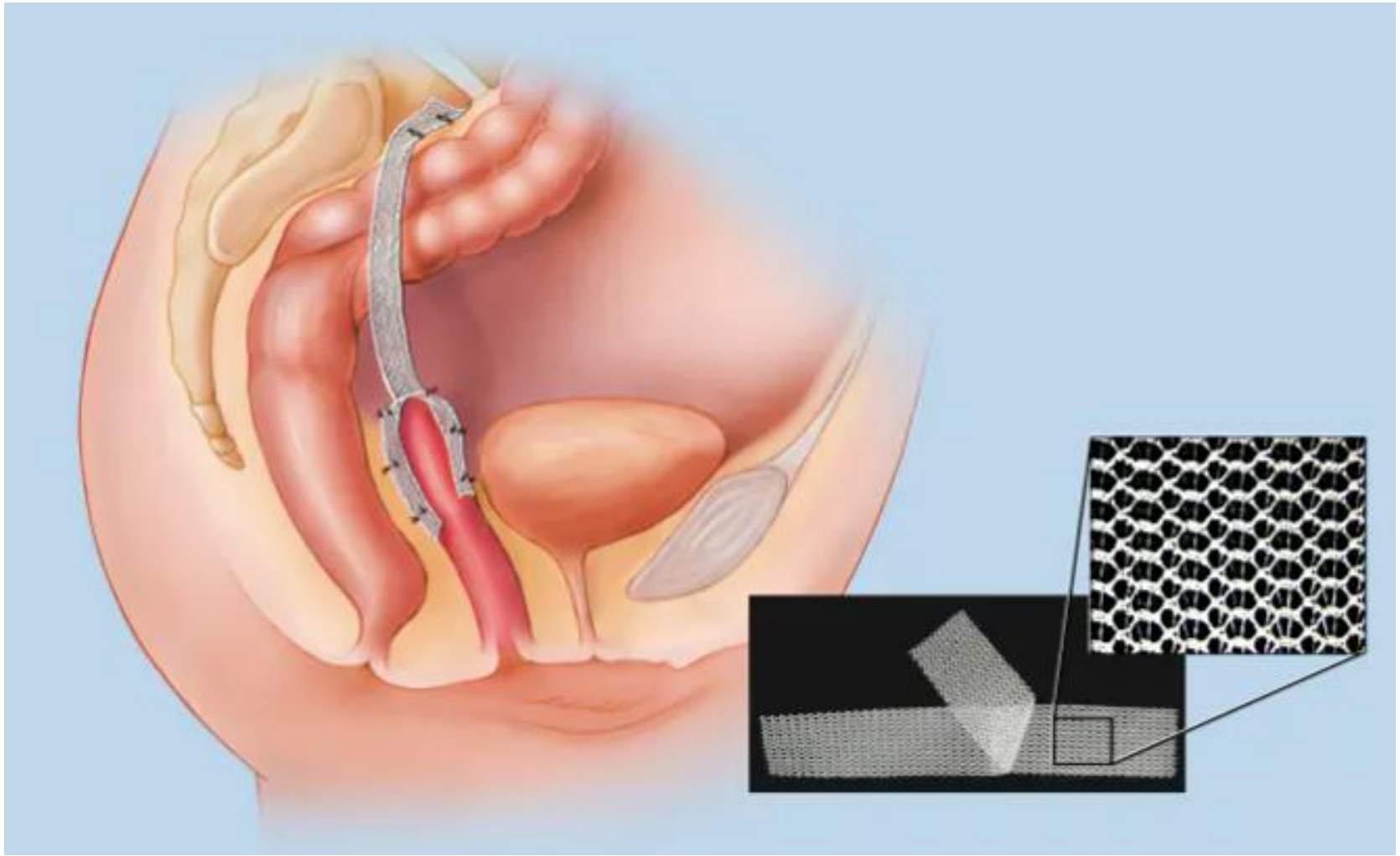
No one set out to cause harm

What is female pelvic mesh?

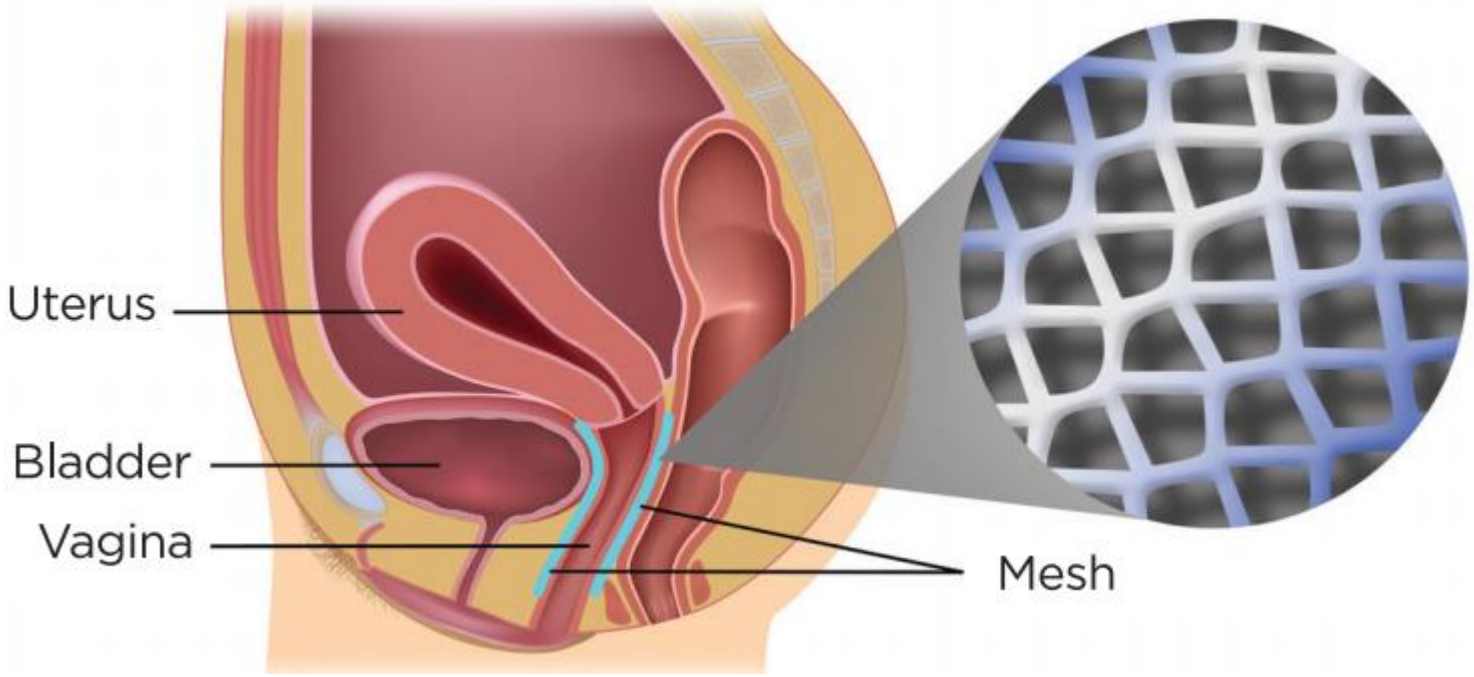
- Manufactured synthetic net-like medical implant
- Used to surgical treat
  - **Pelvic organ prolapse (POP)**
  - **Stress urinary incontinence (SUI)**
- Inserted into the female pelvis to provide additional support to weakened structures such as the bladder, uterus and vagina
- The surrounding tissue grows into the mesh, stabilising its position within the pelvis.
- Intended to be permanent
- It has been used worldwide since the mid-1990s and in New Zealand for over 20 years.

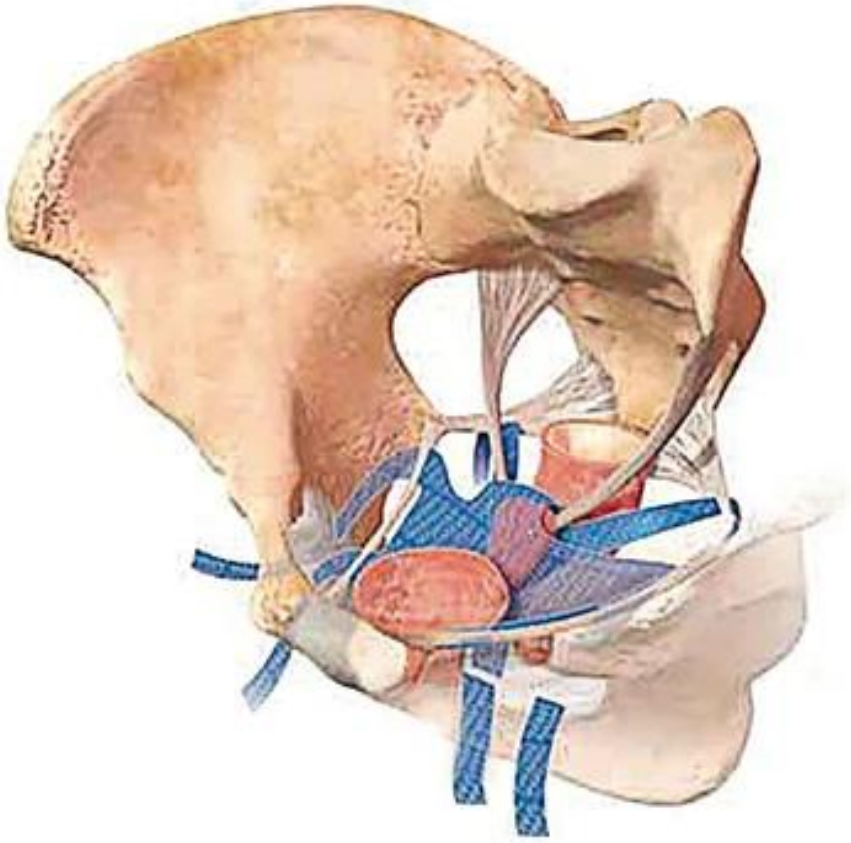
(Waitemata DHB, 2019)

Trans abdominal mesh – for Pelvic Organ Prolapse Repair

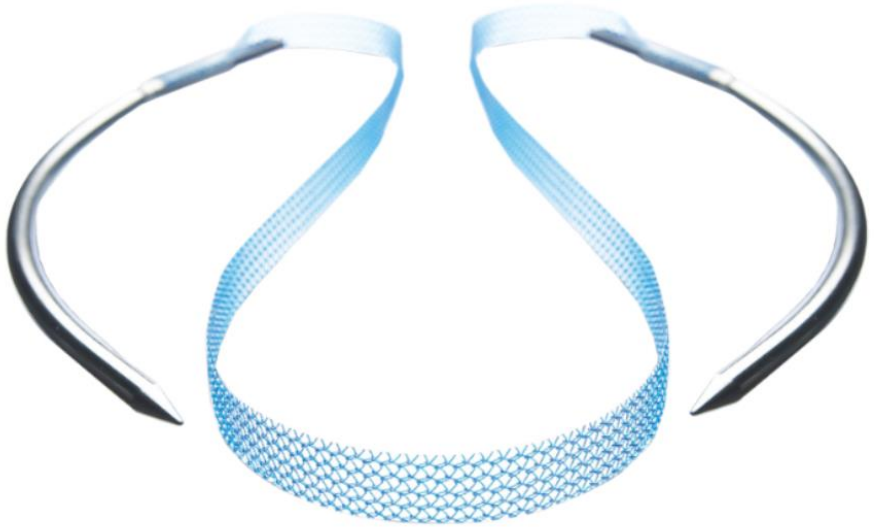


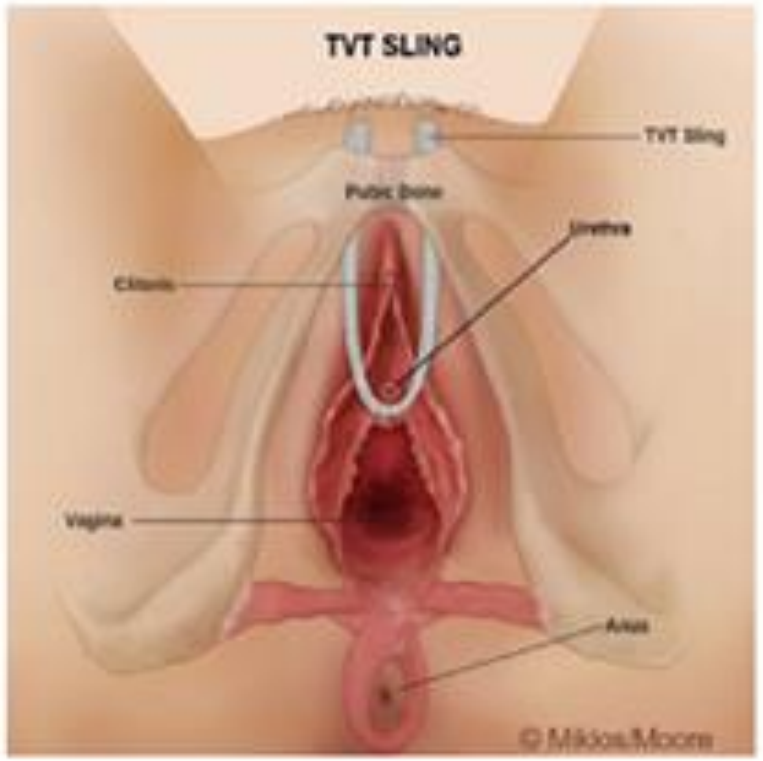
Trans vaginal mesh – for Pelvic Organ Prolapse Repair

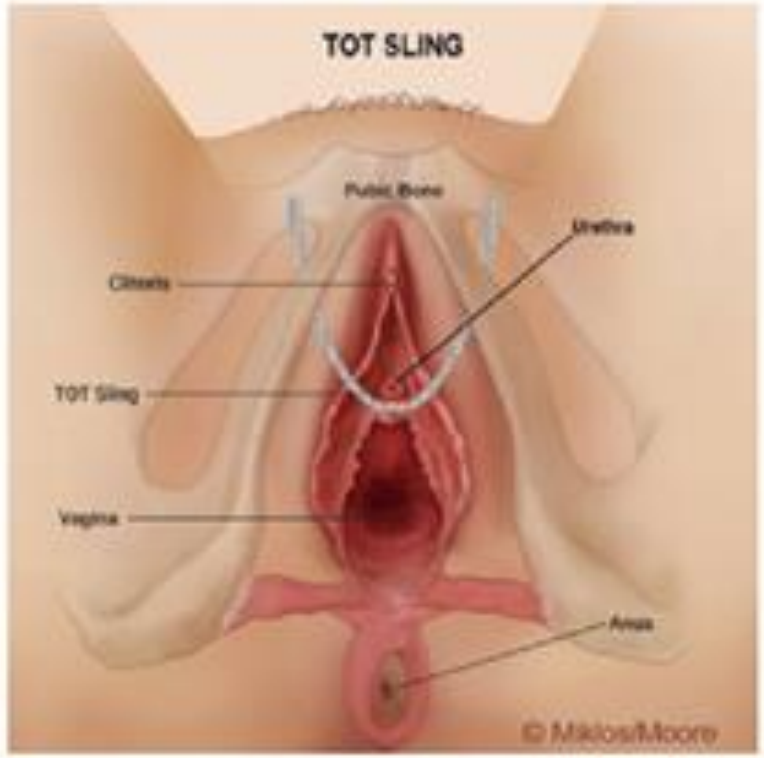


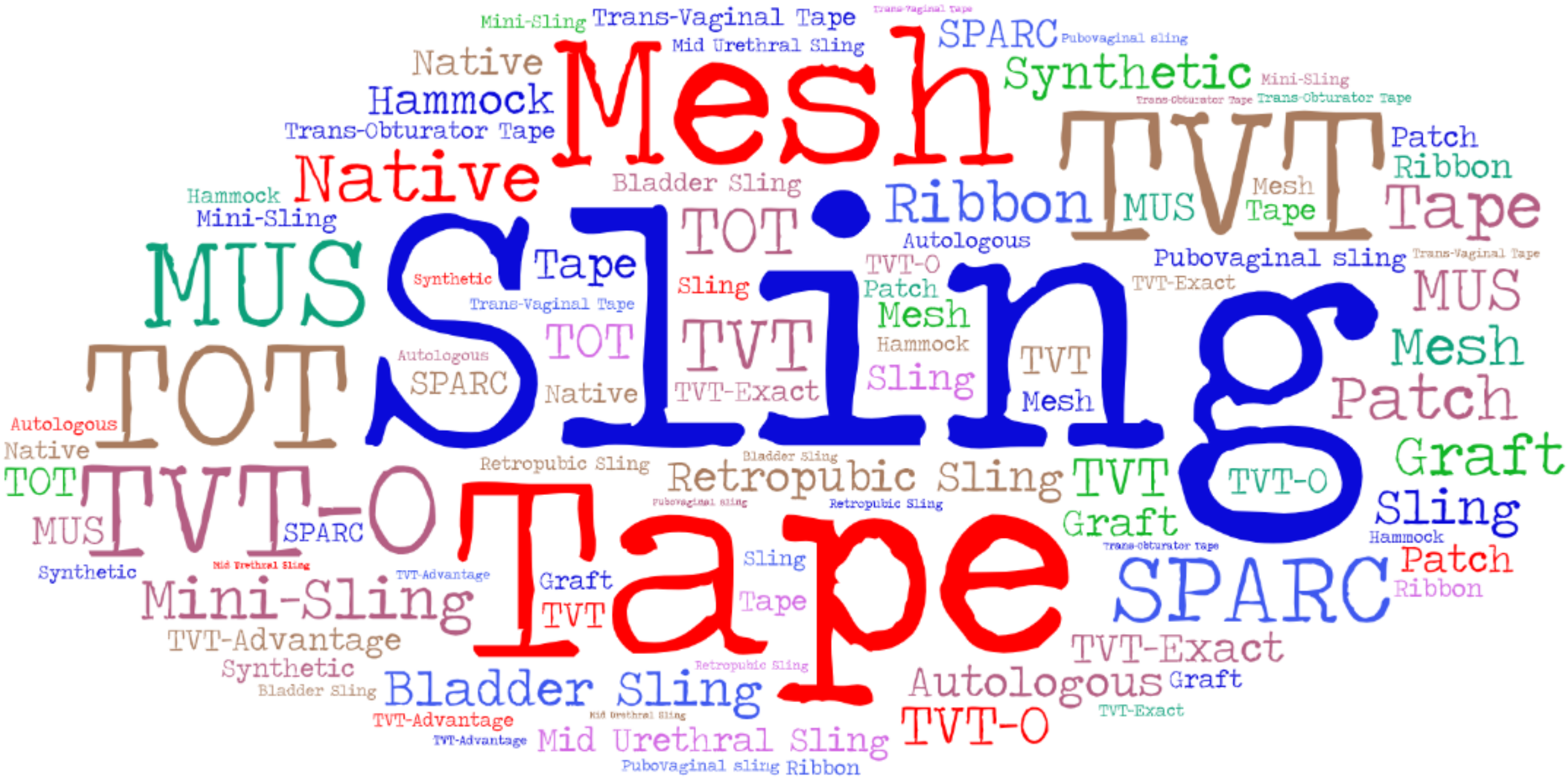


Mid urethral sling – for Incontinence

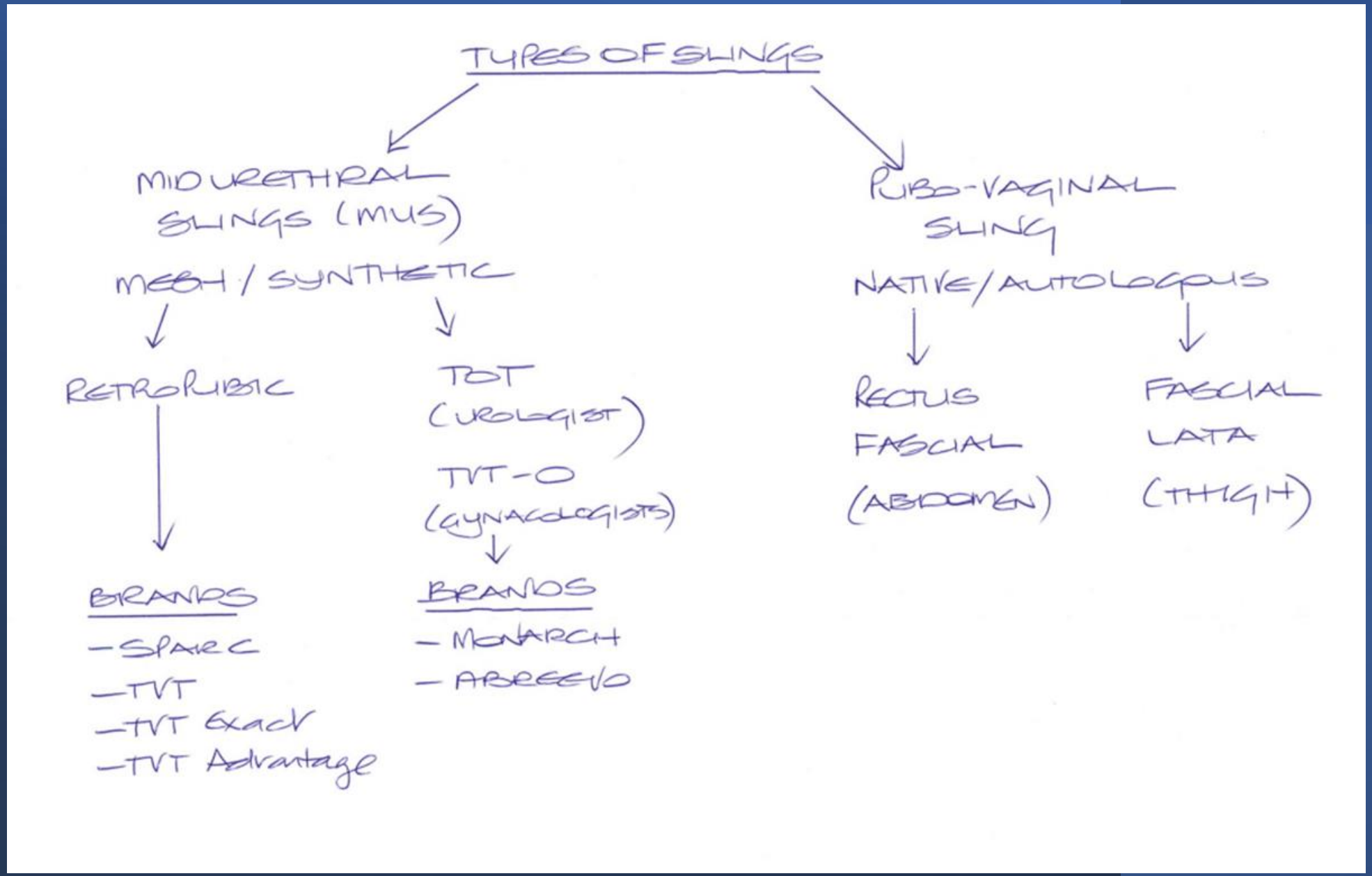


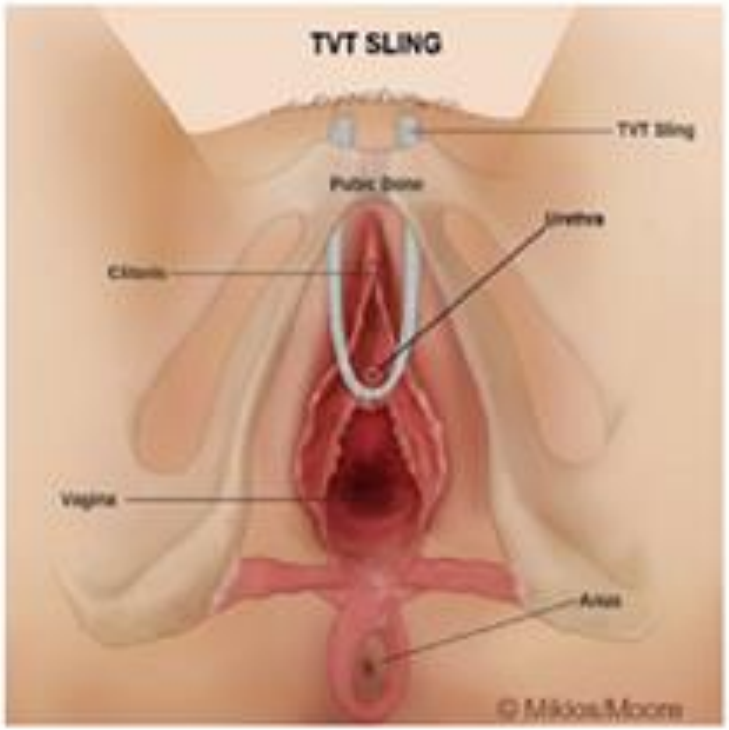


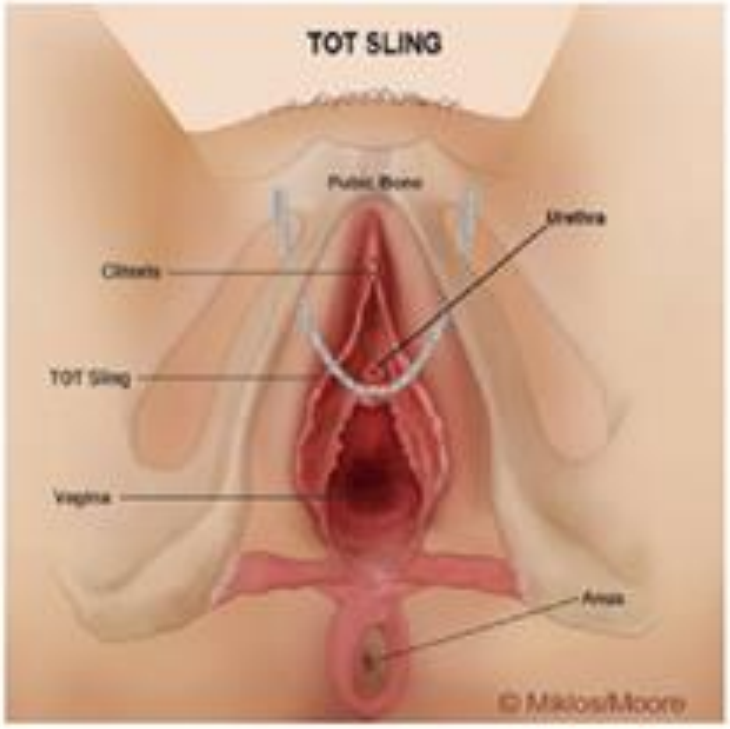



Mini-Sling
Trans-Vaginal Tape
Trans-Vaginal Tape
Mid Urethral Sling
SPARC
Pubovaginal sling
Native
Synthetic
Mini-Sling
Hammock
Trans-Obturator Tape
Trans-Obturator Tape
Trans-Obturator Tape
Mesh
TVT
Patch
Native
Ribbon
Bladder Sling
Hammock
TOT
Ribbon
MUS
Mesh
Tape
Tape
Mini-Sling
Autologous
MUS
Synthetic
Tape
TVT-O
Pubovaginal sling
Trans-Vaginal Tape
Sling
Patch
TVT-Exact
MUS
Trans-Vaginal Tape
Mesh
TOT
Autologous
Hammock
Mesh
TOT
Sling
TVT
SPARC
TVT
Native
TVT-Exact
Sling
Mesh
Patch
Autologous
Native
Graft
Retropubic Sling
Bladder Sling
TOT
Retropubic Sling
TVT
TVT-O
TVT-O
Pubovaginal sling
Retropubic Sling
Sling
MUS
SPARC
Graft
Hammock
Trans-Obturator Tape
Patch
Synthetic
Mid Urethral Sling
TVT-Advantage
Sling
Graft
Ribbon
Mini-Sling
Graft
Tape
SPARC
TVT
TVT-Exact
TVT-Advantage
Synthetic
Retropubic Sling
Autologous
Graft
Bladder Sling
Bladder Sling
TVT-Exact
TVT-Advantage
Mid Urethral Sling
TVT-Advantage
TVT-O
TVT-Advantage
Mid Urethral Sling
Pubovaginal sling
Ribbon

Confused???


TYPES OF SLINGS
MID URETHRAL SLINGS (MUS)
MESH / SYNTHETIC
RETROPUBIC
BRANDS
- SPARC
- TVT
- TVT Exact
- TVT Advantage
TOT (UROLOGIST)
TVT-O (GYNAECOLOGISTS)
BRANDS
- MONARCH
- ARREGIO
PUBO-VAGINAL SLING
NATIVE/AUTOLOGOUS
RECTUS FASCIAL (ABDOMEN)
FASCIAL LATA (THIGH)


TVT SLING
TVT Sling
Pubic Bone
Urethra
Clitoris
Vagina
Anus
© MikosMoore


TOT SLING
Pubic Bone
Urethra
Clitoris
TOT Sling
Vagina
Anus
© MikosMoore

In our experience…

Gynaecologists tend describe the sling by brand ie: TVT, SPARC

Urologists tend describe the sling by route ie: Retropubic

Signs and symptoms of pelvic mesh complication?

Pain

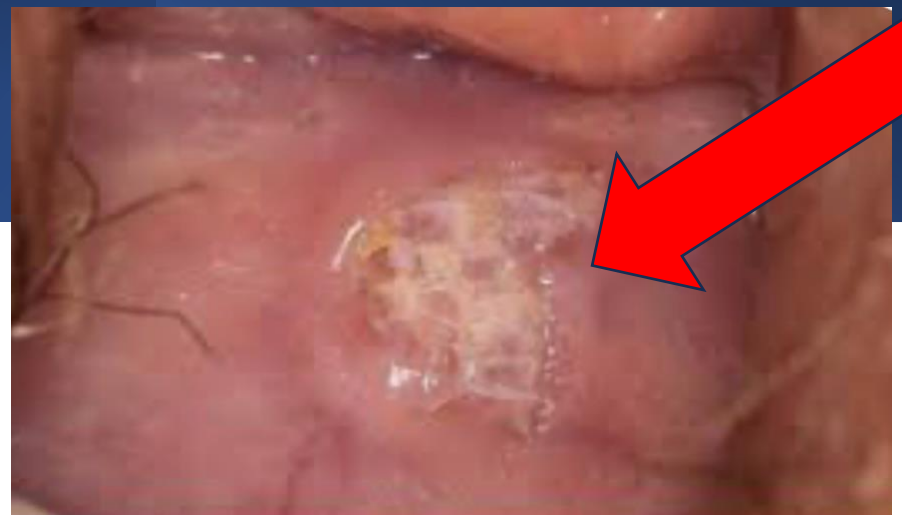
- **Pain localised to the pelvis-** sometimes radiating down legs or around to buttock or lower back
- **Dyspareunia** making sexual intercourse uncomfortable or not possible.
- **Bladder Pain** caused either by erosion or irritation and inflammation
- **Chronic pain syndrome -** pain that persists for a long time, often beyond the expected period of healing, causing significant distress or impairment in daily functioning

Signs and symptoms cont…

The pain can

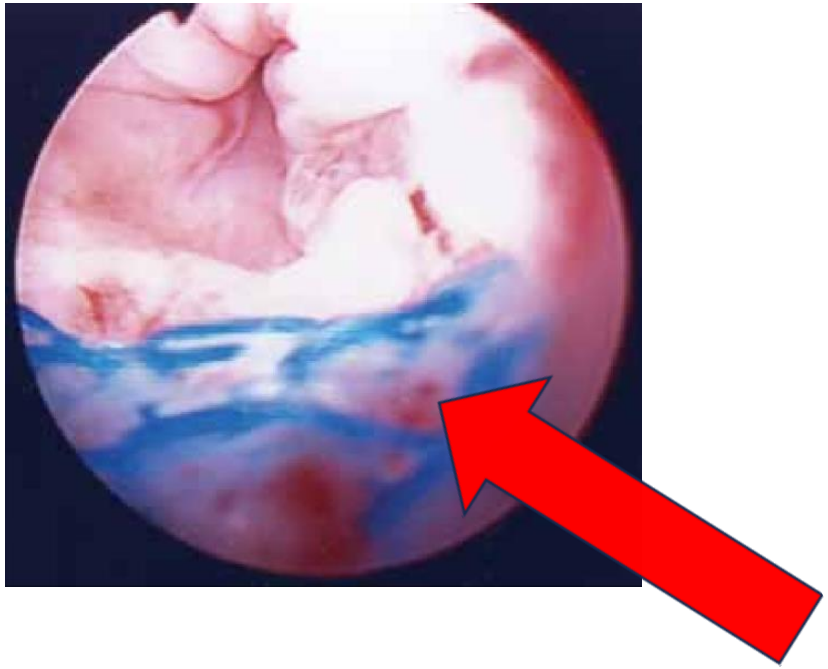
- Begin immediately or develop many years later
- Be constant or intermittent
- Worse on movement or activity
- Achy, crampy, tender
- Throbbing, stabbing, burning, shooting
- Tingling, electric-shock like or numbness

Signs and symptoms cont.



Mesh Erosion

- Where mesh pushes against and into the surrounding tissue, nerves and organs.
- Can occur years after surgery
- Most commonly into the vagina (often caused Exposure)



Mesh Extrusion

- where mesh pushes through or perforates surrounding tissue, nerves and organs including the bladder, urethra or bowel.

Embedded mesh

- Where the mesh embeds into adjacent structures like the urethra

Signs and symptoms cont.

- **Urinary symptoms –** such as frequency, urgency +/- urge urinary incontinence

- **Urinary complications** – such as recurrent infections, voiding dysfunction and bladder outlet obstruction

Signs and symptoms cont.

- **Inflammation -** caused because the mesh is a foreign body that can activate an immune response.
- **Infection -** of damaged tissues, with recurrent urinary tract (bladder) infections being the most common. Or Eroded/ exposures vaginal mesh

Signs and symptoms cont.

- **Reocurrence of Prolapse or Incontinence -** the initial condition might recur, often necessitating further intervention.
- **Neuro-muscular problems -** leg pains, problems walking, or muscle weakness, sometimes as a result of nerve impingement or damage by the mesh.

Emotional and psychological impact of mesh complications

- PTSD
- Anxiety
- Depression
- Suicidal Ideation/attempts

Early 1990s - Gynaecologists began using mesh for surgical treatment of stress incontinence and prolapse

1996 – Food & Drug Administration (FDA) in the United States approved the first mesh sling based almost entirely on research related to previous hernia mesh.

1998 - FDA approved its second sling was approved given approval based on its similarity to first sling

1999 – FDA pulled the first mesh sling due to safety concerns

2002 - FDA clears the first surgical mesh for the treatment of prolapse

Brown (2019)

2005 - Surgical mesh for treatment of incontinence and prolapse has become commonplace in NZ

2006 – Worldwide, height of synthetic mesh use - approximately 1/3 of all POP surgeries used mesh

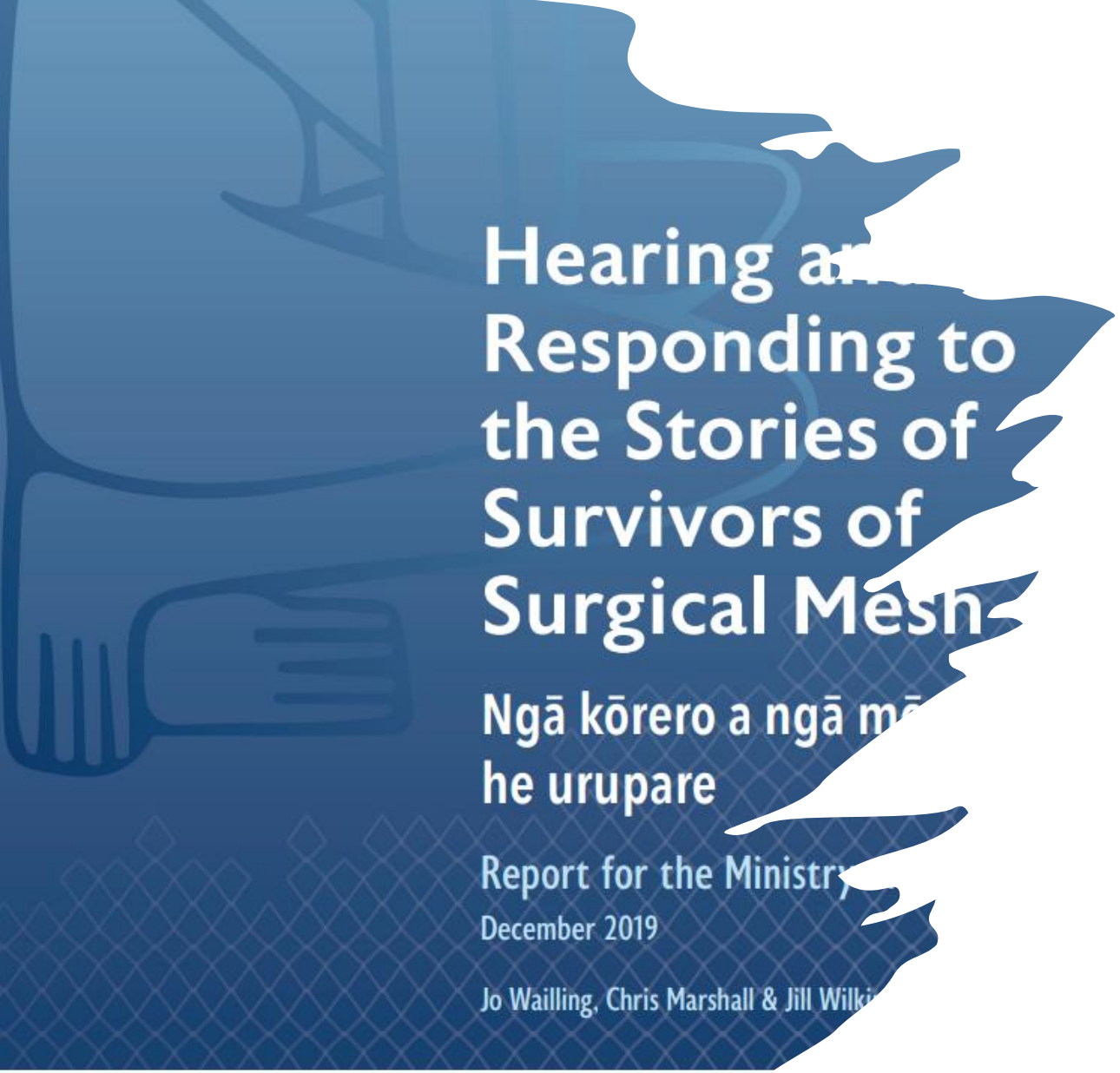
2008 - FDA released a Public Health notification to alert clinicians to adverse events related to pelvic mesh but deemed them “rare”.

2011 - FDA announced adverse events “not rare”.

Brown (2019)

2014 - Two NZ women experiencing mesh complications, Carmel Berry and Charlotte Korte, take a submission to the Parliamentary Health Committee requesting an independent inquiry into the safety of surgical mesh in New Zealand.

2017 – New Zealand and Australia banned the use of surgical mesh for the treatment of vaginal prolapse.



Restorative Justice Process

In 2019, the Ministry of Health led a Restorative Justice process to hear directly from New Zealanders who had been impacted by injury and harm from the insertion of surgical mesh in Aotearoa.

These stories were reviewed by a team led by Diana Unwin Chair in Restorative Justice, Victoria University of Wellington

The report *"Hearing and Responding to the Stories of Survivors of Surgical Mesh"* describes in detail the harm caused and extensive impact on quality of life for the harmed women and their whānau

VICTORIA UNIVERSITY OF WELLINGTON TE HERENGA WAKA

The Diana Unwin Chair in Restorative Justice

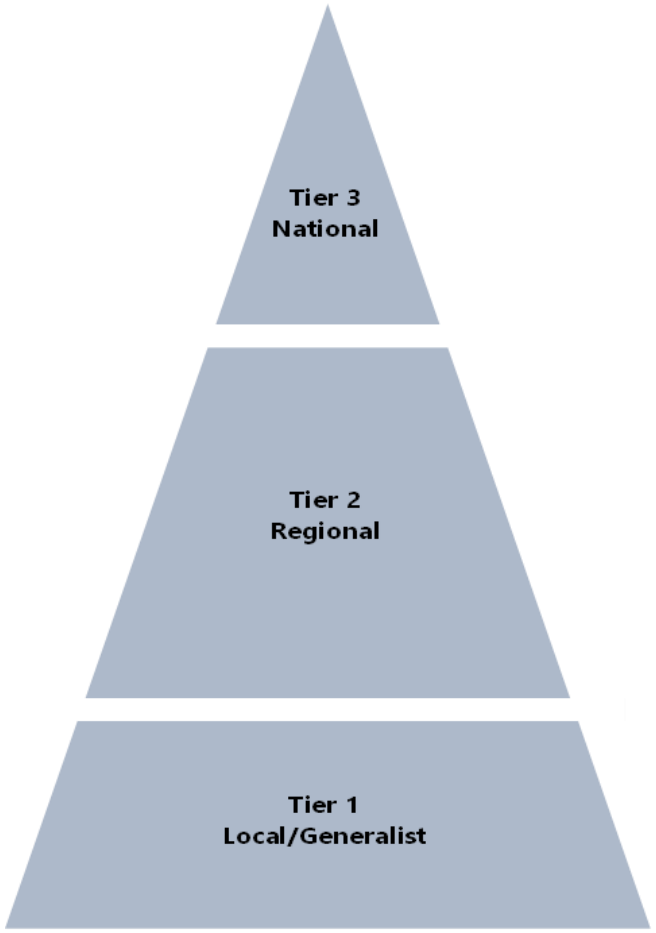
Restorative Justice Process

The report highlighted 19 recommendations and action points:

- Action Point 8 was the establishment of a specialist service to assess and deliver treatment options for consumers suffering from post-mesh implantation complications.
- Action Point 9 was the establishment of a credentialling committee to recommend national standards for individual practitioners and services commencing with urogynaecology procedures.

National Credentialling Framework

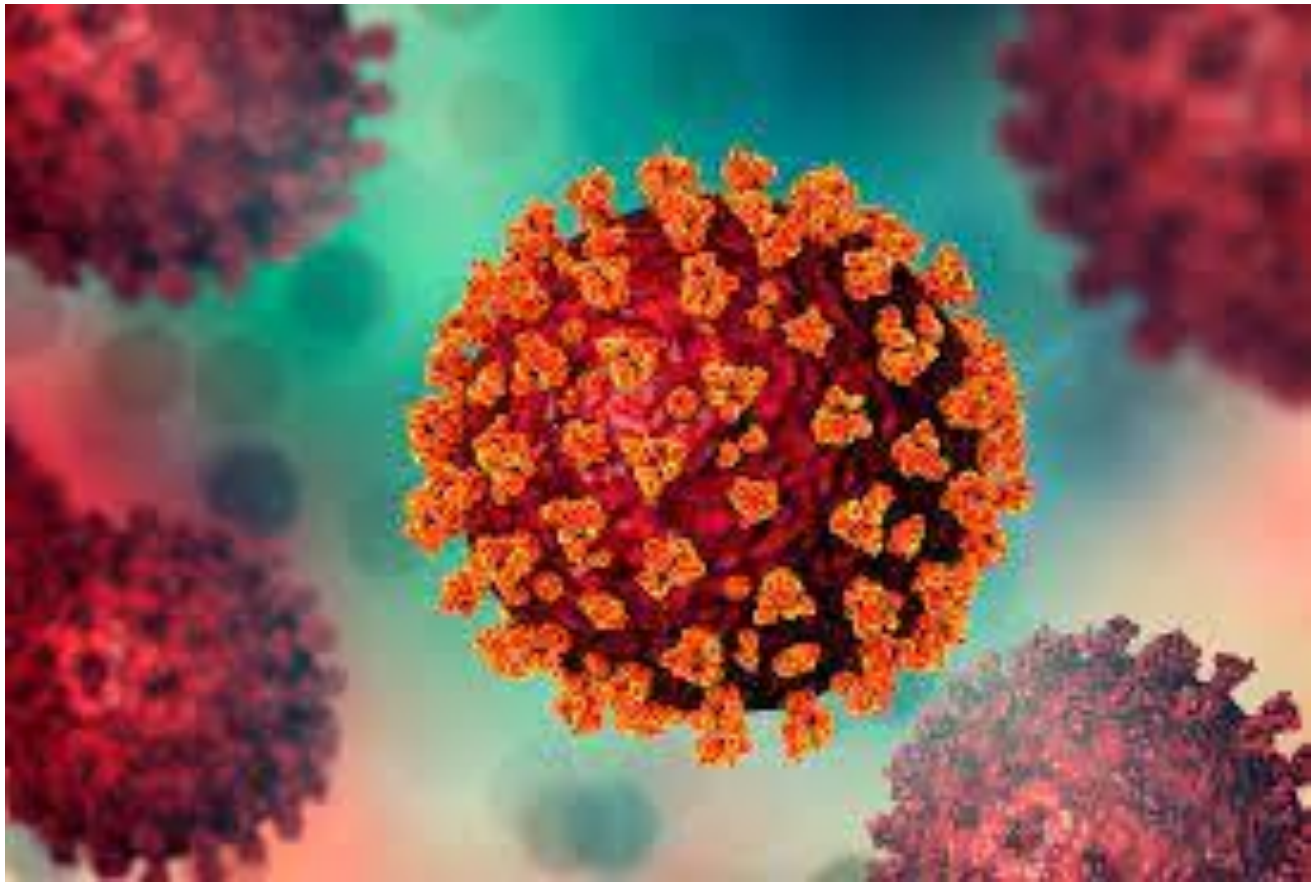
Figure 3: Service configuration



• Highly specialised • Multi-specialty • New or emerging procedures • Very complex / significant safety issues	• Removal of retropubic mid-urethral sling (MUS) (partial (vaginal) or complete) • Removal of trans-obturator MUS (partial (vaginal) or complete) • Removal anterior/posterior vaginal prolapse mesh, body and arms • Removal sacrocolpopexy vaginal attachment mesh • Complete removal rectopexy mesh/bowel repair[1] • Removal of orphan arms • Removal of mesh from bladder, urethra, ureter or bowel • Reconstruction following mesh removal • Removal of bulking agents • Autologous sling removal • Trans-obturator MUS (insertion of)
• Multidisciplinary teams • Moderately complex cases (including recurrent prolapse or SUI) • Referral to tier 3 may be indicated	• MUS (mesh sling) – retropubic • Sacrocolpopexy/Sacrohysteropexy • Sacrospinous hysteropexy (with permanent sutures) • Autologous sling (for example, pubovaginal fascial sling, fascia lata) • Burch colposuspension (open or laparoscopic) • Urethral bulking agents Revision • Acute loosening of sling for voiding dysfunction (mesh and autologous slings) • Acute division of sling for voiding dysfunction (mesh and autologous slings) • Vaginal division of MUS for obstruction • Trimming (excision) of <1 cm exposed vaginal mesh
• Low complexity cases • Surgical management of prolapse with referral when indicated	• High uterosacral ligament suspension (transvaginal or laparoscopic) • Non-mesh apical suspension (without permanent sutures) • Sacrospinous fixation/hysteropexy (without permanent sutures) Acute Non-Mesh Revision • Repair of wound dehiscence along suture line • Treatment of haematoma and infection

[1] It is not expected [under the current Framework] that urologists and gynaecologists are required to be credentialled for this procedure.

Then COVID happened ….



Just when we'd all nearly given up hope …

December 2022 – Te Whatu Ora employs a Female Pelvic Mesh Service National Programme Manager with the directive to "make it happen ASAP"

On 26th April 2023 the service opened to referrals

“Building the plane as we fly it”

French (2023)

The New Zealand Female Pelvic Mesh Service

National service delivered in

2 Centres

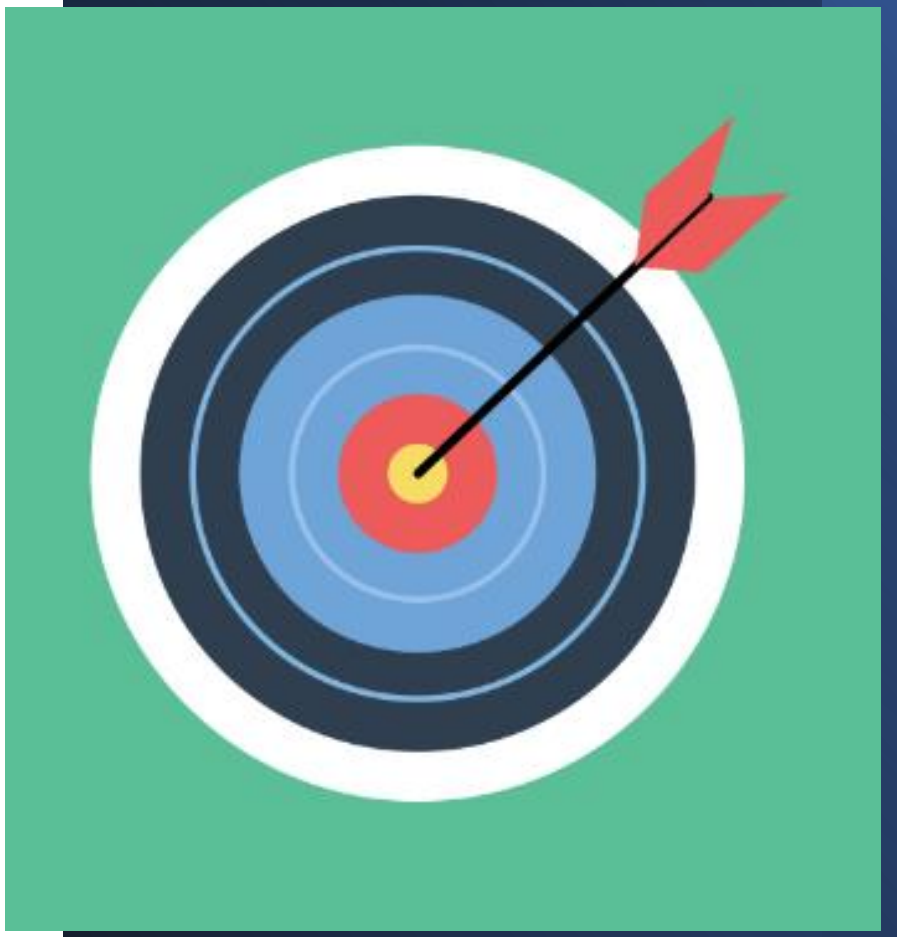
- Southern Centre in Christchurch
- Northern Centre in Auckland

Service Goals

To provide women with

- A comprehensive assessment and patient management plan using a multi-disciplinary team approach
- We want them to have confidence that everyone in the service understands that mesh complications occur.
- We want them to have confidence that we will investigate any new pelvic symptoms (including new pain) for any women who have had pelvic mesh inserted
- And we want them to feel confident that we will do everything we can to prevent further harm

NZFPMS (2023)



ARE YOU
ELIGIBLE

Who we see

- Women who have had pelvic mesh inserted for pelvic organ prolapse or stress urinary incontinence
- Women with fascial slings for SUI will also be included if complications have occurred.

Who we don't see

- Women who have had pelvic mesh inserted for rectal prolapse on its own (Rectopexy).
- Women who have had mesh inserted for hernia repair in the pelvic region

NZFPMS (2023)

The New Zealand Female Pelvic Mesh Service

Women can choose which centre they want to be referred to

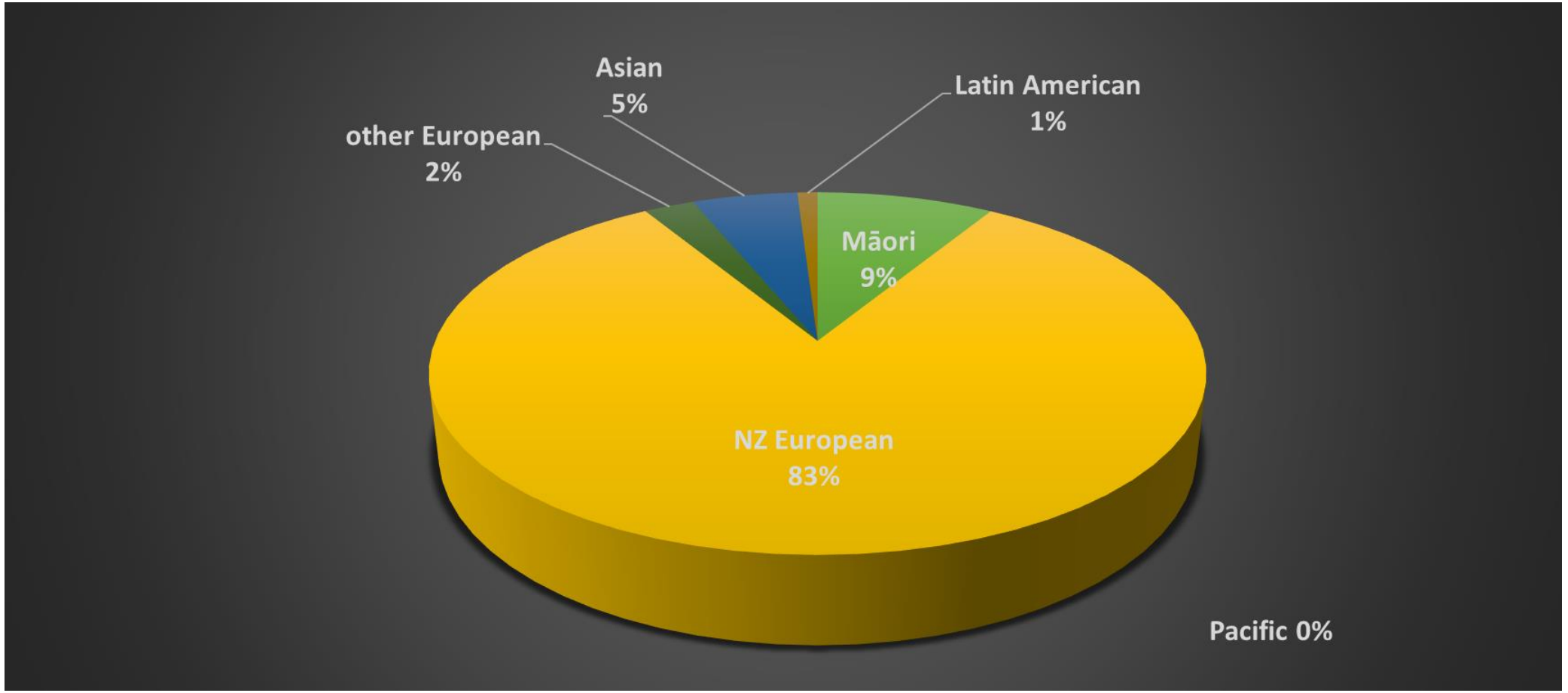
Referrals

Referral by GP / Specialist

We have had almost 360 referrals so far

- 250 to the Northern Centre
- 108 to the Southern Centre

Patient Ethnicity



CNS Triage

Minimum Referral Criteria	
Priority 1 **(Appointment within 28 calendar days)**	• Fistula (constant urinary or faecal incontinence per vagina) • Mesh in viscus • Unexplained haematuria potentially related to mesh within the bladder
Priority 2 **Appointment within 54 calendar days)**	• Recurrent urinary tract infections • Vaginal bleeding related to mesh exposure • Offensive vaginal discharge • Significant pain related to inserted mesh affecting daily activity
Priority 3 **(Appointment 100+ days calendar days)**	• Stable mesh related pelvic or vaginal pain • Asymptomatic mesh exposure • Dyspareunia

CNS Review of Symptoms

- Reason for referral
  - Symptoms and timeframe
- Mesh surgical history
- Past medical & surgical history, including medications
- Overview of symptoms
  - Pain
  - Bladder
  - Bowel
- Social situation
- ACC status / consent
- Treatment Goals
- Plan

Investigations

- 3D Ultrasound
- MRI
- Urodynamics
- Flexible Cystoscopy

The Team

National Co-Leads - Dr Eva Fong & Mr Giovanni Losco

The Team

3 other Surgeons

- Dr Hazel Ecclestone
- Dr Sum Sum Lo
- Dr Anna Lawrence

The Northern Team

The Southern Team

Still being recruited

- Pain Specialist(s)
- Psychologist(s)
- Physiotherapist(s)
- Occupational Therapist(s)

Surgical Mesh Navigators

Tiffani – based in Auckland

Holly - based in Christchurch

Themes from Consumer Journey Interviews

Loss

- Womanhood / Femininity
- Sexual Intimacy
- Ending of marriages/relationships
- Financial Security
- Career loss / change / Early retirement
- Home – can no longer afford mortgage / rent
- Unable to fulfil roles as mother/wife/ daughter
- Social isolation

Themes from Consumer Journey Interviews cont:

Shame

- Due to private nature of injury
- Incontinence / unable to control bladder and bowels
- Body Image issues

Affects on Mental Health

- PTSD
- Anxiety
- Depression
- Disclosure of suicidal Ideation / attempts

Working with ACC

70% of women will have an accepted TI claim

Two funding streams

- Those with an accepted claim
- Those without an accepted claim

PREVENTION. CARE. RECOVERY.

Te Kaporeihana Āwhina Hunga Whara

Non-surgical treatments

- Pain Management
- Physiotherapy
- Medication to control / improve symptoms
- Counselling / Psychology

(WDHB, 2019)

Surgical treatments

Adjustment - The position or tension of the mesh is modified to alleviate complications without removing any of it (usually within six weeks of surgery).

Urethrolysis - to release or free the urethra from surrounding scar tissue or adhesions.

Division - A cut is made in the mesh to relieve tension or pressure

WDHB (2019)

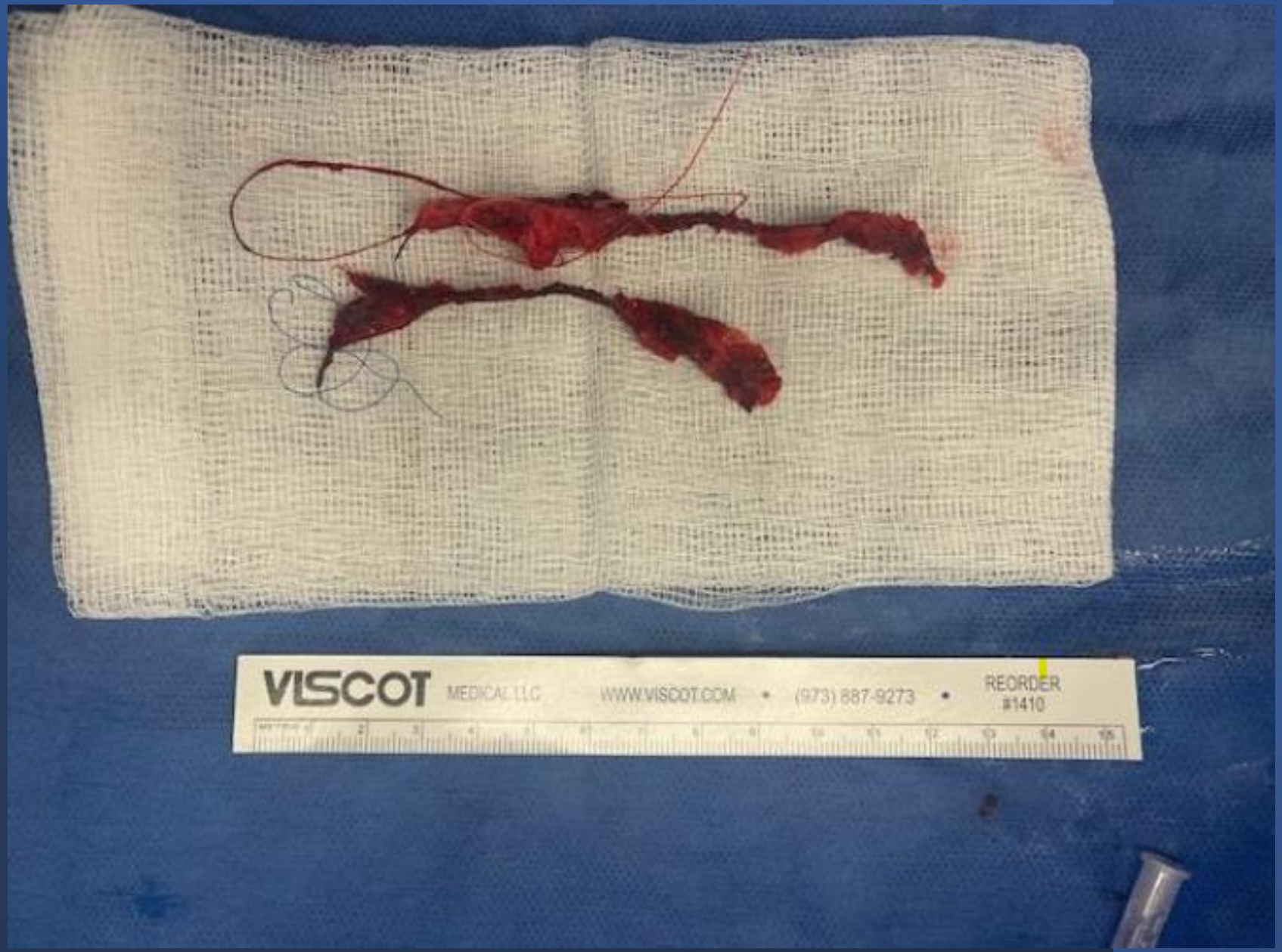
Surgical treatments cont...

Trimming / Excision - Protruding or problematic parts of the mesh are removed, but most of it remains intact.

Partial removal - Only specific sections causing complications are removed, leaving other parts intact ie: the vaginal portion of a mesh sling

Complete removal - The entire mesh is removed, usually in cases of severe complications such as pain or after other methods have been unsuccessful.

WDHB (2019)


VISCOT
MEDICAL LLC
WWW.VISCOT.COM
(973) 887-9273
REORDER
#1410

Currently there is a “pause” on insertion of SUI mesh

The pause will used to facilitate:

- Specialised training and certification for surgeons
- Creation of a comprehensive registry
- Multi-disciplinary reviews
- A more structured and thorough informed consent process for patients.

This is not a permanent ban – there may be some exceptional cases where the procedure might be deemed necessary by an MDT

Sally Walker

New Zealand Local Hero of the Year 2024

What do we want you to take away?

The importance of encouraging women to ask questions

1. Do I really need this test or procedure?
2. What are the risks?
3. Are there simpler safer options?
4. What happens if I don’t do anything?

Unwin (2019)

What do I think (hope!) we have learned?

The critical importance of rigorous clinical testing and post-market surveillance for medical implants.

A greater appreciation for the need to thoroughly understand the long-term risks associated with new treatments

The necessity for transparent, informed consent processes that clearly communicate potential complications to patients.

The significance of listening to and validating patient-reported symptoms, leading to improved patient-centered care approaches.

Where to go if you want to know more?

- https://www.tewhatuora.govt.nz/keeping-well/the-new-zealand-female-pelvic-mesh-service/
- https://whttps://www.health.govt.nz/publication/hearing-and-responding-stories-survivors-surgical-mesh
- www.health.govt.nz/publication/national-credentialling-framework-pelvic-floor-reconstructive-urogynaecological-and-mesh-revision
- https://www.waitematadhb.govt.nz/healthy-living/fph/resources/

Contact

The NZFPMS national email address

nzfpms@TeWhatuOra.govt.nz

Our email addresses

Susan.Rae@waitematadhb.govt.nz

Sara.Behrooze@waitematadhb.govt.nz

Questions ?