

PO Box 32 445, Devonport, Auckland 0744 Email: info@consumeradvocacyalliance.co.nz Website: www.consumeradvocacyalliance.co.nz

# Practical Information on Surgical Mesh and Mesh Complications

Written by Charlotte Korte (updated Feb 2024)

What should I know before choosing to have mesh surgery, or if I am experiencing surgical mesh complications?

# **Surgical Mesh Suspension!**

Surgical mesh stress urinary incontinence procedures have been suspended in New Zealand. Surgical mesh (tape/sling) procedures will only be available for some women- in very highly selected cases. These women must meet the exceptions criteria set out by the Ministry of Health.

#### 1. What products are known as surgical mesh?

The words that health professionals use to describe surgical mesh can be different, so it is important to know what type of mesh is being implanted, the kind of procedure you are having, and if the product they are using is a synthetic polypropylene mesh. (plastic)

Таре

TVT or TVT-0 Tension free support Sling (Mid-urethral sling) Patch Plug Mesh Graft Gauze Hammock The most common mesh used by surgeons today is non-absorbable, it is designed to stay in your body permanently. Surgical mesh is difficult to remove once it has been implanted, so consider this carefully before choosing surgery that uses mesh.

Synthetic mesh is used to treat stress urinary incontinence, rectal, bowel, vaginal, uterine, bladder prolapse and also for hernia repairs. There are also non-mesh procedures to treat these same conditions for example; using your own tissue, cadaver tissue and porcine (pig) tissue. This document primarily focuses on polypropylene (synthetic plastic) mesh. Mesh can be used in other procedures, not covered in this leaflet.

Both men and woman can be affected by mesh complications. Hernia mesh adverse events\* may not be reported as often as pelvic mesh related complications, yet if experienced they can also be severe.

\*An 'adverse event' is unintended or unexpected harm, or an injury associated with the use of an implanted medical device used during a surgical procedure, or harm from a medicine.

It is not always possible to treat mesh-related complications successfully. More than one surgery might be needed, and it may not be possible to fully remove the mesh.

## 2. Recognising the symptoms of surgical mesh complications.

Not everyone will experience mesh related complications, but, because problems can happen many years after it has been implanted, it is important to know what to look out for.

#### Pain is a common symptom

Pain can be extremely debilitating- people also experience different types of pain including a slow burning pain, intense pain, or short stabbing pain sensations, before/during and after bowel motions, pain in your leg, buttocks, back/sacral area, tailbone, groins, vagina, bladder/bowel, pelvic area.

Below is a brief summary of other mesh related symptoms, a more comprehensive list of mesh adverse events is at the end of this document- in Appendix One.

- Recurrent urinary tract infection
- Infection
- Discharge (vaginal or rectal)
- Difficulty urinating, also known as voiding dysfunction (Dysuria)
- Bleeding
- Pain during sexual intercourse (dyspareunia)
- Painful sex experienced by the man- men may feel the mesh during sexual intercourse. (hispareunia) although not as common
- Onset of auto-immune disorders
- Impact on quality of life, sitting, standing, walking, and functioning in everyday activities
- Nerve neuralgia a stabbing, burning, and often severe pain due to an irritated or damaged nerve.

Surgical mesh implants can cause exposure, which is where mesh pushes against and/or into the vagina. It can cut through into the bladder or urethra, surrounding tissue, or nerves, but this occurs much less often than vaginal exposure.

Research shows that mesh is no longer thought of as being inert; after many years the mesh material can shrink, and/or change over time, this is known as mesh contraction. Mesh contraction can cause pain. The formation of excessive adhesions (scarring) is more common with mesh surgery and can contribute to pain. Scarring/adhesions can create tension on nearby organs and tissues and affect bowel/bladder function.

## 3. What should you do if you start to experience any of these symptoms above.

It can be hard to know if your symptoms relate to your mesh implant, especially if your procedure was done years ago. Even if you are unsure if mesh is causing your symptoms, contact your doctor and highlight that you have had mesh implanted, regardless of how long ago it was.

- Go back to your GP or implanting surgeon to talk about your symptoms. If you do not feel as if your questions were answered properly, or you feel 'fobbed off' ask to be referred to another doctor to seek a second opinion.
- Ask your GP/surgeon to lodge a claim for injury cover with ACC. They will fill out an ACC45 and ACC2152 form.
- Ask your surgeon/GP to lodge an adverse event report to Medsafe, if they are unable, information on how to do this is provided later in this document. Reporting to Medsafe is important so we can track mesh injuries over time.
- You may feel more comfortable getting advice from other health professionals first, such as your physio, osteo or acupuncturist. They will need to have a good understanding of surgical mesh related symptoms.

## 4. Questions to ask your doctor – before having surgical mesh implanted.

- Can you explain all options available to me, including non-surgical treatment options, mesh surgery, and non-mesh procedures?
- What are the risks associated with using this mesh product?
- Why is mesh being suggested for me and what are the benefits over non-mesh surgery?
- How many mesh operations have you performed?
- How many removals of mesh have you undertaken?
- How many complications have you come across? What types of complications have your patients had?
- How many years later could I experience mesh related symptoms/complications?
- What brand of mesh will be used? What is the name of the device? Do you have a sample you can show me?

- Can you give me information to take away with me that has the type of device you are using, the brand (and name), and bar code written down?
- Will there be an opportunity to contact you with any questions I have before the day of the operation?
- What will my follow up care be like after the operation?
- What side effects can I expect after surgery and what side effects should I report to you?
- If there is a complication, will you be able to help me?
- Can you completely remove the device? How do you manage mesh complications?
- What happens if it can't be completely removed, what will that mean for me going forward?
- What happens if this surgery does not correct my problem?
- If I need mesh removed, will this fix the problem? Will I still be in pain after it is removed? What will this mean for me?
- I have heard that mesh complications can be severe, what does this mean for me in years to come?

## 5. Questions to ask your doctor – before a mesh removal procedure

There are two mesh specialist services available to help some people with mesh related complications. Not all New Zealanders have access to these services- it depends on the type of mesh device you have implanted.

Men suffering with hernia complications and women implanted with a rectopexy mesh device (only) cannot access these clinics. Hopefully in the future, patients suffering with rectopexy and hernia mesh complications will have access to help at similar specialist clinics, with surgeons experienced in managing mesh injury.

#### The New Zealand Female Pelvic Mesh Service – Te Whatu Ora - Health New Zealand

Seeking a second opinion from a different doctor is always a good idea, it will help you to feel more confident when making decisions regarding treatment. It may not be possible to have your mesh removed completely, this is dependent on your individual case and the type of device implanted.

If only part of the device is removed this can make it difficult to remove the whole implant at a later stage, and partial removals may result in you having to undergo multiple removal procedures. Ask how much of the device will be removed. Discuss if you are able to have a full removal, or if only a partial removal is possible with your surgeon. If your doctor is unable to remove the device fully, and this is what you would like, ask if they can refer you to someone who has the skills to achieve a complete explant (removal).

It helps to write down what you want to ask, before you visit your surgeon. It is good to take someone with you as a support person. If you think of other questions or information you

need to know, make sure you contact the surgeon after your appointment, leave plenty of time prior to your mesh removal surgery so you have time to think.

This bullet points below may help you to think of questions to ask your surgeon.

- Ask about your surgeon's surgical experience in mesh removal, are they are credentialed to remove mesh from difficult areas such as the sacral promontory, obturator muscle, obturator fossa (bone). Have they removed the entire mesh before.
- How much of the mesh will the surgeon remove; will they completely remove the implant or only what mesh is easily accessible?
- Check if the surgeon can remove the mesh fixation points i.e. staples, sutures, arms, anchors.
- Ask how many surgeries will need to be done to remove your mesh?
- If having a partial removal, how much of the mesh will be left in place. Where will the mesh be cut back from? What are the risks of leaving a part of the device in the deep tissues?
- Depending on the type of mesh implanted you may be able to have a trans-labial ultrasound scan to look at where the mesh is. Ask if this available where you live.
- For other mesh devices, you may need a CT scan or MRI. Check to see if this will be funded, or if you have to pay for this yourself.
- How many other surgeons will be involved during your mesh removal procedure, ask who will be the primary surgeon?
- Is the surgeon able to fix the repairs without using mesh? What will they use?
- How many native tissue repairs or non-mesh procedures has the surgeon done and how regularly do they do them?
- Has the surgeon had any problems with native tissue/non-mesh repairs?
- Is there a possibility you may become incontinent after removing the mesh? Can this be fixed at the same time as your mesh removal procedure?
- Ask if you will need a urinary catheter to void after the operation and how long this would be for?
- Ask the surgeon to provide a photo and measurements of your mesh once it has been removed. This can be helpful if you need further mesh removal procedures. You may be able to request that you take your mesh home with you, if this is what you want.
- You can request for your mesh to be sent for testing- talk to your surgeon first about what they would be specifically testing for, so you have a good understanding of why this would potentially be needed.
- Ask if you are eligible to access the mesh specialist clinics and wrap around care services -the two clinics in Auckland or Christchurch.

Some surgeons will sometimes cut a mesh tape to release tension if it is found to be too tight. If you need further surgical procedures later to manage complications, sling division can make it harder for surgeons to remove the mesh once the tape has been cut. Trimming of mesh is not recommended as it only delays problems to a later stage

#### 6. Mesh complications – physiotherapy and exercise

Physiotherapy can be beneficial but must only be done with an experienced pelvic health physiotherapist. You may also be referred to a continence nurse, the same applies.

You will need to check if your physio or continence nurse has knowledge and understanding of mesh injury. Mesh complications can result in nerve injury, therefore physiotherapists and continence nurses working with mesh injured patients need to be aware of pain trigger flares. They need to have a good understanding of mesh injury and the indications for and against vaginal examination.

## What can I expect from my pelvic floor physio?

Pre and post removal gait issues will be looked at, continence management, bowel management, pessary support and increased activity needs to be monitored carefully. Prior to mesh removal or afterwards, the focus is usually on maintenance of muscle strength (especially upper body), restoring full pelvic floor muscle function i.e. ability to fully contract and relax, pain assessment, pain management through exercise with stretching will be tailored to individual needs. Return to intercourse, return to exercise, return to activities of daily living advice is also given.

Internal assessment and examination by a physio or your continence nurse is only a small part of treatment; some find it very helpful, while others have not found it beneficial. More research is needed in this area to determine the benefit vs the risk. Talk with your health provider about both the risks and benefits. An experienced pelvic health physiotherapist will fully explain and talk this through with you beforehand and it will only be done if benefit is thought to be achieved for the patient and with informed consent provided by the patient.

#### Hypertonic floor

Often people suffering with mesh complications will have a hypertonic/overactive pelvic floor; there are a variety of symptoms to look out for, it is good to know what these are. <u>read here</u> A hypertonic pelvic floor means the muscles in your pelvic floor become too tense and are unable to relax. Doing the wrong kind of exercise trigger pain flares so making sure you are not doing the wrong type of exercise is important. For more information on how to relax your pelvic floor- <u>look here</u>

#### Auto-immune conditions and mesh implants

Research has shown a potential link between mesh surgery and the worsening of current auto-immune conditions, or onset of new auto-immune conditions. Clinical studies are ongoing and this link has not yet been fully established.

#### 7. What sort of help can ACC provide?

An ACC advocate can help you to navigate the ACC system after experiencing a surgical mesh adverse event. Getting your treatment injury accepted by ACC and dealing with ACC can be difficult so asking for help is a good idea. Please do not fill out the claim form yourself; this needs to be done by a health professional.

ACC advocate's role and contact details: <u>http://www.accesssupport.co.nz/?gclid=Cl-</u> <u>9tYrYp8ECFUccvAodGqwA9A</u>

ACC guidelines on what ACC covers for surgical mesh injury: <u>pelvic-surgical-mesh-ti-cover-</u> acc8210.pdf

General guidelines for treatment injury cover <u>Understanding complex cover (acc.co.nz)</u>

When your claim is lodged with ACC and your treatment injury has been accepted, you can ask for them to provide home help after your surgery and you are able to claim for other entitlements and supports). See list of entitlements is listed below).

## **ACC Summary of entitlements**

#### This list is a summary only, it may not include all that you are entitled to:

Treatment costs-	Contribution to a range of treatment costs, including but not limited to; visits to general practitioners and other health professionals, for example physiotherapists, psychologists, specialists, surgeons, radiologists, pain management services
Prescription medicine-	Reimbursement of the costs of pharmaceuticals linked to the covered injury
GP costs-	If you visit a GP for an ACC covered claim, there will be a co-payment that the client will pay. The amount payable by the client is dependent on how much the GP bills the client above the \$32.02 (GST excl) that ACC pays for the consultation.
MANAGING AT HOME	
Home help-	Help with general housework such as cleaning, vacuuming, laundry
Attendant care-	Help with personal care such as showering, bathing, getting dressed

Childcare-	Help with care of children, including taking them to and from school
Equipment-	Personal aids to help cope better at home, for example, shower stool, kitchen trolley
AT WORK	
Weekly compensation-	Payment of a weekly amount (usually up to 80% of the client's average weekly income) while off work because of an injury
Rehabilitation plan-	This can include a fitness programme, guidance on gradually returning to work, workplace equipment and retraining if necessary
TRANSPORT	
Travel subsidy-	Payment towards public or private transport costs to and from work or treatment (includes taxis)
Accommodation-	Help with accommodation costs for out-of-town treatment, flights if needed
SERIOUS INJURY	
Lump sum payment-	A tax-free, one-off payment for permanent impairment resulting from an injury
Car and home modifications-	Contribution to the purchase of a car (and/or modification) and home modifications such as ramps, widening doorways

#### Mental Impairment injury-

A client may develop a mental injury as a result of their covered treatment injury, for example depression If this happens the first step is that ACC will arrange a mental injury assessment. The purpose of this assessment is to link the mental injury to the covered physical injury. We call these Mental Injury caused by Physical Injury (MICPI). If a client is then covered for depression, the impairment from that additional diagnosis can be considered for lump sum compensation, alongside the other covered injuries. The assessments are carried out by medical practitioners trained in the use of the AMA Guides to the Evaluation of Permanent Impairment – 4th Edition. Following this assessment, a client is assigned an impairment rating and, if above 10%, clients receive

monetary compensation depending on the extent of the complication. This is a complex situation; ACC encourages anyone in this situation to talk to ACC directly.

The specific entitlements each client will have access to will depend on their individual injury. Historical expenses can be submitted to ACC if the client has receipts for those. The client's recovery team member will be able to help clients work through the entitlements that will be available to them. ACC also have a navigation service, details of which can be found on ACC website; <u>https://www.acc.co.nz/im-injured/claim-help/get-independent-support/</u>

#### 8. How to report surgical mesh adverse events to Medsafe

An 'adverse event' is unintended or unexpected harm, or an injury associated with the use of an implanted medical device used during a surgical procedure.

It doesn't matter how long ago your surgical device was implanted; it is **important** that your injury is reported to Medsafe. "Anyone can report an issue associated with a medical device. An issue may relate to an adverse event, or a quality issue. Patients, caregivers, healthcare professionals and suppliers are all encouraged to lodge an adverse event report if an incident has occurred and there is a concern about the safety of the device or its use".

If you your doctor is unable to fill out this report for you don't worry, Medsafe can help you with this if you need support.

Medsafe can request additional information from your doctor if needed so you don't have to do this yourself. If you would like Medsafe to contact your doctor or health provider you will need to give them signed permission. If you need assistance to complete this report, please contact + 64 4 819 6800 to speak to a Medical Device Advisor".

Medsafe adverse event reporting forms-

Adverse Event Reporting (medsafe.govt.nz) adverse-event-report-consumers.docx (live.com) Report a Problem (medsafe.govt.nz)

## **Appendix One**

Taken from Therapeutic Goods Association (TGA) website - Australia's regulatory body for medical device include: <u>Urogynaecological surgical mesh complications</u> | <u>Therapeutic Goods Administration (TGA)</u>

#### Adverse events associated with urogynaecological mesh procedures:

- punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel (these may require surgical repair)
- transitory local irritation at the wound site
- a 'foreign body response' (wound breakdown, extrusion, erosion, exposure, fistula formation and/or inflammation)
- mesh extrusion, exposure, or erosion into the vagina or other structures or organs as with all foreign bodies, mesh may potentiate an existing infection
- over-correction (too much tension applied to the tape) may cause temporary or permanent lower urinary tract obstruction
- acute and/or chronic pain
- voiding dysfunction
- pain during intercourse
- neuromuscular problems including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area
- recurrence of incontinence
- bleeding including haemorrhage, or haematoma
- seroma
- urge incontinence
- urinary frequency
- urinary retention
- adhesion formation
- atypical vaginal discharge
- exposed mesh may cause pain or discomfort to the patient's partner during intercourse mesh migration
- allergic reaction
- abscess
- swelling around the wound site
- recurrent prolapse
- contracture
- scarring
- excessive contraction or shrinkage of the tissue surrounding the mesh
- vaginal scarring, tightening and/or shortening
- constipation/defecation dysfunction
- atypical vaginal discharge
- exposed mesh may cause pain or discomfort to the patient's partner during intercourse
- mesh migration
- allergic reaction
- abscess
- swelling around the wound site
- recurrent prolapse
- contracture
- scarring
- excessive contraction or shrinkage of the tissue surrounding the mesh
- vaginal scarring, tightening and/or shortening
- constipation/defecation dysfunction
- granulation tissue formation