Treating complications from mesh used for stress urinary incontinence

Options for women referred to specialist centres

Patient decision aid



Is this decision aid for me?

This decision aid is for women who have complications caused by pelvic mesh that was used to treat their stress urinary incontinence. Pelvic mesh has also been called 'tape', 'net' or a 'sling'. Stress urinary incontinence is when you leak urine accidentally, especially during exercise or when you cough, laugh or sneeze.

This decision aid has been written for women who have been referred to a specialist centre to treat complications from mesh used for stress urinary incontinence.

If your mesh was for pelvic organ prolapse, see <u>NICE's decision aid on treating</u> <u>complications from mesh used for pelvic organ prolapse</u> (www.nice.org.uk/guidance/ ng123/resources).

If you have not been referred to a specialist mesh complication treatment centre, but you are concerned about symptoms you think might be caused by pelvic mesh, contact your GP for an assessment.



How this decision aid can help

This decision aid explains what the options are for treating the complications from pelvic mesh that you have. These include non-surgical and surgical options. It was developed with women who have been affected by pelvic mesh complications and healthcare professionals who treat and support them.

The decision aid can help you think about these options and what is most important to you. You and your specialist healthcare team can talk through the options and decide together which is the best option for you. (Your healthcare team might sometimes be called the multidisciplinary team, or MDT, because it includes people from different health professions and specialties.) The evidence on treating mesh complications is limited and there is no expert agreement on the best way to treat them.

Every woman is different, so this decision aid is only a guide. It is important to make the choice that you feel is right for you.

Your decision will depend on your individual circumstances and how you feel about each option. You might decide to try non-surgical options, or a combination of surgical and non-surgical options. You might decide that surgery is right for you. If you decide to have surgery you will be given detailed information about the type of surgery you are thinking of choosing.

You might also decide that you do not want to try any of these options just yet, and see how things go. Your healthcare team can continue to support you and keep your symptoms under review, so that you can try an option later if you wish.

Whatever you choose, you can also get help and support from patient organisations. Your healthcare team can put you in touch with these organisations.



What type of mesh did you have?

To help with your stress urinary incontinence, mesh was placed as a sling under the tube coming out of your bladder (the urethra) to support it.

There are different types of mesh sling and the type of sling you had affects what options are suitable for you. The types of mesh sling are shown in the diagram of a pelvis below. They are:

- (A) retropubic mid-urethral mesh sling (for example, TVT), shown in green.
- (B) single-incision mini-sling, shown in blue.
- (C) transobturator mesh sling (for example, TVT-O or TOT), shown in red.



Diagram based on original developed by NHS Lothian. Used with permission.



How might your mesh have caused complications?

Knowing how mesh can cause some complications is helpful when thinking about options for treating them.

- The mesh can come through into the vagina. This is called **vaginal mesh exposure** or **extrusion**. It can cause pain, vaginal discharge or bleeding, vaginal infections, or pain or problems having sex.
- The mesh can also come through into the **bladder** or the **urethra**. This can happen around the time you had the mesh surgery or some time later. It can cause problems including frequent urinary tract infections (UTIs), blood in the urine, difficulty emptying the bladder, pain when passing urine or having sex, leaking urine or having to get to the toilet quickly.
- The mesh sling may be **too tight**. This can cause problems with emptying the bladder.
- There may not be an obvious cause for some other problems that women who have had mesh surgery may experience. These include pain or changes in sensation (such as numbness or pins and needles) in the back, abdomen, pelvis, leg, vagina, groin or the area between the vagina and anus (the perineum), or problems in other parts of the body such as fibromyalgia (chronic pain in many different parts of the body).
- The type of mesh surgery you had can also lead to complications that are not directly caused by the mesh itself.



What are the options for treating mesh complications?

The options depend on the problems you are experiencing. They include non-surgical or surgical treatments, or you might choose a combination of these. But some options may be more suitable for you than others.

If mesh has come through into your bladder or urethra, your healthcare team will usually recommend surgery to remove this mesh. If your mesh is infected, your healthcare team will recommend specific treatments that may include surgery and antibiotics. It's possible that you also have complications from your mesh surgery that were not caused by the mesh itself. This decision aid does not cover treatments for those complications.

When you are thinking about the possible options for treating your mesh complications, it is important to think about your whole quality of life now and what you hope to gain from treatment. Treatment for mesh complications can take a long time and be mentally and physically demanding for you and your family. Unfortunately, there is no guarantee that your health will improve. There is space on page 11 for you to write down how you feel about the options. This will help you and your healthcare team decide what is likely to be the best option for you.

The next pages will go over what your non-surgical and surgical options are.



Non-surgical options

These include:

- **Specialist pelvic health physiotherapy.** Physiotherapists working in different specialist fields may help you with different aspects of your care. If you decide not to have surgery, physiotherapy can help with a range of mesh complications, including bladder problems, pain and general mobility. If you decide to have surgery, your physiotherapist will work with you before and after the operation to enhance your recovery, help deal with any new or persisting problems and improve your general wellbeing.
- **Specialist pain management.** A team of specialist pain management doctors, nurses, physiotherapists and psychologists work together to offer ways to control pain and its impact on your quality of life. Different approaches are used and these are tailored to you and your pain.
- **Psychological and psychosexual support.** This includes treatment for psychological problems caused by your physical mesh complications, and support throughout your treatment for mesh complications.

If you have only a small area of vaginal mesh exposure, you could try **vaginal oestrogen treatment**. This involves applying cream into the vagina. No mesh is removed. If the mesh insertion helped with your incontinence, you would keep those benefits. You can easily stop treatment if you wish, or think about having surgery later. If you have vaginal symptoms of the menopause it might also help them. However, vaginal oestrogen treatment is not likely to help if you have larger areas of vaginal mesh exposure. It may not be suitable for women with certain other conditions.



Surgical options

The different types of surgical treatments for vaginal mesh exposure or a mesh sling that is too tight are described in the table on the next pages.

The options can all help some women. But it is not possible to say for sure what will happen to any individual woman.

The evidence about how well each type of surgery works is limited and it will also depend on each woman's unique situation.

Surgery can also help with other kinds of complications, such as if the mesh is infected or has come through into your bladder or urethra. You will need to have a discussion with your surgeon about the possible options for you, how likely they are to help you and the likely risks. There is not enough study evidence for NICE to say whether surgery will help with problems in other parts of the body.

Although surgery might help your symptoms, you should also be aware that:

- It is not certain that removing the mesh will improve your symptoms.
- Surgery can cause further complications, which might harm your quality of life.
- For some mesh complications, removing only part of the mesh might work just as well as removing all of it.
- All surgery carries risks such as infection, bleeding and risk from the anaesthetic.



Surgical options to treat vaginal mesh exposure or a mesh sling that is too tight

For more details of what the procedures involve, see the detailed information for the type of surgery you are thinking of choosing.

	Division (cutting) of mesh to relieve the tension	Removing mesh that has come into the vagina	Removal of the vaginal part of the mesh sling	Removal of all the mesh sling, including anchors
What type of complication does this surgery treat?	A mesh sling that is too tight.	Vaginal mesh exposure.	Vaginal mesh exposure or a mesh sling that is too tight.	Vaginal mesh exposure or a mesh sling that is too tight.
What does this involve?	This usually involves an operation through the vagina. It can be done under local, spinal or general anaesthetic. It can usually be done as a day case, with no overnight stay in hospital.	This usually involves an operation through the vagina. It can be done under local, spinal or general anaesthetic. It can usually be done as a day case, with no overnight stay in hospital.	This usually involves an operation through the vagina. It can be done under spinal or general anaesthetic. It may need an overnight stay in hospital.	This may include incisions (cuts) in the vagina, groin and abdomen. It is usually done under general anaesthetic. It will need at least one overnight stay in hospital.
How much mesh is removed?	No mesh is removed.	Only the mesh that has come into the vagina is removed. The rest remains in the body.	The surgeon tries to remove most of the mesh around the vagina. Some mesh remains in the body.	The surgeon tries to remove all the mesh from the body but this is not always possible.
How extensive is the surgery?	The least extensive surgical option.	Less extensive than removing part or all of the mesh sling.	More extensive than just removing mesh that has come into the vagina.	The most extensive surgical option.
How does average time to recover compare? Recovery times vary from woman to woman.	This option usually has the shortest recovery time.	Recovery is usually quicker than if part or all of the mesh sling is removed.	Recovery usually takes longer than if only mesh that has come into the vagina is removed, but it is usually quicker than if all of the mesh sling is removed.	This option usually has the longest recovery time.

Surgical options to treat vaginal mesh exposure or a mesh sling that is too tight

(table continued)

	Division (cutting) of mesh to relieve the tension	Removing mesh that has come into the vagina	Removal of the vaginal part of the mesh sling	Removal of all the mesh sling, including anchors
How likely is it my stress urinary incontinence will come back?	Least likely with this option.	Less likely than if part or all of the mesh sling is removed.	More likely than if only mesh that has come into the vagina is removed.	More likely than with the other surgical options.
How likely is it this surgery will improve my symptoms?	It has been shown to be effective for some women, but your symptoms might not improve. It's possible that mesh will come into the vagina at a later date.	It has been shown to be effective for some women, but your symptoms might not improve and you might get new symptoms. It's more likely that mesh will come into the vagina again than if all or part of the mesh sling is removed.	It has been shown to be effective for some women, but your symptoms might not improve and you might get new symptoms.	It has been shown to be effective for some women, but your symptoms might not improve and you might get new symptoms. You will know that all the mesh has been removed (if this is possible), even if symptoms do not improve or get worse.
How likely am I to have other complications? For example, new or worse bladder problems, damage to nerves or organs, pain, numbness or changes in sensation.	Least likely with this option.	Less likely than if part or all of the mesh sling is removed.	More likely than if only mesh that has come into the vagina is removed.	More likely than with the other surgical options.

Surgical options to treat vaginal mesh exposure or a mesh sling that is too tight

(table continued)

	Division (cutting) of mesh to relieve the tension	Removing mesh that has come into the vagina	Removal of the vaginal part of the mesh sling	Removal of all the mesh sling, including anchors
Will I need further surgery later?	You might need further surgery if mesh comes into the vagina at a later date, or to treat urinary incontinence if that comes back.	You might need further surgery if mesh comes into the vagina again, or to treat urinary incontinence if that comes back.	You might need further surgery to treat complications of the removal surgery or urinary incontinence if that comes back.	You might need further surgery to treat complications of the removal surgery or urinary incontinence if that comes back.
What if it does not work?	You could go on to have surgery later to remove part or all of the mesh. You could try non-surgical treatments such as specialist physiotherapy, psychological support and pain management.	You could go on to have surgery later to remove part or all of the mesh. You could try non-surgical treatments such as specialist physiotherapy, psychological support and pain management.	You could have surgery later to try to remove all the mesh. But if you had a transobturator sling or a mini-sling it may be more difficult to find and remove the groin parts of the mesh sling if the vaginal portion has been removed. You could try non-surgical treatments such as specialist physiotherapy, psychological support and pain management.	You could try non-surgical treatments such as specialist physiotherapy, psychological support and pain management.

How do you feel about the options?

You can use this section to write down what is most important to you and what you think about the options. You might also want to discuss this with family or friends. This will help you and your healthcare team decide together what is likely to be the best option for you.

My goals and fears

Which problems are most troubling to you? Which do you hope will be helped by treatment?

What possible problems from treatment are you most concerned about?

My preference at the moment (I can change my mind later)

What do you think is likely to be the best option for you right now? Why is that? Or are you not sure at the moment?

What other things would you like to talk to your healthcare team about?



About this decision aid

The Independent Medicines and Medical Devices Safety Review published a report that included complications from mesh implants in July 2020. (The report is also known as the Cumberlege review or Cumberlege report, after the Chair, Baroness Julia Cumberlege).

The report recommended that specialist centres should be set up to provide comprehensive treatment, care and advice for those affected by implanted mesh. These specialist centres were commissioned by NHS England and NHS Improvement to begin operating in April 2021. The report also noted that 'Patients must have sufficient understanding of their treatment, including the potential risks it presents, and the alternative treatment options, including doing nothing, in order to decide whether they are willing to have that treatment.' It highlighted the potential value of well-produced decision aids and recommended that NICE should lead in facilitating their development.

NHS England and NHS Improvement asked NICE to develop decision aids for women referred to specialist mesh complication treatment centres. They were developed in line with <u>NICE's process guide for decision aids</u> (see www.nice.org.uk/sdm) and are based on the <u>NICE guideline on urinary incontinence and pelvic organ prolapse in women</u> published in April 2019 (see www.nice.org.uk/guidance/ng123). The decision aids were developed with an oversight group that included women who have been affected by mesh complications and specialist healthcare professionals.

Patient and professional groups, as well as healthcare professionals involved in setting up the specialist treatment centres, were invited to comment on the draft decision aids. This version (March 2021) will be reviewed in practice in the specialist centres once they are in operation and revised as necessary. It will also be updated if relevant recommendations in the NICE guideline are amended.

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