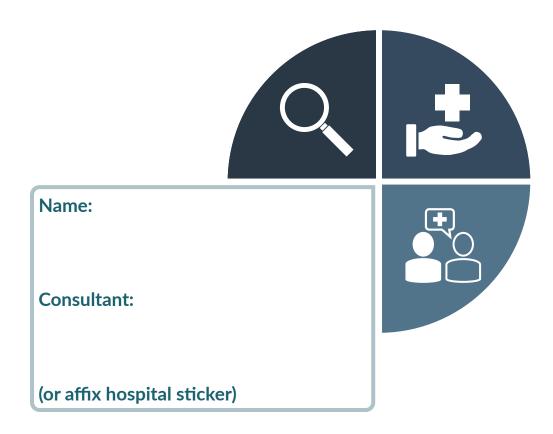


Treating complications from mesh used for pelvic organ prolapse

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 pelvic organ prolapse. Pelvic mesh has also been called 'net'. Pelvic organ prolapse is when one or more of the organs in the pelvis, such as the vagina, uterus, bladder or bowel, slips down from its normal position.

This decision aid has been written for women who have been referred to a specialist centre to treat complications from mesh used for pelvic organ prolapse.

If your mesh was for stress urinary incontinence, see <u>NICE's decision aid on treating complications from mesh used for stress urinary incontinence</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?

Mesh has been used in different ways to help with pelvic organ prolapse. The way it was inserted affects what options are suitable for you.

Vaginally inserted mesh

Mesh inserted through incisions (cuts) in the vagina was used for:

- Prolapse of the **bladder** into the vagina (also called cystocele).
- Prolapse of the **rectum** into the vagina (also called rectocele).

The mesh will have been stitched into place to strengthen the repair and support the wall of the vagina.

Abdominally inserted mesh

Mesh inserted through incisions (cuts) in the abdomen can be used for:

- Prolapse of the womb (uterus). This procedure is called sacrohysteropexy.
- Prolapse of the **vagina** in women who have had a hysterectomy. This procedure is called sacrocolpopexy.
- Prolapse of the **rectum**. This procedure is called rectopexy. Sacrohysteropexy or sacrocolpopexy is sometimes done at the same time as rectopexy.

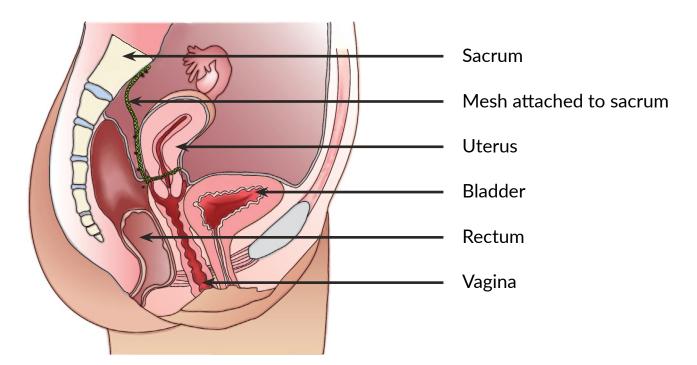
These procedures involve attaching mesh from the prolapsed organ to a bone at the base of the spine, called the sacrum.

The diagrams on the next page show where the mesh was placed for sacrohysteropexy and sacrocolpopexy.

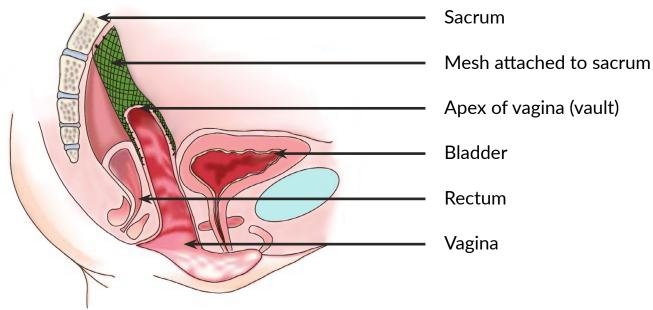


What type of mesh did you have?

Sacrohysteropexy



Sacrocolpopexy



Diagrams based on originals developed by the British Society of Urogynaecology. 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 bowel, the bladder or the tube coming out of your bladder (the urethra). This can happen around the time of surgery or some time later. This might cause bladder problems, including frequent urinary tract infections (UTIs), blood in the urine, difficulty emptying the bladder or having sex, pain when passing urine, leaking urine or having to get to the toilet quickly. Possible bowel problems include pain or difficulty when you open your bowels, not getting to the toilet in time, bleeding from the anus or passing mucus.
- 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, and whether your mesh was inserted through incisions in your vagina or your abdomen.

Options 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 urethra, bladder or bowel, 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 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 12 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 and bowel 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 a cream into the vagina. No mesh is removed. If the mesh insertion helped with your prolapse, 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

If your mesh was inserted through incisions in the vagina, the options are explained in the table on the next pages.

If your mesh was inserted through incisions in your abdomen, you will need to have a discussion with your surgeon about the possible options for you and how likely they are to help you. It may not be possible to remove all the mesh and your symptoms may not improve. You will usually need surgery to your abdomen, a general anaesthetic and one or more overnight stays in hospital.

This kind of surgery can cause particular complications and you might need further surgery to treat them. These include your prolapse coming back or damage to your bowel or bladder. Depending on where the mesh is removed from, it's possible that you could develop a fistula (an opening between your vagina and your bladder), or you might need a temporary or permanent stoma after mesh removal (a stoma is when one end of the bowel is diverted to a new opening in the abdomen).

Surgery can 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. 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 risks from the anaesthetic.



Surgery for complications from mesh that has been inserted through your vagina

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

	Removal of mesh that has come into the vagina	Removal of mesh from the vagina wall	Removal of all of the mesh from the vagina wall and the pelvis
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 spinal or general anaesthetic. It will need an overnight stay in hospital.	This usually involves an operation through the vagina but may also need cuts in the groin. It is usually done under general anaesthetic. It will need at least one overnight stay in hospital.
How much 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 from the vagina wall. Mesh embedded deep in the pelvis 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?	This is the least extensive surgical option.	More extensive than just removing the mesh that has come into the vagina, but less extensive than removing all the mesh.	This is the most extensive surgical option.
How does the average time to recover compare? Recovery times can vary from woman to woman.	This option usually has the shortest recovery time.	Recovery usually takes longer with this option compared with just removing the mesh that has come into the vagina.	This option usually has the longest recovery time.

Surgery for complications from mesh that has been inserted through your vagina

(table continued)

	Removal of mesh that has come into the vagina	Removal of mesh from the vagina wall	Removal of all of the mesh from the vagina wall and the pelvis
Will my prolapse come back?	This is less likely than with the other surgical options.	This is more likely with this option than just removing the mesh that has come into the vagina.	This is 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 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.	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 with this option than if all or part of the mesh is removed.		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? These might be new or worse problems, including damage to nerves or organs, bladder or bowel problems, problems having sex, pain, numbness or changes in sensation.	Complications are least likely with this option.	Complications are more likely with this option compared with just removing the mesh that has come into the vagina.	Complications are more likely than with the other surgical options.

Surgery for complications from mesh that has been inserted through your vagina

(table continued)

	Removal of mesh that has come into the vagina	Removal of mesh from the vagina wall	Removal of all of the mesh from the vagina wall and the pelvis
Will I need further surgery later?	You might need further surgery if mesh comes into the vagina again.	 You might need further surgery: if mesh comes into the vagina again to treat complications of the removal surgery if your prolapse comes back. 	 You might need further surgery: to treat complications of the removal surgery if your prolapse 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 have surgery later to try to remove all of the mesh, but this may be more difficult if part of the mesh has already 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 NICE's process guide for decision aids (see www.nice.org.uk/sdm) and are based on the NICE guideline on urinary incontinence and pelvic organ prolapse in women 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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