

Central Manchester University Hospitals NHS Foundation Trust

Saint Mary's Hospital Gynaecology Service – Warrell Unit

What do I need to know about Mesh Implants in Prolapse Surgery?

Information for Patients

Central Manchester University Activities Diss Saint Mary's Hospital

Manchester Royal Eye Hospital Manchester Royal Infirmary Grafton Street

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What is a mesh?

A mesh is a material used in prolapse surgery. A prolapse is a bulge or lump in the vagina caused by sagging of the vaginal walls and/or uterus (womb). This sagging happens because the natural supporting tissues which hold the vaginal walls and uterus in place have become weak. The mesh is used to try to replace or strengthen these supporting tissues.

There are lots of different meshes available. Some are absorbed by the body and some stay in place forever.

What is the advantage of using a mesh?

During operations for prolapse, the surgeon tries to repair or strengthen the weakened supporting tissues. However, it has been known for a long time that these repairs can fail. This can mean that the prolapse comes back.

In order to reduce the risk of surgery failing, mesh materials have been developed with the aim of strengthening the repair. Permanent mesh provides lifelong strength.

The first meshes used were similar to the strong meshes used by surgeons to treat a hernia (rupture) in the tummy wall. However, the vagina is very different to the tummy wall and the meshes have changed over the years as we have learnt more about how they behave once they have been inserted.

What are the disadvantages of a permanent mesh?

Unfortunately, there are disadvantages of inserting any artificial material into the body. Rarely, the material can become infected or recognised by the body as 'foreign' and be rejected. Scar tissue can form around the mesh making the vagina stiffer and causing pain, especially during intercourse. Over time, the mesh can wear through the tissues so that it pokes through the vaginal skin, or less commonly, through the wall of the urethra, bladder or bowel. This is called erosion and can occur many years after the mesh has been put in.

All meshes are not the same and some seem to have much lower risks of problems than others. However, erosion often needs further surgery to remove parts or all of the mesh/tape. Removing mesh/tape from the urethra, bladder or bowel can be complicated surgery.

In contrast, prolapse is not dangerous or harmful condition. The risk of having complications from the mesh needs to be weighed carefully against the bother you are getting from your condition.

What are the disadvantages of an absorbable mesh?

Absorbable meshes are gradually absorbed by the body. The speed at which this happens is different for everyone. For some women, the mesh may disappear very quickly before the body has had time to heal fully from the surgery. This may make it more likely that the prolapse will come back. For some women, the mesh is absorbed very slowly and can be still there many years after it was put in.

Absorbable meshes can become infected or rejected in the same way as permanent meshes. They have less risk of wearing though tissues over time. However, they seem to have a much lower chance of preventing the prolapse coming back than permanent meshes. Some clinical trials have suggested that they are no better than a traditional repair with no mesh of any kind.

For some kinds of prolapse surgery, such as keyhole surgery to support the top of the vagina after a hysterectomy (laparoscopic sacrocolpopexy), absorbable mesh doesn't work.

If I would like a prolapse repair that uses mesh, what can be done to reduce the risk of a mesh complication?

Most women in the UK having an operation for prolapse will **<u>not</u>** need mesh.

Mesh can be very helpful in operations for vault prolapse (Laparoscopic sacrocolpopexy) or for keyhole surgery to treat uterine prolapse (Laparoscopic sacrohysteropexy). Leaflets are available about both of these operations. At the start of these operations, antibiotics are given to reduce the risk of the mesh becoming infected.

The type of mesh used in the Warrell Unit appears to have a very low rate of erosion compared to other meshes. The risk of the mesh wearing into the vagina can be further reduced by avoiding making cuts in the vaginal skin. If this is not possible, such as in a sacrohysteropexy, they are kept as small as possible.

Smokers are at much higher risk of mesh erosion than nonsmokers. Stopping smoking may, therefore reduce the risk.

Some women, who have already had a vaginal repair for prolapse which hasn't lasted, may consider a vaginal mesh to try and prevent another recurrence. Inserting mesh through cuts in the vagina increases the risk of mesh complications, especially if a hysterectomy is done at the same time. It may be best to avoid a hysterectomy and consider the advantages and disadvantages of using mesh in a vaginal repair carefully before going ahead. Around 5 in 100 (1 in 20) women have pain which continues after the wounds have healed. Around 6 in 100 women will develop mesh erosion after having mesh inserted during a vaginal repair. Around 15 in 100 (1 in 7) women feel their sex life has worsened after having mesh inserted at the time of a vaginal repair.

What do other doctors/organisations think about using mesh?

Surgeons have had concerns for many years about the potential for meshes to cause complications in some women. Several studies have been performed to try to find out exactly what the advantages and disadvantages of these operations are. So far, the results have given different, sometimes opposite, results.

Some very large studies are being performed in the UK at the moment and they will provide more information over the next few years.

The FDA (the US Food and Drug Administration, who regulate mesh in the USA) have also been concerned about mesh complications. They have published advice for both doctors and patients in the USA about using mesh.

They are more concerned about vaginal mesh repairs for prolapse rather than keyhole procedures.

The National Institute for Health and Clinical Excellence (NICE) have also published advice for doctors about using mesh in the UK.

How will I know if I have developed a problem with my mesh?

Although problems can occur, most women will never have a problem with their mesh.

Often, the symptoms of mesh problems are 'non-specific'. This means that they could be caused by other things and not your mesh. However, problems with mesh can be difficult to spot and being seen at a specialist centre, such as the Warrell Unit, can be very helpful. Mesh problems can give symptoms such as:

- Pain in the vagina or bladder.
- Pain during sex for you or your partner.
- Discharge or bleeding from the vagina.
- Frequent urinary tract infections.
- Worsening problems with having to rush to pass water or going to pass water very frequently.

If you have concerns, you should discuss them with your doctor at the Warrell Unit.

If you do experience a mesh complication, you can expect us to:

- Explain the diagnosis and treatment necessary to you in a way that you can understand.
- Report the mesh complication to the relevant authority (in the UK this is the Medicines and Healthcare products Regulatory Agency (MHRA) in a way that protects your medical confidentiality.

I have had a mesh inserted in the past, should I be worried?

As it says above, most women will never have a problem with their mesh. If you have no symptoms which might suggest a problem, there is no need to worry.

If symptoms start and you are worried, speak to your GP and ask to see a specialist if necessary.

Stopping smoking might help to reduce the risk of a problem occurring in the future.

Checklist of questions to ask your doctor before having a mesh inserted

You should let your doctor know if you have had a reaction in the past to mesh materials such as polypropylene. You might find it helpful to ask your doctor the following questions before having an operation which involves mesh:

- What are the pros and cons of using mesh in my particular case?
- Could the operation be done without mesh?
- What is your experience of using this particular mesh? What experience have your other patients had with this product?
- What is your experience of dealing with complications from this product?
- What should I expect to feel after my operation and for how long?
- Are there any specific side effects that I should let you know about after the surgery?
- What happens if the mesh doesn't help my problem?
- If I have a complication, can the mesh be removed and what would the consequences be?
- Is there a patient information leaflet that comes with the product? Can I have a copy?

Other sources of information

The Royal College of Obstetricians and Gynaecologists has a statement about mesh use, which includes some useful links to other websites, here:

www.rcog.org.uk/news/rcog-statement-report-commissionedmhra-vaginal-tape-and-mesh-implants

The FDA advice regarding mesh can be found here:

www.fda.gov/MedicalDevices/Safety/Alertsand Notices/ ucm142636. htm#popsui

There is information about medical devices, such as mesh, available from the MHRA. Their website can be found at:

www.mhra.gov.uk

The NICE guidelines about mesh procedures for prolapse can be found on their website:

www.nice.org.uk

Violence, Aggression and Harassment Control Policy

We are committed to the well-being and safety of our patients and of our staff. Please treat other patients and staff with the courtesy and respect that you expect to receive. Verbal abuse, harassment and physical violence are unacceptable and will lead to prosecutions.

Suggestions, Concerns and Complaints

If you would like to provide feedback you can:

- Ask to speak to the ward or department manager.
- Write to us: Patient Advice and Liaison Services, 1st Floor, Cobbett House, Manchester Royal Infirmary, Oxford Road, Manchester M13 9WL
- Log onto the NHS Choices website www.nhs.uk click on 'Comments'.

If you would like to discuss a concern or make a complaint:

- Ask to speak to the ward or department manager they may be able to help straight away.
- Contact our Patient Advice and Liaison Service (PALS) Tel: 0161 276 8686 e-mail: pals@cmft.nhs.uk. Ask for our information leaflet.

We welcome your feedback so we can continue to improve our services.

Please use this space to write down any questions or concerns you may have.		

No Smoking Policy

The NHS has a responsibility for the nation's health.

Protect yourself, patients, visitors and staff by adhering to our no smoking policy. Smoking is not permitted within any of our hospital buildings or grounds.

The Manchester Stop Smoking Service can be contacted on Tel: (0161) 205 5998 (www.stopsmokingmanchester.co.uk).

Translation and Interpretation Service

It is our policy that family, relatives or friends cannot interpret for patients. Should you require an interpreter ask a member of staff to arrange it for you.

تنص سياستنا على عدم السماح لافر اد عائلة المرضى او اقاربهم او اصدقائهم بالترجمة لهم. اذا احتجت الى مترجم فيرجى ان تطلب ذلك من احد العاملين ليرتب لك ذلك.

ہماری یہ پالیسی ہے کہ خاندان ، رشتہ دار اور دوست مریضوں کےلئے ترجمہ نہیں کرسکتے۔ اگر آپ کومترجم کی ضرورت ہےتو عملے کےکسی رُکن سے کہیں کہ وہ آپ کےلئے اس کا بندوبست کردے۔

ইহা আমাদের নীভি যে, একজন রোগীর জন্য তার পরিবারের সদস্য, আত্মীয় বা কোন বন্ধু অনুবাদক হতে পারবেন না। আপনার একজন অনুবাদকের প্রয়োজন হলে তা একজন কর্মচারীকে জানান অনুবাদকের ব্যবস্থা করার জন্য।

Nasze zasady nie pozwalają na korzystanie z pomocy członków rodzin pacjentów, ich przyjaciół lub ich krewnych jako tłumaczy. Jeśli potrzebują Państwo tłumacza, prosimy o kontakt z członkiem personelu, który zorganizuje go dla Państwa.

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我们的方针是,家属,亲戚和朋友不能为病人做口译。如果您需要口译员,请叫员工给您安排。







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