Royal Cornwall Hospitals
NHS Trust

Mesh in gynaecological operations

Information for women considering surgical treatment options

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What is mesh?

'Mesh' is a broad term used to describe a number of different types of manufactured biological or synthetic implantable devices. It is important to understand the difference:

- graft – a sheet of absorbable biological material commonly made from either bovine (cow) or porcine (pig) sources. Such tissues are highly processed so that only a fibrous material remains.
- implant – a flat strip of a synthetic structure made from absorbable (graft) or non-absorbable (mesh) material.
- mesh – a net-like synthetic fabric with open spaces. It is a permanent implant usually made from non-absorbable polypropylene (prolene) material.

Is mesh use new in surgical operations?

Mesh is used in a range of surgical procedures to support tissues. Mesh has been used in inguinal hernia repairs since the 1930's. In gynaecology, use of synthetic mesh is one of the surgical options for the treatment of stress urinary incontinence (SUI) and for vaginal pelvic organ prolapse (POP). Synthetic mesh has been used for abdominal approach to the vault (top of the vagina after hysterectomy) prolapse operation since the 1950's.

What is this leaflet about?

There is some current controversy over the use of mesh in gynaecology.
For many women, surgical procedures using mesh provide an effective form of treatment for the distressing effects of SUI and POP. However, some women experience complications and there are a number of patient communities who are campaigning to raise awareness of these concerns.

There is certainly a need to be aware of these risks. However, it is equally important to understand that there are a lot of women who have benefitted from the use of vaginal mesh tapes for treatment of SUI.

There is no proven scientific explanation so far for the concerns raised such as vaginal pain. Factors that can contribute to reported symptoms of vaginal pain and exposure of mesh tape in the vagina include: patient age, obesity, smoking, background history of chronic pain, fibromyalgia, associated procedures

(eg hysterectomy) and the surgeon's experience. Long term data on the use of vaginal mesh tapes is needed.

How does this affect me?

If you have been diagnosed with SUI or POP, you may be offered a number of different options (non-surgical and surgical) to treat or manage your condition. These will depend on the severity of your symptoms, your age and health, and whether you are planning to have children in the future.

Non-surgical treatment options for both conditions include pelvic floor exercise and lifestyle changes, such as losing weight, eating a high-fibre diet, cutting down on caffeine and alcohol, and avoiding heavy lifting and standing for long periods.

It is currently recommended that operations using mesh are only performed by specialists with expertise in this technique, and only after a full discussion about the benefits and risks of such surgery with the patient. Detailed information should be given to help with decision-making. The retropubic (tape that goes behind the pubic bone) is the preferred option to surgically treat SUI compared to other routes of synthetic mesh tape insertion for SUI.

If you are considering an operation using mesh (vaginal/keyhole/open operation through the tummy) you should have a detailed discussion with an expert healthcare professional about the benefits and risks of the operation for you. If you decide to go ahead with a procedure using mesh, the operation should only be performed by a specialist with expertise in this technique.

What information is available?

NHS England has developed two information leaflets to support women's decision-making. These look at the benefits and risks of mesh surgery to help you decide whether this is the best option for you. To help your decision, please discuss this information with your healthcare team and feel free to ask any questions you may have.

- Synthetic vaginal mesh tape procedure for the surgical treatment of stress urinary incontinence in women
  www.rcog.org.uk/globalassets/documents/patients/patient-information-leaflets/gynaecology/suimeshleaflet.pdf

- Surgical procedures for treatment of pelvic organ prolapse in women www.rcog.org.uk/globalassets/documents/patients/patient-information-leaflets/gynaecology/popmeshleaflet.pdf

The Royal College of Gynaecology (www.rcog.org.uk) provides additional information about alternative treatments for:

- incontinence and bladder problems
- pelvic organ prolapse.

What do we do at The Royal Cornwall Hospital?

Patient-centred care is fundamental to the treatment of patients with stress urinary incontinence and prolapse – this should include patient choice and shared decision making supported by robust clinical governance.

There is a lack of long-term follow up and related outcome data, including information on quality of life and activities of daily living. At Royal Cornwall Hospital (RCHT) we enter surgical outcomes on the British Society of Urogynaecology (BSUG) audit database (operation data and follow-up data). Since 2013 this has been presented on a yearly basis to the gynaecology audit and governance meeting. You will be asked permission to enter your information into the national BSUG database. (At Royal Cornwall Hospital we have not been offering vaginal synthetic mesh for POP surgery since 2013.)

- We follow agreed care pathways and recognise the importance of multidisciplinary team (MDT) assessment.
- Any patient-raised concerns and reported adverse serious concerns are reported to MHRA and entered on BSUG.

What has been done nationally?

Informed consent is a fundamental principle underlying all healthcare interventions.

Most hospital Trusts in the United Kingdom have their own Trust-specific leaflets. However, the BSUG has various working committees and its 'Information Committee' works on developing patient information leaflets in

urogynaecology. These are available on the BSUG website under 'information for patients': www.bsug.org.uk/pages/information-for-patients

The committee continues to develop further information leaflets and the information on mesh use in urogynaecology operations is under progress.

Support groups

There are a number of patient groups that provide information and support:

- TVT Mum – www.tvt-messed-up-mesh.org.uk/tvt-mum-support-group-uk.html
- TVT Info – www.tvtinfo.wordpress.com
- Scottish Mesh Survivors – www.scottishmeshsurvivors.com
- Sling The Mesh – www.slingthemesh.wordpress.com

Further information

There have been a number of national reports into the use of mesh which provide more detail about the current debate around use of mesh. The reports also provide a number of recommendations:

- NHS England – Mesh Oversight Group Report (July 2017) www.england.nhs.uk/publication/mesh-oversight-group-report
- Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women – Final Report (March 2017) www.gov.scot/Publications/2017/03/3336
- NHS England – Mesh Working Group: Interim Report (December 2015) www.england.nhs.uk/ourwork/qual-clin-lead/mesh
- Medicines and Healthcare products Regulatory Agency (MHRA) – Vaginal mesh implants: summary of benefits and risks (November 2014) www.gov.uk/government/publications/vaginal-mesh-implants-summary-of-benefits-and-risks

- The government has announced plans for an audit of problems caused by vaginal mesh. The audit, which aims to better understand complications related to mesh implants used for incontinence and prolapse, is expected to be completed by April 2018. More details can be found on: www.bmj.com/content/360/bmj.k586.full
- As part of the regular update programme, National Institute of Clinical Excellence (NICE) is currently revising its guidelines on female urinary incontinence and pelvic organ prolapse and these are due to be published in 2019.

What if I have had a prolapse or urinary incontinence procedure using synthetic mesh?

If you have had a prolapse or urinary incontinence procedure using synthetic mesh and have not experienced any concerns such as vaginal pain soon after the procedure, it is unlikely that you will have such concerns in future. Other risks such as vaginal exposure of the mesh is more related to vaginal thinning and lack of oestrogen that comes with ageing. If you experience symptoms such as vaginal bleeding, pain or bleeding with sexual activity, please report these to your doctor/healthcare professional. There is a central database of units that can see women who are experiencing significant problems following mesh surgery for SUI or POP. You can access this through the link:

www.bsug.org.uk/pages/information-for-patients

Your healthcare professional should report the complication to a national registry. This will ensure the NHS has full details of the number and type of complications experienced by women across the country, which will inform decisions about future guidance. You can also report complications yourself, directly to the Medicines and Healthcare products Regulatory Agency (MHRA) via their website, which also includes FAQs for members of the public:

www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

If you would like this leaflet in large print, braille, audio version or in another language, please contact the General Office on 01872 252690

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