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South Tees Hospitals
NHS Foundation Trust

Retropubic mid urethral sling (RP-MUS)

(also know as tension free vaginal tape, TVT)

An operation for stress incontinence using a plastic mesh tape

Obstetrics and Gynaecology
Patient information

Retropublic mid urethral sling

Contents

About this leaflet

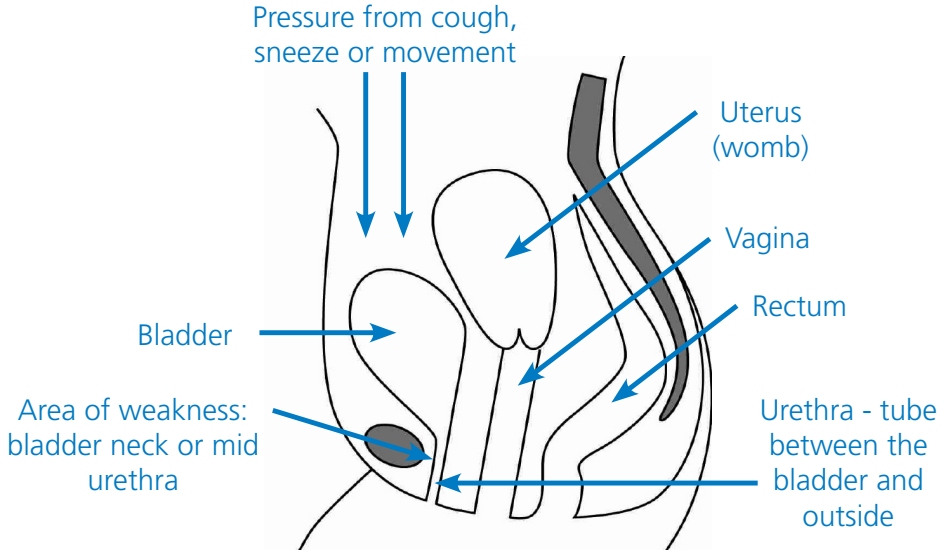
We advise you to take your time to read this leaflet, any questions you have please write them down on the sheet provided (towards the back) and we can discuss them with you at our next meeting. It is your right to know about the operations being proposed, why they are being proposed, what alternatives there are and what the risks are. These should be covered in this leaflet.

This leaflet firstly describes what stress incontinence is, it then goes on to describe what alternatives are available within our trust, the risks involved in surgery and finally what operation we can offer.

What is stress incontinence?

Stress incontinence is the leakage of urine usually caused by an increase in pressure in the abdomen (tummy) when there is a weakness in the bladder neck.

Figure 1: Your anatomy - woman in upright position showing pressure above the bladder and a weak bladder neck.



This weakness is usually caused by childbirth in the first instance when the pelvic floor muscles are damaged. Further weakening occurs during the menopause because the quality of the supporting tissues deteriorates.

The pressure in the abdomen rises when you cough, sneeze or even bend, turn or jump and results in urine leakage. This can cause a lot of distress and limits your quality of life.

It must be understood that these operations will not cure all urinary symptoms. They will only cure urinary symptoms caused by a weakness in the bladder neck. Many urinary symptoms seen in clinic are not caused by a weakness in the bladder neck.

Are there any alternatives to this surgery?

Do nothing – if the leakage is only very minimal and is not distressing then treatment is not necessarily needed.

Pelvic floor exercises (PFE) - The pelvic floor muscle runs from the coccyx at the back to the pubic bone at the front and off to the sides. This muscle supports your pelvic organs (uterus, vagina, bladder and rectum) and your bowel. Any muscle in the body needs exercise to keep it strong so that it functions properly. This is more important if that muscle has been damaged. PFE can strengthen the pelvic floor and therefore give more support to the pelvic organs. These exercises may not get rid of the leakage but they may make it less troublesome.

PFE are best taught by an expert who is usually a physiotherapist. These exercises have little or no risk and even if surgery is required at a later date, they will help your overall chance of being more comfortable.

Devices - There are numerous devices (none on the NHS) which essentially aim to block the urethra. The devices are inserted either into the vagina or the urethra. They are not a cure but their aim is to keep you dry whilst in use, for example during 'keep fit' etc. Please speak to your consultant if you want further advice.

Alternative operations - please see leaflet 41: TO-MUS

An alternative operation to the RP MUS:

1. Bulking agent
2. TO-MUS (No. 41)
3. Colposuspension (No. 32)
4. Autologous fascial sling

The benefits of stress incontinence surgery

80% (80 in every 100) women are substantially improved. This means you may get back to: physical activity – running, dancing, gym, horse riding etc, gardening, resuming sexual relations if you have had to stop.

This also means you may have renewed confidence so that:

- You can go shopping etc without fear of leaking
- You do not have to worry about damp patches on clothing, in the car etc
- You do not have to worry about unpleasant odours.

General risks of surgery

Anaesthetic risk. This is very small unless you have specific medical problems. This will be discussed with you.

Haemorrhage. There is a risk of bleeding with any operation. The risk from blood loss is reduced by knowing your blood group beforehand and then having blood available to give you if needed. It is rare that we have to transfuse patients after their operation.

Infection. There is a risk of infection at any of the wound sites. A significant infection is rare. The risk of infection is reduced by our policy of routinely giving antibiotics with major surgery.

Deep vein thrombosis (DVT). This is a clot in the deep veins of the leg. The overall risk is at most four or five percent although the majority of these are without symptoms. Occasionally this clot can migrate to the lungs which can be very serious and in rare circumstances it can be fatal (less than one percent of those who get a clot). DVT can occur more often with major operations around the pelvis and the risk increases with obesity, gross varicose veins, infection, immobility and other medical problems. The risk is significantly reduced by using special stockings and injections to thin the blood (heparin).

Specific risks of this surgery

Although there are specific risks and complications, which you may have heard about in the media; the risk of these complications overall, is less than the risk of other complications in some of the other operations that can be performed.

Failure: 20% (20 in every 100) of women do not gain adequate benefit from the operation. The operation however can be repeated.

Voiding difficulty: Approximately 10% (10 in every 100) of women will have some difficulty in emptying their bladder in the short term and if this happens, we may send you home with a catheter for a week or two.

If you still have difficulty emptying your bladder after that 3% (3 in every 100 women), then the options will be either learning how to catheterise yourself (you may need to do that few times a day after passing urine, to get rid of any urine left behind in your bladder), or going back to theatre to have the tapes cut. Once the tape is cut, you may re-develop incontinence, but there is an option of having another tape at a later date. Some women need to change position to satisfactorily empty their bladder.

Bladder over activity (12% - 12 out of every 100 women): Any operation around the bladder has the potential for making the bladder overactive leading to symptoms such as urgency (needing to rush to the toilet) and frequency (needing to visit the toilet more often than normal).

Tape exposure and extrusion (1% - 1 out of every 100 women)**:** The vaginal area over the tape may not heal properly or get infected and therefore part of the tape may need removing. This may result in a return to theatre and may result in the operation being ineffective. Alternatively an attempt to re-cover the tape can be made. Very rarely the tape might erode into the urethra (urine pipe) or the bladder which would require a further operation as well. The risk of exposure is increased by smoking and with certain diseases.

Chronic pain on intercourse and pain in the pelvis (beyond 6 months): This may arise from scar tissue in the vagina as a result of the incision. It is unusual (5% - 5 out of every 100 women) but unpredictable. Occasionally a steroid injection at the site may help – sometimes the tape can be removed. However a small number of patients may have lifelong pain.

Visceral trauma: During the operation the needle used may traumatise an abdominal organ such as the bladder (6% - 6 out of every 100 women), bowel (<1% - less than 1 out of every 100 women) or major blood vessels (<1% - less than 1 out of every 100). This is rare but if occurs and is noticed at the time of surgery, it may require an abdominal incision (open tummy operation) to repair the damaged organ. If it is noticed after return from theatre to the ward it may necessitate going back to theatre for a general anaesthetic and an abdominal incision to repair the damaged organ.

Haematoma: a collection of blood can occur in the pelvis which might need drainage (<1% or less than 1 out of every 100 women).

The above risks may require revision surgery (overall risk 6% or 6 in every 100 women).

The Operation: Retro pubic midurethral sling (RP-MUS)

Facts and Figures.

- This operation was invented in 1996 and more than one million procedures have been performed worldwide.
- 80% (80 in every 100) of women are substantially better after the operation. Some of these women will still leak from time to time, for example, with a bad cold in the winter (sneezing).
- It seems to be as effective as the traditional colposuspension operation for up to 17 years after the operation.
- We do not know whether it will have complications in the long term.

How is the operation performed?

If done under local anaesthetic, the relevant areas (vaginal wall under the urethra and abdominal wall) are injected with a fine needle and allowed to go numb with local anaesthetic. This will remove any sharp sensation but a pressure sensation will still be felt. Most women will also have a sedative into the veins and this will make you feel very sleepy. In these circumstances most women cannot remember the operation.

A spinal anaesthetic involves an injection in the lower back, similar to what we use when women are in labour or for a caesarean section. The spinal anaesthetic numbs you from the waist down. This removes any sharp sensation but a pressure sensation will still be felt.

A general anaesthetic will mean you will be asleep (unconscious) during the entire procedure.

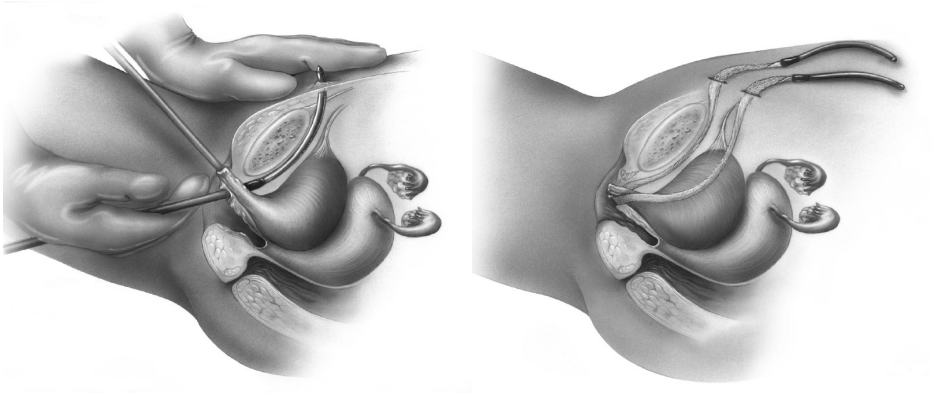
The legs are placed in stirrups (supported in the air) and a catheter is placed into the bladder through the urethra.

A small cut is made in the vagina and two small cuts are made in the lower abdominal wall above the pubic bone about 4cm (2 inches) apart.

The tape introducer (special needle) is pushed through the tissues on each side of the urethra as shown in the diagram. We then look inside the bladder using a cystoscope (bladder telescope) to see whether the bladder has been punctured. If this has occurred, the tape introducer is removed.

The tape introducers are then pushed through the abdominal wall incisions on both sides so that the tape lies underneath the urethra supporting it.

Figure 2: How the tape is placed in position



The tape introducer being pushed either side of the bladder neck, through the abdominal wall.

The position of the tape having been placed either side of the bladder neck.

After the operation (post-operative care)

- After the operation you will be taken back to the ward, where the nurses will check your blood pressure, pulse and wound.
- You may eat and drink immediately on return from theatre. A mild pain killer may be required.
- Most women do not have a catheter and can go home once they have urinated satisfactorily and been checked by a bladder scan that the bladder is empty on two occasions.
- Some women will return from theatre with a urethral catheter to drain the bladder. Once this is removed and they have emptied their bladder satisfactorily as above on two occasions they can go home.
- You may be given injections to keep your blood thin and reduce the risk of blood clots normally once a day until you go home or longer in some cases.
- The wound is not normally very painful but sometimes you may require tablets or injections for pain relief.
- There will be slight vaginal bleeding like the end of a period after the operation. This may last for a few weeks.

At home after the operation

It is important to avoid straining particularly in the first weeks after surgery. Therefore, avoid constipation and heavy lifting.

After any operation you will feel tired and it is important to rest. It is also important not to take to your bed. Mobilisation is very important. Simply pottering around the house will use your leg muscles and reduce the risk of clots in the back of the

legs (DVT) which can be very dangerous. Activity will also help to get air into your lungs and reduce infections.

You can do pelvic floor exercises but build these up very gently. If you do too much it will be uncomfortable.

It is advisable to have showers rather than baths for three weeks and to keep puncture wounds clean and dry. They heal in about five days, dressings are given.

Avoiding constipation:

- Drink plenty of water / juice
- Eat fruit and green vegetables, especially broccoli
- Plenty of roughage e.g. bran / oats

Do not use tampons, have intercourse or swim for six weeks otherwise you put yourself at risk of the tape eroding into the vagina.

There are stitches in the skin wound in the vagina. The surface knots of the stitches may appear on your underwear or pads after about two weeks, this is quite normal. There may be little bleeding again after about two weeks when the surface knots fall off, this is nothing to worry about. There are also stitches in the tummy. These will dissolve too.

At two weeks gradually build up your level of activity.

After four to six weeks, you should be able to return completely to your usual level of activity.

You should be able to return to a light job after about three to four weeks. Leave a very heavy or busy job until six weeks.

You can drive as soon as you can make an emergency stop without discomfort, generally after two weeks, but you must check this with your insurance company, as some of them insist that you should wait for six weeks.

Please look at the post op tracker to see what to expect on a week by week basis.

Time (Post Op)	Pain	Activities	Sutures	Miscellaneous
2 weeks	Vaginal and general pelvic discomfort. Pulling and tugging sensation.	Mobilising. No lifting or strenuous activity / short walks.	May Persist	Intermittent light bleed. Avoid intercourse.
4 weeks	Vaginal and general pelvic discomfort. Pulling and tugging sensation.	Mobilising. No lifting strenuous or activity / longer walks.	Should have gone away	Brown discharge may be present. Avoid intercourse.
6 weeks	Vaginal and general pelvic discomfort. Pulling and tugging sensation.	Increase walking. Start building up activity.	Should have gone away	Avoid intercourse.
9 weeks	The above described pain should start to diminish.	Continue build up.	Should have gone away	Avoid intercourse.
12 weeks	May continue with the above described pain on activity.	Continue to build up activity but may have feelings of tugging in vagina & groin.	Should have gone away	May try returning to intercourse after approximately 12 weeks, cautiously.
6 months	Minimal.	Normal activity.	Should have gone away	

Information about the British Society of Urogynaecology Surgical Database (Surgical Register)

The British Society of Urogynaecology ("**BSUG**") is a national group of gynaecologists with a special interest and expertise in the treatment of incontinence and prolapse. BSUG has developed a database of clinical and surgical data for the purposes of publishing **anonymous** statistical information for research purposes and to enable individual NHS Trusts and consultants to audit information about operations to ensure that the procedures performed at their hospitals are as safe and effective as possible.

The patient information held in the BSUG database comprises name, hospital number and date of birth, together with clinical and surgical information ("**patient identifiable data**"). Because this information is confidential to each patient and is that patient's personal data within the meaning of the Data Protection Act 1998,we do not disclose patient identifiable data to BSUG without written consent.

If you agree to allow us to enter your patient identifiable data into the BSUG database, please sign in the relevant section on the operation consent form.

The benefits the BSUG database may bring to you:

- Improving patient awareness of the outcomes of incontinence and prolapse surgery.
- Finding out how long the different operative procedures last.
- Helping to identify individual patients who have received an implant and where there may be a need for urgent clinical review

The BSUG database will also be used to bring additional long-term benefits by:

- Providing feedback to gynaecological surgeons and teams to help maintain high clinical standards
- Promoting open publication about the performance of implants used in operations.
- Providing feedback on implant performance to regulatory authorities
- Providing feedback to suppliers about the performance of their implants
- Monitoring and comparing the performance of hospitals

Data collection – its security and confidentiality

The **BSUG database** uses an electronic system for data collection. The data is sent securely to a protected database, avoiding the need to send paper records through the post, to ensure your data receives maximum protection.

Your personal information is confidential and cannot be used outside of the BSUG database. Strict procedures are in place to protect your information and keep it confidential; it will only be available to you and your surgeon. If you wish, you can obtain access to a copy of your own record in accordance with the Data Protection Act 1998.

BSUG database Consent

I consent to:

1. the processing of my patient identifiable data for the research and auditing purposes described in this information sheet.
2. the disclosure by BSUGs of my patient identifiable data to its IT service provider or any future IT service provider, where such IT service provider has:

   (a) agreed to adopt appropriate technical and organisation measures to protect the security of my patient identifiable data and only to process it in accordance with BSUGDL's instructions;

   (b) been instructed NOT to store my patient identifiable data on a server which is located outside of the United Kingdom; and

   (c) been informed of the existence of my legal right to confidence in respect of my patient identifiable data.
3. the disclosure of my patient identifiable data to the consultant team (and the NHS Trust employing that consultant team) who disclosed it to BSUG.
4. the disclosure of my patient identifiable data to BSUG or any legal entity which is wholly owned by BSUG, for processing in accordance with the consents in this section.

Your participation is voluntary

The form asks for your consent for your personal information to be recorded by the **BSUG database**. Your participation in the BSUG database is entirely voluntary. You can request access to view your entry on the BSUG database from your consultant team.

If you agree and then change your mind, you may revoke this permission at any time by sending a written notice to your consultant OR to the address below. If you do not agree, your data will not be entered.

BSUG
Royal College of Obstetricians & Gynaecologists
27 Sussex Place
Regents Park
London
NW1 4RG

If you consent to the above please sign in the relevant section on the operation consent form.

Useful contact numbers

The James Cook University Hospital
Appointments Desk: 01642 854861 / 282714 / 854883
Gynaecology Outpatients Dept. (Including Pre-admission Service): 01642 854243
Surgical Admissions Unit: 01642 854603
Gynaecology Unit / Theatre 23: 01642 282745
Women's Health Unit / Ward 19: 01642 854519

The Friarage Hospital
Appointments Desk: 01609 764814
Gynaecology Outpatients Dept: 01609 764814
Pre-admission Service: 01609 764845 / 01609 763769
Surgical Admissions Unit Reception: 01609 764847 Nursing Staff: 01609 764657
From 7am Mondays until 5pm Fridays, Allen POS.D.U.: 01609 764405
From 5pm Fridays until 7am Mondays, Allerton Ward: 01609 764404

Things I need to know before I have my operation

Please list below any questions you may have, having read this leaflet.

1. .....

2. .....

3. .....

4. .....

5. .....

6. .....

Please describe what your expectations are from surgery.

1. .....

2. .....

3. .....

4. .....

5. .....

6. .....

Useful references

You may find the address and websites useful to obtain more information. We can however bear no responsibility for the information they provide:

- Bladder & Bowel Foundation SATRA Innovation Park Rockingham Road Kettering, Northants, NN16 9JH
- Bladder & Bowel Foundation Nurse Helpline for medical advice: 0845 345 0165
- Bladder & Bowel Foundation Counsellor Helpline: 0870 770 3246
- Bladder & Bowel Foundation General enquiries: 01536 533255
- Bladder & Bowel Foundation Fax: 01536 533240
- mailto:info@bladderandbowelfoundation.org
- www.bladderandbowelfoundation.org

Also:

- http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con205383.pdf
- https://www.gov.uk/government/publications/vaginal-mesh-implants-summary-of-benefits-and-risks
- https://ec.europa.eu/health/scientific committees/consultations/public consultations/scenihr consultation 27 en
- https://ec.europa.eu/health/sites/health/files/scientific committees/emerging/docs/scenihr o 049.pdf

- https://beta.gov.scot/publications/scottish-independent-review-use-safety-efficacy-transvaginal-mesh-implants-treatment-9781786528711/
- Retropubic versus transobturator MUS: time to revisit? - NCBI
- Int Urogynecol J. 2017 Aug; 28 (8): 1113-1114. doi: 10.1007/s00192-017-3403-7. Epub 2017 Jul 4.
- https://www.ncbi.nlm.nih.gov/pubmed/28676935

For further information regarding mesh for stress incontinence procedures please see the following web links:

- www.cochrane.org/CD006375/INCONT_mid-urethral-sling-operations-for-stress-urinary-incontinence-in-women
- www.rcog.org.uk/en/news/rcogbsug-statement-on-the-cochrane-review-of-mid-urethral-sling-operations/
- www.nice.org.uk/guidance/cg171/chapter/1-Recommendations#surgical-approaches-for-sui-2
- www.ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_049.pdf
- www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con205383.pdf

We hope that you have found this information helpful. Please remember our staff will be happy to answer any questions you have about any aspect of your care and welcome any comments about this leaflet.

Comments, compliments, concerns or complaints

South Tees Hospitals NHS Foundation Trust is concerned about the quality of care you receive and strives to maintain high standards of health care.

However we do appreciate that there may be an occasion where you, or your family, feel dissatisfied with the standard of service you receive. Please do not hesitate to tell us about your concerns as this helps us to learn from your experience and to improve services for future patients.

Patient Advice and Liaison Service (PALS)

This service aims to advise and support patients, families and carers and help sort out problems quickly on your behalf.

This service is available, and based, at The James Cook University Hospital but also covers the Friarage Hospital in Northallerton, our community hospitals and community health services. Please ask a member of staff for further information.

If you require this information in a different format please contact Freephone 0800 0282451

Acknowledgement:
Images courtesy of Americal Medical Systems, Inc and Ethicon

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Version 3, Issue Date: November 2017, Revision Date: November 2019

MICB2064