

An Operation for Stress Incontinence

Transobturator Tape (TOT, TVT-O)

Patient Information Leaflet

BSUG Patient Information Sheet Disclaimer

This patient information sheet was put together by members of the BSUG Governance Committee paying particular reference to any relevant NICE Guidance. It is a resource for you to edit to yours and your trusts particular needs. Some may choose to use the document as it stands, others may choose to edit or use part of it. The BSUGs Governance Committee and the Executive Committee cannot be held responsible for errors or any consequences arising from the use of the information contained in it. The placing of this information sheet on the BSUGs website does not constitute an endorsement by BSUGs.

We will endeavour to update the information sheets at least every two years.

Version 2 (TOT BSUG F2)

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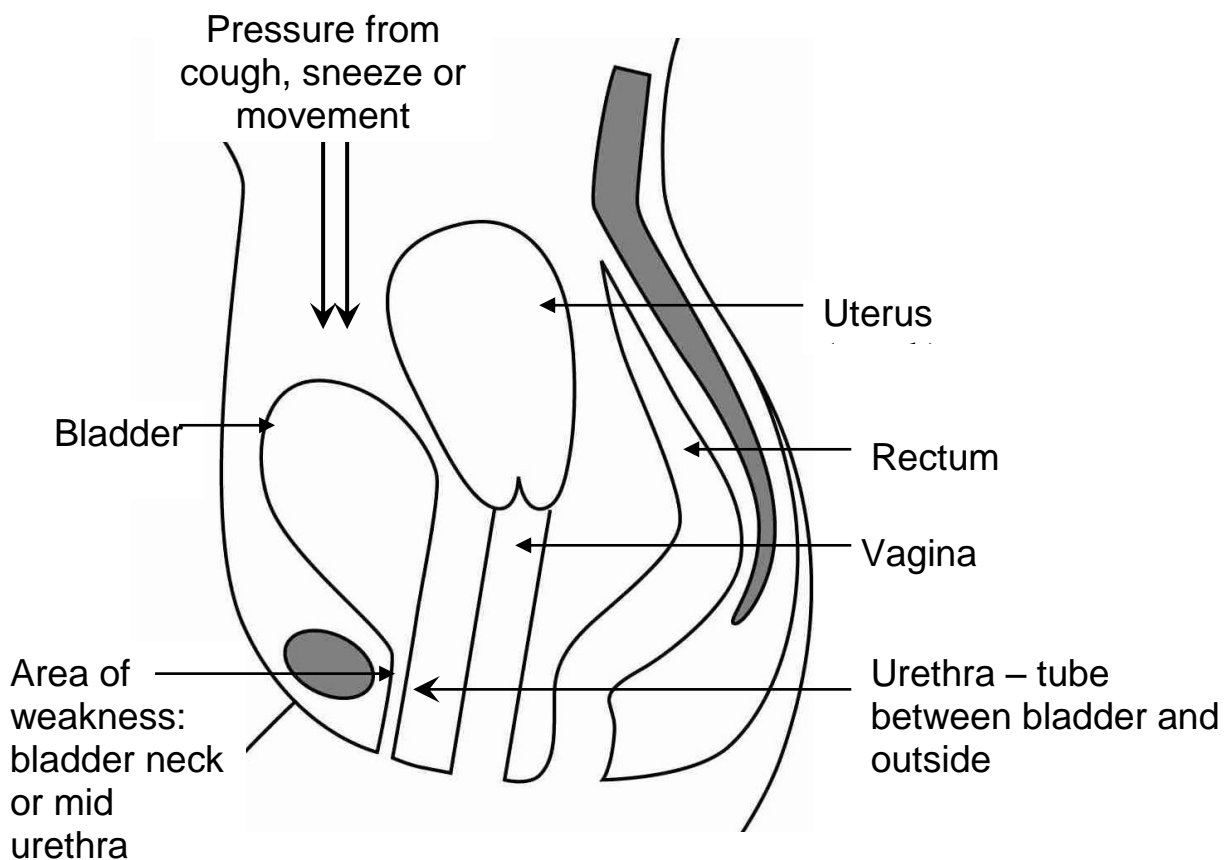
We advise you to take your time to read this leaflet, any questions you have please write them down on the sheet provided (towards the back) and we can discuss them with you at our next meeting. It is your right to know about the operations being proposed, why they are being proposed, what alternatives 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) such as when coughing or sneezing – figure 1.
- This weakness is usually caused by childbirth in the first instance when the pelvic floor muscles and ligaments (attachments) are damaged. Further weakening occurs as one goes through the menopause because the quality of the supporting tissues deteriorates.
- The pressure in the abdomen rises when one coughs, sneezes or even bends, turns or jumps and results in urine leakage. This can cause a lot of distress and can limit ones 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 urethra (urine pipe) and bladder neck. Many urinary symptoms we see in clinic have other causes.

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



When women cough, sneeze, bend, jump or even laugh the pressure in the abdomen is increased and this may result in leakage of urine

Alternatives to 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 muscles run from the coccyx at the back to the pubic bone at the front and off to the sides. These muscles support your pelvic organs (uterus and bladder) 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 correct or reduce stress incontinence. 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 becoming continent.
- **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. A leaflet is available if you require further information.

The Benefits of Stress Incontinence Surgery

- 80-90% women are substantially improved.
- This means you may get back to:-
 - Physical activity – running, dancing, gym etc
 - Horse riding
 - Gardening
 - Resume sexual relations if hindered beforehand
- We have been doing this operation from 2003 (compared to 1996 for TVT) so long term data is not available, but the information we have so far suggests that the outcome following TOT is similar to TVT.
- This also means you may have renewed confidence so that:-
 - You can e.g. 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 4-5% although the majority of these are without symptoms (1/10 to 1/100 i.e. common). Occasionally this clot can migrate to the lungs which can be very serious and in rare circumstances it can be fatal (less than 1% 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

The table below is designed to help you understand the risks associated with this type of surgery (based on the RCOG Clinical Governance Advice, Presenting Information on Risk)

Term	Equivalent numerical ratio	Colloquial equivalent
Very common	1/1 to 1/10	A person in family
Common	1/10 to 1/100	A person in street
Uncommon	1/100 to 1/1000	A person in village
Rare	1/1000 to 1/10 000	A person in small town
Very rare	Less than 1/10 000	A person in large town

- **Failure:** 10% (1/10 to 1/100 i.e. common) of women do not gain benefit from the operation. The operation however can be repeated.
- **Voiding difficulty:** Approximately 10% of women (1/10 to 1/100 i.e. common) 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 up to a week. If you still have difficulty emptying your bladder after 10 days (3%), 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 tape 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 may need to change position to satisfactorily empty their bladder.

- **Bladder overactivity:** (12% - 1/1 to 1/10 i.e. very common): 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** (10% - 1/10 to 1/100 i.e. common): The vaginal area over the tape may not heal properly or get infected and therefore part of the tape may need excising. This may need 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 an operation as well. The risk of exposure is increased by smoking and with certain diseases.
- **Pain on intercourse:** This may arise from scar tissue in the vagina as a result of the incision. It is unusual but unpredictable.
- **Visceral trauma:** During the sub-urethral sling operations the needle used may traumatise the bladder, or urethra (urine pipe). This is rare. If it is noticed after return from theatre to the ward it may necessitate going back to theatre for a general anaesthetic and an operation to repair the damaged organ.
- **Leg or groin pain:** occasionally some patients describe pain in the groin or down the legs (<1% - 1/100 to 1/1000 i.e. uncommon).

The Operation: Trans-Obturator Tape (TOT or TVT-O)

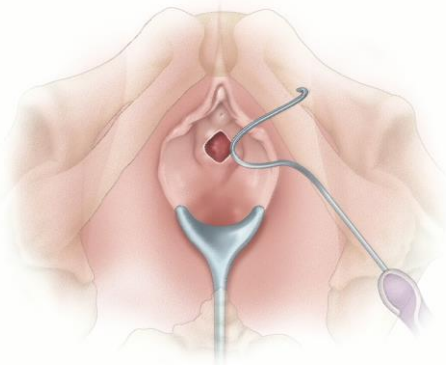
Facts and Figures

- This is a recently developed operation and therefore less operations overall have been performed.
- The main advantage however is that the procedure is performed through a less risky operative field.
- The short-term results seem comparable to operations like the TVT, but the long-term results are unknown.
- The tape material used is similar to TVT.

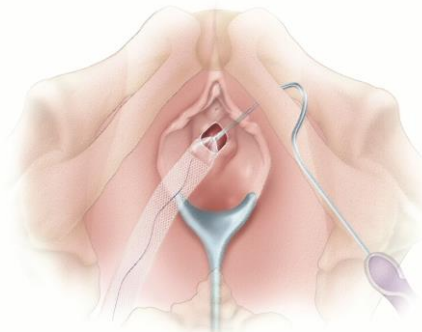
How is the operation performed

- The operation can be performed under Spinal or General Anaesthetic as described above.
- Special needles are used. The exit point for these needles is the groins – see figure 2 and 3.
- There will therefore be a small incision in each groin as well as the incision in the vagina. These incisions will have a suture in after the operation.

Figure 2: Insertion of Trans Obturator Tape (TOT) (Images courtesy of American Medical Systems, Inc)

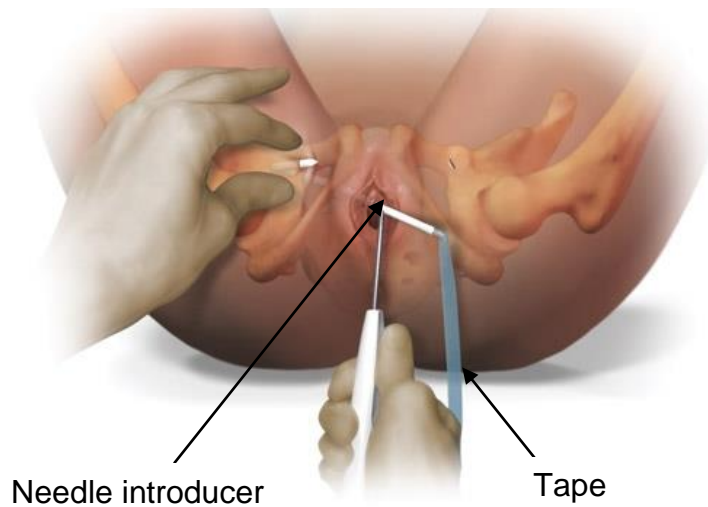


The helical needle is pushed through the groin incision and around the pubic bone into the vagina



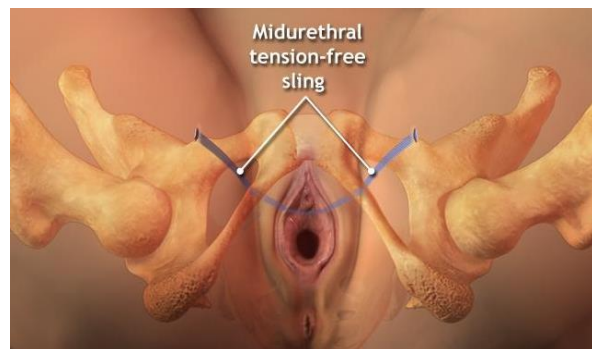
The needle collects the tape which is pulled through the vagina to lie under the bladder neck

Figure 3: Insertion of Trans-Obturator Tape (TVT-O)
(Images courtesy of Ethicon)



The needle is inserted from inside the vagina out through the groin carrying the tape with it. The same procedure is followed on the other side,

The final position of the tape is under the urethra (tube between bladder and the outside)



An Alternative Operation to the TOT: The Tension – Free Vaginal Tape (TVT)

TVT: This operation involves inserting a synthetic tape through the vagina in order to sit like a hammock under the urethra (urine pipe) and prevent it moving down when the intra-abdominal pressure increases such as when coughing. It now has data to show that it gives comparable success rate to the above traditional operation (Colposuspension) up to 17 years after the operation, whilst allowing patients to go home on the same day in most cases.

Its main drawback is a small risk of injury to bladder, urethra or bowels; and an extremely rare risk of damage to a major blood vessel which has resulted in a few deaths (out of greater than a

million procedures). There is a small risk of voiding difficulty and a small risk of overactive bladder symptoms (urgency and frequency).

As with the TOT, it can cause tape erosion and difficulty emptying the bladder (explained above).

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.
- 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 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. Mobilization 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.

Avoiding constipation

- Drink plenty of water / juice (prune)
- Eat fruit and green vegetables esp. broccoli
- Plenty of roughage e.g. bran / oats
- Do not use tampons, have intercourse or swim for 6 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 groins.
- At 2 weeks gradually build up your level of activity.
- After 4-6 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 3-4 weeks. Leave a very heavy or busy job until 6 weeks.
- You can drive as soon as you can make an emergency stop without discomfort, generally after 2 weeks, but you must check this with your insurance company, as some of them insist that you should wait for six weeks.

What the Medicines and Healthcare Products Regulatory Agency suggest?

In response to reported adverse events and concerns about mesh products the Medicines and Healthcare Products Regulatory Agency (MHRA), on behalf of the Department of Health (DOH), commissioned a review of evidence related to most frequent adverse events. The risks quoted in this leaflet are based on the MHRA report. It is now mandatory that any complications related to mesh are reported to the MHRA. In addition the MHRA have published a list of questions patients should discuss with their surgeon before proceeding with the surgery and these are listed below.

- Why have you chosen the use of surgical tape or a traditional non-tape repair in my particular case?
- What are the alternatives?
- What are the chances of success with the use of tape versus use of other procedures such as traditional surgery?
- What are the pros and cons of using tape including associated side-effects and what are the pros and cons of alternative procedures?
- What sexual problems may be encountered with use of tape and traditional surgery and/or other procedures?
- If tape is to be used, what experience have you had with implanting these devices?
- What have been the outcomes from the people whom you have treated?
- What has been your experience in dealing with any complications that might occur?
- What if the tape does not correct my problems?
- What other treatments are available?
- What can I expect to feel after surgery and for how long?
- If I have a complication related to the tape, can the tape be removed and what are the consequences associated with this?

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

Nurse helpline for medical advice: 0845 345 0165

Counsellor helpline: 0870 770 3246

General enquiries: 01536 533255

Fax: 01536 533240

<mailto:info@bladderandbowelfoundation.org>

<http://www.bladderandbowelfoundation.org/>

<http://www.nice.org.uk/nicemedia/pdf/word/CG40publicinfo.doc>

www.continet.org. (International Continence Society)

Things I need to know before I have my operation.

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

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Please describe what your expectations are from surgery.

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