The British Association of Urological Surgeons

SYNTHETIC VAGINAL TAPES FOR STRESS INCONTINENCE

Procedure Specific Information

What is the evidence base for this information?

This publication includes advice from consensus panels, the British Association of Urological Surgeons, the Department of Health and evidence-based sources. It is, therefore, a reflection of best urological practice in the UK. It is intended to supplement any advice you may already have been given by your GP or other healthcare professionals. Alternative treatments are outlined below and can be discussed in more detail with your Urologist or Specialist Nurse.

What does the procedure involve?

Vaginal tapes are implanted to treat stress incontinence (leakage of urine when you cough, sneeze or strain). The tape is placed under the urethra like a sling or hammock to support the urethra (water pipe) and keep it in the correct position.

Synthetic tapes are made from a plastic material, usually a non-absorbable poylpropylene mesh, and are usually well-accepted by the body. This means that the tape will remain in the body forever.

The first tape of this kind was introduced 15 years ago and is called the tension-free vaginal tape (TVT); many other manufacturers now sell similar tapes. An alternative introduced more recently is the trans-obturator tape (TOT); this is introduced in a slightly different way and has been carried out in the UK for 5 years. These operations (TVT & TOT) are now the most commonly performed operations for stress incontinence in the UK.

Both procedures are relatively short, taking around 30 minutes to perform, either under general or local anaesthetic. The operations are often performed as a day case, meaning that you can go home on the same day.

The results of TVT and TOT are very similar. About 2 out of 3 women will be completely dry and 1 out of 3 will have some degree of leakage, usually better than it was before surgery. Nine out of 10 women declare themselves satisfied with the result of these procedures.

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What are the alternatives to this procedure?

The most common surgical procedure for stress incontinence was a Burch colposuspension but this involves a cut in the lower abdomen and is much more invasive.

Injection therapy (around the urethra) is sometimes used and, although less invasive, is less likely to be successful than synthetic vaginal tapes.

Other alternatives include observation, physiotherapy and usage of pads.

What should I expect before the procedure?

A pre-operative visit will be arranged by the hospital to check on your fitness for anaesthesia and surgery, at which:

- blood tests, heart tracing (ECG) and chest X-ray may be performed to ensure that you are on good health
- you may be given oral or vaginal oestrogen (hormone) if you are near or already menopausal. It is important to comply with this medication because it thickens your vaginal tissues for easier surgery and faster healing
- all your medications and medical conditions, if any, must be made known to the doctor and must be optimally controlled
- if you are taking Aspirin or other blood thinning drugs, please let us know. You may have to stop taking them a week prior to surgery
- you will be advised when and what you can eat or drink before surgery
- culture swabs will be taken for MRSA

You will usually be admitted on the same day as your surgery. After admission, you will be seen by members of the medical team which may include the Consultant, Specialist Registrar, House Officer and your named nurse.

You may be given an injection of a blood thinning agent before surgery, and afterwards until you are adequately mobilised. You may also be given a preparation to clear your bowels. You will be given intravenous antibiotics at the time the anaesthetic is given, and possibly after surgery too.

You may be given a pre-medication by the anaesthetist which will make you dry-mouthed and pleasantly sleepy.

Please be sure to inform your surgeon in advance of your surgery if you have any of the following:

- an artificial heart valve
- a coronary artery stent
- a heart pacemaker or defibrillator
- an artificial joint
- an artificial blood vessel graft

- a neurosurgical shunt
- any other implanted foreign body
- a regular prescription for Warfarin, Aspirin or Clopidogrel (Plavix®)
- a previous or current MRSA infection
- a high risk of variant-CJD (if you have received a corneal transplant, a neurosurgical dural transplant or previous injections of human-derived growth hormone)

At some stage during the admission process, you will be asked to sign the second part of the consent form giving permission for your operation to take place, showing you understand what is to be done and confirming that you wish to proceed. Make sure that you are given the opportunity to discuss any concerns and to ask any questions you may still have before signing the form.

Fact File 1 • The NHS Constitution
Same-Sex Accommodation

As a result of the new NHS constitution, the NHS is committed to providing same-sex accommodation in hospitals by April 2010. This is because feedback from patients has shown that being in mixed-sex accommodation can compromise their privacy. The NHS pledges that:

- sleeping and washing areas for men and women will be provided
- the facilities will be easy to get to and not too far from patients' beds

To help accomplish this, the Department of Health has announced specific measures designed to "all but eliminate mixed-sex accommodation" by 2010. These include:

- more money for improvements in hospital accommodation
- providing help and information to hospital staff, patients and the public
- sending improvement teams to hospitals that need extra support
- introducing measures so that the Department can see how hospitals are progressing

What happens during the procedure?

Either a full general anaesthetic (where you will be asleep throughout the procedure) or a spinal anaesthetic (where you are awake but unable to feel anything from the waist down) will be used. All methods minimise pain; your anaesthetist and surgeon will explain the pros and cons of each type of anaesthetic to you.

The TVT operation involves two small incisions (each 0.5cm long) in the lower part of your tummy (below the pubic hairline) and a 1.5cm incision in the front wall of the vagina. The TVT tape is inserted from the vagina, then up to the small incisions in your abdomen. The tape lies between the vaginal skin and your urethra (water pipe).

The TOT operation is similar except that it is done by making a small incision at the top of each of your thighs, on the inner side, just below the groin. For both operations, the tape is cut off level with the skin, so it is not sticking out at the end of the operation, and a stitch is used to close the incisions.

At the end of the procedure, a urinary catheter may be inserted into your bladder to allow free urine flow and a vaginal pack may also be inserted,

What happens immediately after the procedure?

In general terms, you should expect to be told how the procedure went and you should:

- ask if what was planned to be done was achieved
- let the medical staff know if you are in any discomfort
- ask what you can and cannot do
- feel free to ask any questions or discuss any concerns with the ward staff and members of the surgical team
- ensure that you are clear about what has been done and what is the next move

You may experience nausea, vomiting and pain from the wound which usually respond rapidly to medications. If you have an epidural or spinal anaesthetic, a 6-hour period of rest is recommended before getting out of bed.

You will be allowed to eat and drink as soon as you are able.

If a vaginal pack has been inserted it will be removed before you go home (or arrangements made to have it removed later).

If a urinary catheter has been inserted, it is usually removed on the same day as the operation or arrangements may be made for you to have it removed later. You will be encouraged to pass urine on your own and the volume of the remaining urine will be measured.

The average hospital stay is 1 day.

Are there any side-effects?

Most procedures have a potential for side-effects. You should be reassured that, although all these complications are well-recognised, the majority of patients do not suffer any problems after a urological procedure.

Common (greater than 1 in 10)

- Need to go to the toilet frequently, due to a feeling of having to rush (urgency) and, sometimes, with urine leakage due to urgency. Often, you will have experienced this before the procedure as well

- Failure to improve urinary incontinence so that you still have bad leakage (some women still have mild leakage)
- Inability to empty the bladder completely so that you need either to keep a catheter on all the time or you need to use a catheter several times a day to empty the bladder (intermittent self-catheterisation)
- Infection
- Slow urine flow
- Recurrence of urinary incontinence; this can happen years after the tape has been inserted at later time
- Pain; you will get some discomfort/pain for a while, usually where the skin was cut during the operation. TOT can cause thigh or groin pain. This can be relieved by simple painkillers in most cases but there are occasions where more powerful drugs are needed

Occasional (between 1 in 10 and 1 in 50)

- Injury to the bladder during the TVT operation; the risk is much less for TOT surgery
- Misplacement of the tape; this should be discovered at the time of surgery and the tape re-positioned correctly
- Injury to surrounding tissues (e.g. bladder, rectum and blood vessels)
- Erosion and migration of the tape into the vagina, bladder or urethra; this can happen several years after the tape was inserted. Symptoms such as recurrent urinary infection, change in urinary symptoms, vaginal discharge and discomfort during intercourse may occur

Rare (less than 1 in 50)

- Reaction to the sling material (inflammation, infection or allergic) requiring removal

Hospital-acquired infection

- Colonisation with MRSA (0.9% - 1 in 110)
- Clostridium difficile bowel infection (0.2% - 1 in 500)
- MRSA bloodstream infection (0.08% - 1 in 1250)

The rates for hospital-acquired infection may be greater in high-risk patients e.g. with long-term drainage tubes, after removal of the bladder for cancer, after previous infections, after prolonged hospitalisation or after multiple admissions.

What should I expect when I get home?

By the time of your discharge from hospital, you should:

- be given advice about your recovery at home
- ask when to resume normal activities such as work, exercise, driving, housework and sexual intimacy
- ask for a contact number if you have any concerns once you return home

- ask when your follow-up will be and who will do this (the hospital or your GP)
- ensure that you know when you will be told the results of any tests done on tissues or organs which have been removed

When you leave hospital, you will be given a “draft” discharge summary of your admission. This holds important information about your inpatient stay and your operation. If you need to call your GP for any reason or to attend another hospital, please take this summary with you to allow the doctors to see details of your treatment. This is particularly important if you need to consult another doctor within a few days of your discharge.

You may require pain-killing tablets at home for several days and it may take a week at home to become comfortably mobile.

You should avoid driving for at least one week, and it may be longer before this is possible.

Sexual intercourse and douching of the vagina should be avoided for at least a month.

Heavy lifting (of more than 5kg) should be avoided for a month.

If you work, you will need a minimum of two weeks off, unless you and your surgeon agree something different. If you have an infection or other complications(s), your recovery is likely to take longer.

What else should I look out for?

If you find it increasingly difficult to pass urine, or If you develop symptoms of a urine infection (burning, frequency and urgency), you should see your doctor promptly.

You should seek help from your doctor if you experience:

- severe vaginal bleeding
- severe abdominal pain or swelling
- foul-smelling discharge from the wound
- high fever (you should take your temperature if you suspect this)
- pain when passing urine
- difficulty in passing urine
- pain or swelling of the calves

Are there any other important points?

Different hospitals have different policies for reviewing women after sling surgery. Some like to see all their patients, usually 3-6 months after the operation, whilst others will arrange a routine telephone follow-up at a similar time. All hospitals, however, would wish to see you again if you have any problems or there is anything you are worried about.

If you would like further information, please look up the documents listed below:

- Abrams P et al. Synthetic Vaginal Tapes for Stress Incontinence: Proposals for Improved Regulation of New Devices in Europe. European Urology (2011) - Available on the European Urology website
- Further guidance of the use of incontinence tapes on the NICE (National Institute for Health and Clinical Excellence) website - Urinary incontinence: the management of urinary incontinence in women
- NICE also provides advice for patients contemplating this procedure – Urinary incontinence: understanding NICE guidance
- The MHRA is still gathering information about the use and complications of these devices and would encourage reporting of adverse events - Reporting a safety problem with a device

Driving after surgery

It is your responsibility to ensure that you are fit to drive following your surgery. You do not normally need to notify the DVLA unless you have a medical condition that will last for longer than 3 months after your surgery and may affect your ability to drive. You should, however, check with your insurance company before returning to driving. Your doctors will be happy to provide you with advice on request.

Is there any research being carried out in this area?

Before your operation, your surgeon or Specialist Nurse will inform you about any relevant research studies taking place, and, in particular, if any surgically-removed tissue may be stored for future study. If this is the case, you will be asked if you wish to participate and, if you agree, to sign a special form to consent to this.

All surgical procedures, even those not currently the subject of active research, are subjected to rigorous clinical audit so that we can analyse our results and compare them with those of other surgeons. In this way, we can learn how to improve our techniques and our results; this means that our patients will get the best treatment available.

Who can I contact for more general help or information?

For further information on the internet, here are some useful sites to explore:

Best Health (prepared by the British Medical Association)
NHS Clinical Knowledge Summaries (formerly known as Prodigy)
NHS Direct
Patient UK
Royal College of Anaesthetists (for information about anaesthetics)
Royal College of Surgeons (patient information section)

What should I do with this information?

Thank you for taking the trouble to read this publication. If you wish to sign it and retain a copy for your own records, please do so below.

If you would like a copy of this publication to be filed in your hospital records for future reference, please let your Urologist or Specialist Nurse know. However, if you do agree to proceed with the scheduled procedure, you will be asked to sign a separate consent form which will be filed in your hospital record. You will, if you wish, be provided with a copy of this consent form.

I have read this publication and I accept the information it provides.

Signature..... Date.....

How can I get information in alternative formats?

Please ask your local NHS Trust or PALS network if you require this information in other languages, large print, Braille or audio format.

Most hospitals are smoke-free. Smoking increases the severity of some urological conditions and increases the risk of post-operative complications. For advice on quitting, contact your GP or the **NHS Smoking Helpline** free on **0800 169 0 169**

Disclaimer

Fact File 2 • The NHS Constitution
Patients' Rights & Responsibilities

The constitution, as a result of extensive discussions with staff and the public, sets out new rights for patients which will help improve their experience within the NHS. These new rights include:

- a right to choice and a right to information that will help them make that choice
- a right to drugs and treatments approved by NICE when it is considered clinically appropriate
- a right to certain services such as an NHS dentist and access to recommended vaccinations
- the right that any official complaint will be properly and efficiently investigated, and that they be told the outcome of the investigations
- the right to compensation and an apology if they have been harmed by poor treatment

The constitution also lists patient responsibilities, including:

- providing accurate information about their health
- taking positive action to keep themselves and their family healthy
- trying to keep appointments
- treating NHS staff and other patients with respect
- following the course of treatment that they are given
- giving feedback, both positive and negative, after treatment