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AUTOLOGOUS VAGINAL TAPES FOR STRESS INCONTINENCE INFORMATION FOR PATIENTS

What evidence is this information based on?

This booklet includes advice from consensus panels, the British Association of Urological Surgeons, the Department of Health and other sources. As such, it is a reflection of best urological practice in the UK. You should read this booklet with any advice your GP or other healthcare professional may already have given you. We have outlined alternative treatments below that you can discuss in more detail with your surgeon or specialist nurse.

What does the procedure involve?

Autologous fascial sling placement is a procedure to treat **stress incontinence** (leakage of urine when you exercise, sneeze or strain). Fascia is a sheet of supporting, fibrous tissue that holds body organs in their correct position. The fascia used in this operation can come from the abdominal wall or from the top of the leg.

The terms **rectus fascia sling** (using fascia form the abdominal wall) or **fascia lata sling** (using fascia from the outside of the thigh) are sometimes used to describe variations of this procedure.

Your bladder and urethra (waterpipe) are supported by your pelvic floor muscles and ligaments. If this support is weakened, urine may leak with coughing, sneezing, laughing, lifting or exercise..



Autologous slings are placed around the waterpipe (urethra) via the vagina to treat complicated stress incontinence (leakage in women who have undergone previous procedures on the urethra or bladder). The sling is placed under the urethra and cradles it like a hammock. It is then passed through the muscles of the abdominal wall and tightened to provide support.

By using tissue from your body to construct an autologous sling, we reduce the risk of infection and your body's reaction to it.

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The procedure usually requires an overnight stay and takes approximately 1 - 2 hours to perform. It may be performed under general or spinal anesthetic.

What are the alternatives to this procedure?

There are several non-surgical and surgical treatment options for women with stress urinary incontinence:

Non-surgical treatment

- **Pelvic floor muscle exercises** exercises are the most effective non-surgical treatment. Many women who undergo this treatment, supervised by a physiotherapist, will not require surgery;
- Drug treatment using Duloxetine tablets, may be suitable for some women;
- **Continence pessaries** these, and similar devices, placed inside the vagina or urethra may occasionally be useful for managing leakage, especially during exercise;
- **Absorbent products** incontinence pants or pads may provide extra ways of managing urinary problems in some women or
- **Do nothing** if leakage is not troublesome, no treatment may be needed

Surgical treatment

If non-surgical treatment has not been successful or is not appropriate/suitable, the following interventional procedures may be considered:

- **Synthetic vaginal mesh tapes** these are synthetic (manufactured) tapes, rather than the body's own tissue, and involve placing "foreign" material into the body, which may cause a reaction;
- **Colposuspension** an abdominal operation (open or "keyhole") which aims to lift the vagina up below the urethra using permanent, synthetic stitches or
- **Urethral bulking agents** using a bulking material, either absorbable or permanent, which is injected in or around the urethra to strengthen it.

Please ask you doctor about leaflets which cover the dcetails of these optiobns, and familiarise yourself with their pros and cons. You can get more information from http://www.nhs.uk/Conditions/Incontinence-urinary/Pages/treatmentoptions.aspx

Questions for your surgeon

Here are some questions you should ask your surgeon, before the procedure, if you are thinking of having an autologous sling inserted for incontinence:

- What are the alternative surgical and non-surgical treatments?
- What does the procedure involve?
- What are the potential side-effects or adverse events, associated with the procedure?
- Is this type of treatment right for me?
- What happens if this particular treatment does not work?
- Have you (as the surgeon) looked at your results for the operation? and
- If so, what is the success rate and risk of complications?

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:

- You may have blood tests, a heart tracing (ECG) and a chest X-ray to check that you are in good health;
- Your up-to-date list of medications (drugs) will be reviewed; you must tell your surgeon about all the drugs you are taking;
- If you are taking blood-thinning drugs (warfarin, aspirin or clopidogrel), please let us know because you may have to stop taking them before surgery;
- Culture swabs will be taken for MRSA.

You will usually be admitted to hospital on the same day as your surgery. Once you have been admitted, 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 drug called Clexane under your skin. Together with elasticated stockings provided by the ward, this will help to prevent venous thrombosis (clots in your legs). You may also be given a mild laxative to clear your bowels.

You may be given intravenous antibiotics at the time the anaesthetic is given, and possibly after surgery too.

You will be asked not to eat and drink for six hours before surgery. Immediately before the operation, the anaesthetist may give you a pre-medication which will make you dry-mouthed and pleasantly sleepy.

Please tell your surgeon, nurse or pre-assessment clinic (before 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 a blood thinning agent such as warfarin, aspirin, clopidogrel (Plavix®), rivaroxaban, prasugrel or dabigatran
- A previous or current MRSA infection
- A high risk of variant-CJD (if you have had a corneal transplant, a neurosurgical dural transplant or injections of human-derived growth hormone).

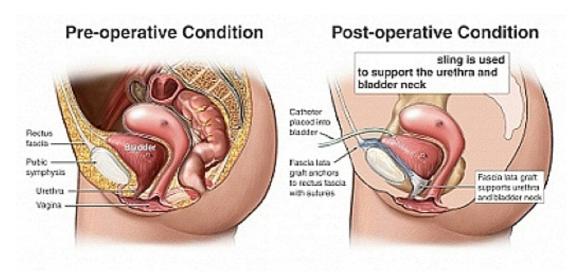
When you are admitted to hospital, you will be asked to sign the second part of your operation consent form giving permission for your operation to take place, showing you understand what is to be done and confirming that you want to go ahead. Make sure that

you are given the opportunity to discuss any concerns and to ask any questions you may still have before signing the form.

What happens during the procedure?

Autologous sling surgery is usually performed either under spinal anaesthetic (when you will be awake) or under general anaesthetic (when you are asleep). All methods reduce the leve of pain afterwards. Your anaesthetist will explain the pros and cons of each type of anaesthetic to you.

During the operation, we remove a small section of fascia (approximately 1cm by 10cm). This is taken either from your thigh (through a small cut on the outside of the leg) or from your lower abdomen (through a small incision in your "bikini line"). The defect in the fascia is then sewn back together.



We then make a small (1.5cm long) incision in the front wall of your vagina which allows us to place the sling around your urethra. The sling is inserted upwards from the vagina, towards your tummy, where the ends are joined together under the skin using a strong stitch. We then close all the incisions using absorbable stitches.

Finally, we sometimes put a catheter into your bladder and a temporary pack into your vagina.

What happens immediately after the procedure?

You will return to the ward after a period of observation in the recovery suite. You should be told how the procedure went and you should:

- ask the surgeon if it went as planned;
- 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; and
- make sure that you are clear about what has been done and what happens next.

You may experience sickness and occasional vomiting but we will give you drugs to relieve these symptoms. Pain from the wound is usually mild and you will be given painkillers to use as required.

If you have had a spinal anaesthetic, a six-hour period of rest is recommended before you can get out of bed; after that, we will encourage you to move around. You will be allowed to eat and drink on the same day as the operation.

Your vaginal pack, if put in, will be removed before you go home (or arrangements made to have it removed later). If you have had a bladder catheter, we usually remove it the same day as the operation but arrangements may be made for you to have it removed later. You will be encouraged to pass urine on your own and we will measure how well you empty your bladder.

The average hospital stay is one day.

Are there any side-effects?

Most procedures have possible side-effects. But, although the complications listed below are well-recognised, most patients do not suffer any problems.

Common (greater than 1 in 10)

- Need to go to the toilet frequently, due to a feeling of having to rush to the bathroom (urgency), sometimes with urine leakage due to urgency; especially if you had this before the operation.
- Failure, so that you still have leakage.
- Inability to empty the bladder completely so that you need either to keep a catheter in all the time or insert a catheter several times a day (intermittent self-catheterisation).
- Infection.
- Slow urine flow.
- Recurrence of stress incontinence can happen years after a sling has been inserted, even if your symptoms were cured at first.
- Discomfort/pain for a while, where the abdominal skin was cut during the procedure, in the thigh or in the vaginal wall; this can be relieved by simple painkillers in most patients. There are occasions when more powerful painkillers may be needed.

Occasional (between 1 in 10 and 1 in 50)

- Injury to the bladder requiring repair, catheter replacement and, sometimes, abandonment of the procedure. We can usually be complete the procedure but there may be a slight increase in the length of time you need to keep your bladder catheterised.
- Bleeding.
- Erosion of the sling into the urethra or bladder.

Rare (less than 1 in 50)

Injury to surrounding tissues (e.g. bladder, rectum and blood vessels).



Hospital-acquired infection

- Colonisation with MRSA (0.9% 1 in 110).
- MRSA bloodstream infection (0.02% 1 in 5000).
- Clostridium difficile bowel infection (0.01% 1 in 10,000).

Please note: The rates for hospital-acquired infection may be greater in "high-risk" patients. This group includes, for example, patients with long-term drainage tubes, patients who have had their bladder removed due to cancer, patients who have had a long stay in hospital or patients who have been admitted to hospital many times.

What should I expect when I get home?

When you are discharged from hospital, you should:

- be given advice about your recovery at home;
- ask when you can begin normal activities again, such as work, exercise, driving, housework and sex:
- 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); and
- be sure that you know when you get the results of any tests done on tissues or organs that have been removed.

When you leave hospital, you will be given a "draft" discharge summary. This contains important information about your stay in hospital and your operation. If you need to call your GP or if you need to go to another hospital, please take this summary with you so the staff can see the details of your treatment. This is important if you need to consult another doctor within a few days of being discharged.

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

You are advised:

- Not to drive for at least one week after surgery (you should be confident that you can perform an emergency stop);
- Not to douche your vagina or have sex for at least a month after surgery;
- Not to carry weights of more than 5kg for a month; and
- To take at least four weeks off work after, 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?

You should seek help from your doctor or your surgeon 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 on passing urine;
- Difficulty passing urine; or
- Pain or swelling of the calves.

Are there any other important points?

Different hospitals have different policies for reviewing women after sling surgery. Most like to see all their patients six weeks after the operation; others simply arrange telephone follow-up. All hospitals, however, would wish to see you again if you have any problems or there is anything you are worried about.

Make sure you keep a record of the name of your consultant, the ward you were on, the date of your operation, the telephone number of the hospital and the ward you were on.

Driving after surgery

It is your responsibility to make sure you are fit to drive following your surgery. You do not normally need to tell the DVLA that you have had surgery, unless you have a medical condition that will last for longer than three 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 give you advice on this.

Is any research being carried out in this area?

Before your operation, your surgeon or specialist nurse will tell you about any relevant research studies taking place. In particular, they will tell you if any tissue that is removed during your surgery will be stored for future study. If you agree to this research, you will be asked to sign a special form giving your consent.

All surgical procedures, even those not currently undergoing research, are audited so that we can analyse our results and compare



them with those of other surgeons. In this way, we learn how to improve our techniques and results; this means that our patients will then get the best treatment available.

What should I do with this information?

Thank you for taking the trouble to read this booklet. If you want to keep a copy for your own records, please sign below. If you would like a copy of this booklet filed in your hospital records for future reference, please let your urologist or specialist nurse know. However, if you do agree to go ahead with the scheduled procedure, you will be asked to sign a separate consent form that will be filed in your hospital records; we can give you a copy of this consent form if you ask.

I have read this booklet and I accept the information it provides.	
Signature	Date

Sources of additional information

The following articles will provide additional information about the use of fascial slings in the treatment of stress urinary incontinence in women:

- 1 NICE guidance Interventional procedures: overview of biological slings for stress urinary incontinence https://www.nice.org.uk/guidance/ipg154/resources/interventional-procedures-overview-of-biological-slings-for-stress-urinary-incontinence-2
- 2 NICE guidance Insertion of biological slings for the treatment of stress urinary incontinence in women. Understanding NICE guidance information for people considering the procedure, and for the public http://www.nice.org.uk/guidance/ipg154/resources/ipg154-insertion-of-biological-slings-for-stress-urinary-incontinence-in-women-information-for-the-public2
- 3 Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence Novara G, Artibani W, Barber MD et al European Urology 2010; 58: 218 – 238 abstract
- 4 Short-term complications of pubovaginal sling procedure for genuine stress incontinence in women Chan PT, Fournier C, Corcos J Journal of Urology 2000; 55: 207 – 211 <u>abstract</u>

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 can make some urological conditions worse and increases the risk of complications after surgery. For advice on stopping, contact your GP or the free NHS **Smoking Helpline** on **0800 169 0 169**

Disclaimer

While we have made every effort to be sure the information in this booklet is accurate, we cannot guarantee there are no errors or omissions. We cannot accept responsibility for any loss resulting from something that anyone has, or has not, done as a result of the information in this booklet.

The NHS Constitution Patients' Rights & Responsibilities

Following extensive discussions with staff and the public, the NHS Constitution has set out new rights for patients that will help improve your experience within the NHS. These rights include:

- a right to choice and a right to information that will help you 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 patients will be told the outcome of the investigations;
- the right to compensation and an apology if you have been harmed by poor treatment.

The constitution also lists patients' responsibilities, including:

- providing accurate information about their health;
- taking positive action to keep yourself and your family healthy.
- trying to keep appointments;
- treating NHS staff and other patients with respect;
- following the course of treatment that you are given; and
- giving feedback (both positive and negative) after treatment.

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