Autologous fascial sling to treat stress urinary incontinence

Patient Information Leaflet
About this leaflet

The information provided in this leaflet should be used as a guide. There may be some variation in how each gynaecologist performs the procedure, the care procedures on the ward immediately after your operation and the advice given to you when you get home. You should ask your gynaecologist about any concerns that you may have.

You should take your time to read this leaflet. A page is provided at the end of the leaflet for you to write down any questions you may have. It is your right to know about your planned operation/procedure, why it has been recommended, what the alternatives are and what the risks and benefits are. These should be covered in this leaflet. You may also wish to ask about your gynaecologist’s personal experience and results of treating your condition.

Benefits and risks

The success and the risks of most operations carried out to treat prolapse and incontinence have been poorly studied and so it is often not possible to define them clearly. In this leaflet risks may be referred to as common, rare etc. or an approximate level of risk may be given. Further information about risk is explained in a leaflet published by the Royal College of Obstetricians and Gynaecologists “Understanding how risk is discussed in healthcare”.


The following table is taken from that leaflet

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<th>Risk table</th>
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<tr>
<td><strong>Verbal description</strong></td>
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<tr>
<td>Very common</td>
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<tr>
<td>Common</td>
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<tr>
<td>Uncommon</td>
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<tr>
<td>Rare</td>
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<td>Very rare</td>
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* EU-assigned frequency
* Unit in which one adverse event would be expected

British Society of Urogynaecology (BSUG) database

In order to better understand the success and risks of surgery for prolapse and incontinence the British Society of Urogynaecology has established a national database. All members of the society are asked to enter all procedures that they carry out onto the database and you may be asked to consent to this for your operation. The data collected are being used to develop an overall picture of what procedures are being performed throughout the United Kingdom together with complications and outcomes. Individual surgeons can also use it to evaluate their own practice.
What is an autologous fascial sling?
Autologous is material taken from your own body. Fascia is a sheet of supporting fibrous tissue that holds body organs in their correct positions.

An autologous fascial sling operation creates a sling underneath the urethra (water-pipe from the bladder to the outside) using a strip of your own tissue (fascia) taken from the wall of your abdomen.

What condition does an autologous fascial sling treat?
There are a number of reasons for urinary incontinence (leakage of urine) and stress urinary incontinence (often referred to just as stress incontinence) is one of these. It happens when there is a lack of support around the opening of the bladder allowing urine to leak out if any downward pressure (stress) is put on the bladder such as when coughing, lifting or exercising.

This sling under your urethra acts as a support, and holds it closed when the bladder is pushed downwards; this prevents urine leakage. The procedure works in a similar way to mid-urethral mesh tape operations but uses your own tissue and thus avoids mesh.

It has been approved by the National Institute for Health and Care Excellence (NICE).

How is an autologous fascial sling done?
- The operation is usually done under general anaesthetic. A general anaesthetic will mean you will be asleep during the entire procedure. Occasionally it is done using a spinal anaesthetic which numbs you from the waist downwards following an injection in your back
- The operation involves a bikini line cut in your lower abdomen (tummy)
- A strip of the strong tissue that encases the muscle of your abdomen is removed through the incision
- A small cut is made in the vaginal wall just under the urethra
- This strip of tissue is then threaded on either side of the neck of your bladder to create a sling under the urethra
- At the end of the operation a cystoscopy (camera examination of the bladder) is performed to check that there is no injury to the bladder
- A catheter is needed to drain the bladder for 1-2 days. This is likely to come out through the urethra (urethral catheter) however occasionally it will be placed through the abdomen (suprapubic catheter)
Other operations which may be performed at the same time.
Surgery for prolapse of the uterus or vagina.
You should also refer to an information leaflet about any planned additional procedure.

Before considering surgery

- It is recommended that you should have tried pelvic floor exercises for at least 3 months, supervised by a trained women’s health physiotherapist, before considering surgery.

- Surgery is not usually recommended if you plan to have further children as pregnancy and delivery can result in a recurrence of the stress incontinence even if you are delivered by caesarean section.

- Although urodynamic tests are not absolutely essential before the first surgery that is tried to treat stress incontinence they are often carried out to confirm that you do have stress incontinence. These tests should however be carried out before repeat surgery or if you also have symptoms of urgency.

- Discussion at a multidisciplinary team (MDT) meeting is considered good practice before carrying out surgery for stress incontinence. Your medical notes and the results of any tests are reviewed at the MDT meeting which is attended by urogynaecologists, specialist nurses and physiotherapists as well as urologists in many hospitals. Taking into account any preferences you have expressed, a team decision is made as to whether your proposed treatment is appropriate.
Benefits

- Cure or significant improvement of stress incontinence. It has similar success rates to a colposuspension or a suburethral synthetic mesh tape.
- Avoids the implantation of mesh

Risks

General Risks of Surgery

- Anaesthetic risk. This is very small unless you have specific medical conditions, such as a problem with your heart, or breathing. Smoking and being overweight also increase any risks.
  - What can I do? Make the anaesthetist aware of medical conditions such as problems with your heart or breathing. Bring a list of your medications. Try to stop smoking before your operation. Lose weight if you are overweight and increase your activity.
- Bleeding. There is a risk of bleeding with any operation. It is rare that we have to transfuse patients after their operation.
  - What can I do? Please let your doctor know if you are taking a blood-thinning tablet such as warfarin, aspirin, clopidogrel or rivaroxaban as you may be asked to stop them before your operation.
- Infection. There is a small risk of infection with any operation (about 5 to 13 cases in 100 operations). If it occurs, an infection can be a wound infection, vaginal infection or a urinary infection, and is usually treated with antibiotics. The risk of infection is reduced by routinely giving you a dose of antibiotic during your operation. Chest infection may also occur as a result of a general anaesthetic.
  - What can I do? Treat any infections you are aware of before surgery. After surgery, regular deep breathing exercises can help prevent chest infections; the nurses will guide you how to do this.
- Deep Vein Thrombosis (DVT). This is a clot in the deep veins of the leg. Occasionally this clot can travel to the lungs (pulmonary embolism) which can be very serious and in rare circumstances it can be fatal (less than 1 in 100 of those who get a clot). The risk increases with obesity, severe varicose veins, infection, immobility and other medical problems. The risk is significantly reduced by using special stockings and injections to thin the blood.
  - What can I do? Stop taking any hormones such as hormone replacement therapy (HRT) and some types of birth-control pills 4 weeks before surgery. These can usually be restarted 4 weeks following surgery when the risk of blood clots has reduced. Do not arrange surgery the day after a long car journey or flight. As soon as you are awake start moving your legs around. Keep mobile once you are at home and continue to wear your compression stockings during times when you are less mobile.
• **Wound complications.** Wounds can become infected or occasionally stitches can become loose allowing the wound to open up or alternatively tighten up causing discomfort.

  o **What can I do?** Keep the surrounding area clean and dry carefully after washing using a clean towel or a hairdryer on a cool setting. Do not douche the vagina or use tampons.

**Specific risks of an autologous fascial sling**

• **Failure to cure** stress incontinence (10-20% of cases).

• **Recurrence of stress incontinence** even if it has been cured initially (about 10% of cases).

  o **What can I do?** Keep doing your pelvic floor exercises even after the surgery.

• **Overactive bladder symptoms** (urinary urgency and frequency with or without incontinence) often improve after the operation, but can start or worsen after the operation (about 10% of cases).

  o **What can I do?** If you experience this, please let your doctor know so that treatment can be arranged.

• **Bladder emptying or voiding problems.** When you first pass urine, it may be uncomfortable and the urine flow may be slower than usual. The nurses will measure the amount of urine you pass and then check a scan of the bladder afterwards to make sure you are emptying well. If your bladder does not empty well, the bladder catheter may be replaced for a few days or you may be asked to carry out self-catheterisation. This happens in about 10% of patients (1 in 10) but is rarely needed for more than a few days. If it does persist and you cannot pass a catheter yourself then you can go home with a catheter in place, returning to the hospital for it to be removed after a few days. The problem can continue in the long term in 5-10% of women. Often before the operation you will be taught how to pass a catheter yourself when your bladder feels full (intermittent self-catheterisation or ISC) in case you do have long term difficulties emptying your bladder.

  o **What can I do?** Master the skill of intermittent self-catheterisation before the operation in case you need it.

• **Bladder injury.** As the operation requires a tunnel to be made from the vagina to the abdomen around the bladder there is a risk of injury to the bladder which occurs in 5-10% of these operations. Any injury would usually be repaired during the operation. If this occurs you may need to have a catheter draining your bladder for about 10 days to allow the injury to heal. Although it is much less common the urethra can also be damaged and this can be more difficult to repair.
• **Injury to other structures in the abdomen.** As all structures are close together in the pelvis where this surgery is carried out there is a small risk that during surgery injury can occur to the bowel, large blood vessels or the ureter (tube from the kidney to the bladder).

• **Hernia** formation through the scar on your abdomen. It is difficult to be certain how often this occurs but it may be in up to 10% of women.

• **Pain lasting more than 6 months or pain on intercourse.** This may arise from the vagina as a result of the changed position of the vagina after surgery. It is uncommon (less than 1.5%) but unpredictable. Some people develop pain in their groin following surgery. This is rare but can require an operation to release the stitches.

**Before the operation - Pre-op assessment**

Usually you are seen in a preoperative clinic some weeks before your planned operation. At that visit you will be seen by a nurse and possibly also a doctor. You will be asked about your general health and any medications you take. Your blood pressure will be checked and you may have tests to assess your heart and breathing. Blood tests will be taken to check you for anaemia and other things according to your medical condition. Swabs may be taken from your nose and groin to make sure that you do not carry MRSA (bacteria that are very resistant to antibiotics and may cause problems after your operation). You may be asked to sign a consent form if this has not been done already.

**After the operation - in hospital**

• **Pain relief.** As there is a cut on your abdomen for this procedure it will be uncomfortable. Pain can be controlled in a number of ways depending on the preference of your anaesthetist and/or gynaecologist. Options are an epidural, injection of local anaesthetic into the tissues during the operation, self-administration of pain relief (patient controlled analgesia - PCA), drugs in a drip, tablets or suppositories. It is usually best to take the pain killers supplied to you on a regular basis aiming to take a pain killer before the pain becomes a problem.

• **Drip.** This is to keep you hydrated until you are drinking normally. The drip is usually removed within 24 hours.

• **Catheter.** You may have a tube (catheter) draining the bladder. The catheter may give you the sensation as though you need to pass urine but this is not the case. It is usually removed 1-2 days after this surgery.
• **Drain.** If there has been more than average bleeding during the operation a drain (tube) from inside the tummy to outside may be placed beside a wound to let out any blood which has collected. This is usually taken out the next day.

• **Vaginal bleeding.** There may be slight vaginal bleeding like the end of a period after the operation. This usually settles over the first week but may persist longer.

• **Eating and drinking.** You can drink fluids soon after the operation and will be encouraged to start eating as soon as tolerated.

• **Preventing DVT (deep vein thrombosis).** The same day or the day after your operation, you will be encouraged to get out of bed and take short walks around the ward. This improves general wellbeing and reduces the risk of clots in the legs. You may be given a daily injection to keep your blood thin and reduce the risk of blood clots until you go home or longer in some cases.

• **Going home.** You are usually in hospital for between two and five days. If you require a sick note or certificate please ask.

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**After the operation – at home**

- Mobilisation is very important; using your leg muscles will reduce the risk of clots in the back of the legs (DVT)
- Bath or shower as normal
- Do not use tampons for 6 weeks and avoid douching the vagina
- The stitches in your abdominal wound may need to be removed or may dissolve away. If the stitches need to be removed usually the district nurse will visit you at home to do this
- Any of the stitches under the skin in the vagina will melt away by themselves. The surface knots of the stitches may appear on your underwear or pads after about 2 weeks, this is quite normal. There may be little bleeding again after about 2 weeks when the surface knots fall off, this is nothing to worry about
- You are likely to feel tired and may need to rest in the daytime from time to time for a month or more, this will gradually improve
- It is important to avoid putting pressure on the sling particularly in the first weeks after surgery. Therefore, avoid constipation and heavy lifting.
- Avoiding constipation
  - Drink plenty of water / juice
  - Eat fruit and green vegetables e.g. broccoli
Plenty of roughage e.g. bran / oats

- Any constant cough is to be treated promptly. Please see your GP as soon as possible.
- At 6 weeks gradually build up your level of activity
- After 3 months, 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 six weeks, a busy job in 12 weeks. Avoiding all unnecessary heavy lifting will possibly reduce the stress incontinence recurring
- You can drive as soon as you can operate the pedals and look over your shoulder without discomfort, generally after three weeks, but you must check this with your insurance company, as some of them insist that you should wait for six weeks
- You can start having sex after six weeks. You will need to be gentle and may wish to use lubrication
- You usually have a follow up appointment anything between 6 weeks and six months after the operation. This maybe at the hospital (doctor or nurse), with your GP or by telephone. Sometimes follow up is not required.
- The RCOG leaflet on recovering well after an abdominal hysterectomy contains advice much of which is also applicable to this surgery See link: https://www.rcog.org.uk/globalassets/documents/patients/patient-information-leaflets/recovering-well/abdominal-hysterectomy.pdf

What to report to your doctor after surgery

- Heavy vaginal bleeding
- Smelly vaginal discharge
- Severe pain
- High fever
- Pain or discomfort passing urine or blood in the urine
- Difficulty opening your bowels.
- Warm, painful, swollen leg
- Chest pain or difficulty breathing
Alternative Treatments

Non-surgical

Do nothing. If the stress incontinence is not bothersome, treatment is not necessarily needed. Incontinence may or may get worse over time, but it is not easy to predict if this will happen.

Devices. There are a number of devices (an example of a vaginal ring is shown below) which can be inserted to block the urethra. The devices are inserted into the vagina. Devices inserted into the urethra are not recommended. They are not a cure but their aim is to keep you dry whilst in use, e.g. during exercise etc. Some women find inserting a tampon useful though care should be taken not to leave in place for too long as this can be harmful.

Weight loss. Losing weight has been shown to reduce leakage of urine.

Pelvic floor exercises (PFE) – The pelvic floor muscles support the pelvic organs. Strong muscles can help to prevent or reduce leakage of urine. A women’s health physiotherapist can explain how to perform these exercises with the correct technique. It is important that you try these to help to manage the symptoms of your prolapse and to prevent it becoming worse. It is also very important to continue with your pelvic floor exercises even if you have opted for other treatment options. These exercises have little or no risk.

Duloxetine. This is a medication that can help reduce incontinence. It needs to be taken continuously as stopping the drug will result in the leakage returning. Some women find that it causes unacceptable side effects. It is not usually recommended as a first line treatment but is an option to consider if you do not want to have a surgical procedure or are unfit to do so.
**Surgical**

The following table lists the different operations that can be considered to treat stress urinary incontinence. Further information on the operations is available in separate leaflets. All operations are not available in all hospitals. Your consultant may recommend a particular operation depending on his or her preference and expertise, or your individual needs.

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<tr>
<th>Treatment</th>
<th>Advantages</th>
<th>Disadvantages</th>
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<tbody>
<tr>
<td><strong>Urethral bulking injection</strong></td>
<td>No incisions (cuts)</td>
<td>Long term success lower than for the other procedures</td>
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<td></td>
<td>Can be done under local anaesthetic with or without sedation</td>
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<td></td>
<td>Can be done as an outpatient treatment</td>
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<td>Less pain compared to the other operations</td>
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<td></td>
<td>Lower risk of complications compared to other operations</td>
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<td></td>
<td>Quick recovery</td>
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<td><strong>Midurethral synthetic mesh tape</strong></td>
<td>Good chance of curing or improving stress incontinence</td>
<td>Worsening of urinary urgency</td>
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<td></td>
<td></td>
<td>Difficulty passing urine</td>
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<td></td>
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<td>Mesh complications</td>
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<td>Mesh exposure and erosion into the vaginal urethra or bladder</td>
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<td></td>
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<td>Can cause pain in the pelvis which sometimes persists long term</td>
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| **Colposuspension**  
(suspension of the neck of the bladder and urethra through the tummy) | Does not involve insertion of mesh  
Can be done via key-hole surgery  
Success rate similar to a mesh tape  
Treats prolapse of the anterior (front) wall of the vagina (cystocele) | Usually requires a general anaesthetic  
Worsened urinary urgency similar to a mesh tape  
Difficulty passing urine similar to a mesh tape  
Higher risk of bleeding than mesh tape  
Stitches causing bladder stones if they work their way into the bladder over time  
Developing a prolapse of the posterior (back) wall of the vagina (rectocele)  
Longer recovery |
|---|---|---|
| **Autologous fascial sling**  
(a suspension of the urethra and bladder neck using your own tissue). | Does not involve insertion of mesh  
Success rate similar to a synthetic mesh tape | Usually requires a general anaesthetic  
Requires a cut across the bottom of your tummy (not done via key-hole surgery)  
Longer recovery  
Higher risk of difficulty passing urine than with other procedures  
Higher risk of urinary urgency than other procedures  
Similar risk of bleeding to colposuspension.  
Risk of hernia developing through the scar  
Not available in all hospitals |
More information

If you would like to know more about stress urinary incontinence and the treatments available for it, you may try the following sources of information.

- Ask your GP.
- Ask the Doctor or Nurse at the hospital.
- Look at a website such as
  - Patient UK at http://patient.info/health
  - Patient information leaflets for your own hospital and others (usually available on line)

Acknowledgements

Dr Jennifer Davies, BSUG patient information committee project lead for this leaflet, on behalf of BSUG.

Miss Farah Lone, Consultant Urogynaecologist, Royal Cornwall Hospitals for the photograph of vaginal pessary

Miss Swati Jha for the diagram

West of Scotland MCN for sharing their draft leaflet with us
Making a decision - 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) ..............................................................................................................

Please describe what your expectations are from surgery.

1) ..............................................................................................................

2) ..............................................................................................................

3) ..............................................................................................................