

Insertion of biological slings for stress urinary incontinence in women

Interventional procedures guidance

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[nice.org.uk/guidance/ipg154](https://www.nice.org.uk/guidance/ipg154)

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Guidance

- 1.1 Current evidence on the safety and short-term efficacy of the insertion of biological slings for stress urinary incontinence in women is adequate to support the use of this procedure provided that normal arrangements are in place for consent and clinical governance.

- 1.2 Data on the long-term efficacy of the insertion of biological slings for stress urinary incontinence in women are limited to autologous slings. Clinicians should therefore audit patients in the longer term. Publication of further audit data and research will be helpful in determining the usefulness of different types of sling for this procedure.
- 1.3 Clinicians should ensure that patients understand that slings made of cadaveric or animal tissue may be implanted, and that the use of such slings is acceptable to the patient.

2 The procedure

2.1 *Indications*

- 2.1.1 Stress urinary incontinence is the involuntary leakage of urine during exercise or movements such as coughing, sneezing and laughing. It is usually caused by weak or damaged muscles and connective tissues of the pelvic floor, or by weakness of the urethral sphincter itself. It is estimated that 10–52% of adult women have some form of stress incontinence.
- 2.1.2 Typically, first-line treatment is conservative and includes lifestyle changes such as weight loss, pelvic floor muscle training, electrical stimulation and biofeedback. If the condition does not improve, surgical alternatives in women may include colposuspension, the use of tension-free vaginal tape, transobturator foramen procedures or traditional suburethral slings.

2.2 *Outline of the procedure*

- 2.2.1 Biological slings may be made from the patient's own fascial tissue (autograft), from human donor tissue (allograft) or from animal tissue (xenograft). Allografts are solvent dehydrated or freeze dried, and may be gamma irradiated. Autologous fascial slings are the most established option.
- 2.2.2 Suburethral sling procedures involve making an incision in the lower abdomen and one in the anterior vaginal wall. An instrument is tunnelled between the incisions to introduce the sling and position it around the bladder neck where it forms a supportive hammock. There are three main methods of positioning the sling, depending on its length. A full-length sling passes through the retropubic

space, underneath the urethra to the other side, and is fixed by sutures to the anterior abdominal wall. Shorter slings are attached by suspending sutures at each end of the sling to the anterior abdominal wall. Alternatively, bone screws may be used to secure the sutures into the pubic bones. Once the sling is in position, a cystoscopy may be performed to check that there has been no bladder perforation.

2.3 *Efficacy*

2.3.1 Two non-randomised controlled trials compared allograft slings with autograft slings. These reported similar improved rates of continence: 71% (45/63) and 74% (77/104) for the allograft groups; and 77% (55/71) and 73% (22/30) for the autograft groups. One of these studies reported that 89% (93/104) of women with allograft slings and 90% (27/30) of women with autograft slings were satisfied and would undergo the procedure again. In another study comparing long-term outcomes, subjective stress continence was reported by 92% (24/26) of patients with allograft slings at 42 months, and 91% (19/21) of patients with autograph slings at 35 months. A case series of 198 women with autograft slings reported an overall success rate of 72% (142/197) after a median follow-up of 6 years. Another case series reported that 85% (75/88) of patients who were followed up for longer than 5 years were continent.

2.3.2 One randomised controlled trial reported that 82% (56/68) of women had improved rate of continence with a xenograft sling, compared with 88% (53/60) of women who had had a vaginal tape procedure (not statistically significant). The patient satisfaction rates were similar for the two groups. In a second randomised study of 139 patients, published in abstract form, 12.5% patients (6/48) with a xenograft sling required reoperation within 12 months for delayed failure. There were no reports of failure in the vaginal tape or autograft group at 12 months. For more details, refer to the Sources of evidence.

2.3.3 The Specialist Advisors stated that there are concerns about the long-term efficacy of this procedure.

2.4 *Safety*

2.4.1 The two most commonly reported complications were urge incontinence and urinary retention. Urge incontinence affected between 3% (5/152) and 50% (5/

10) of women. One study reported that 94% (232/247) of women had transient urinary retention (for longer than 1 day postoperatively; mean duration of catheterisation was 8.4 days), and prolonged urinary retention was reported in 2% (1/63) to 10% (3/30) of women. Two studies reported severe or persistent pain in 1% (1/74) and 4% (5/134) of women, respectively. Other complications included infection, pelvic haematoma, haemorrhage and urethral stenosis.

2.4.2 The Specialist Advisors noted that potential adverse effects include urethral obstruction and retention, bladder perforation, haemorrhage, infection and urgency. There is also an additional potential risk of infection associated with the use of cadaveric tissue.

2.5 *Other comments*

2.5.1 It was noted that a variety of types of biological slings are available, including allogenic, xenogenic or autogenic grafts; and that outcomes may vary according to the type of graft used. It was also noted that a variety of methods are used for the implantation of slings.

2.5.2 It was noted that this procedure is different from the tension-free vaginal tape insertion procedure (which is subject to NICE guidance – see Further information).

3 Further information

3.1 NICE has issued guidance on [tension-free vaginal tape](#) (replaced by NICE clinical guideline 40, '[Urinary incontinence: the management of urinary incontinence in women](#)'), [insertion of extraurethral \(non-circumferential\) retropubic adjustable compression devices for stress urinary incontinence in women](#) and [intramural urethral bulking agents for stress urinary incontinence in women](#).

Andrew Dillon
Chief Executive
January 2006

Information for patients

NICE has produced [information on this procedure for patients and carers](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

['Interventional procedures overview of biological slings for stress urinary incontinence'](#), April 2005.

4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE [interventional procedure guidance](#) process.

We have produced a [summary of this guidance for patients and carers](#). Information about the evidence it is based on is also [available](#).

Changes since publication

20 January 2012: minor maintenance.

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Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Contact NICE

National Institute for Health and Clinical Excellence
Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT

www.nice.org.uk

nice@nice.org.uk

0845 033 7780

Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).