NICE National Institute for Health and Care Excellence

NICE guidance

Single-incision short sling mesh insertion for stress urinary incontinence in women

HealthTech guidance

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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, and specifically any special arrangements relating to the introduction of new interventional procedures. 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.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

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. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

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.

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This guidance replaces IPG262 and IPG566.

1 Recommendations

1.1 The evidence on the safety of single-incision short sling mesh insertion for stress urinary incontinence in women shows infrequent but serious complications. These include lasting pain, discomfort and failure of the procedure. The mesh implant is intended to be permanent but, if removal is needed because of complications, the anchoring system can make the device very difficult or impossible to remove. The evidence on efficacy in the long term is inadequate in quality and quantity. Therefore, this procedure should not be used unless there are special arrangements in place for clinical governance, consent, and audit or research.

1.2 Clinicians wishing to do single-incision short sling mesh insertion for stress urinary incontinence in women should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy, including that there is the potential for the procedure to fail and for serious long-term complications from the device, and that the mesh implant is intended to be permanent so removal, if needed, may be difficult or impossible. Provide patients with clear written information. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having single-incision short sling mesh insertion for stress urinary incontinence in women (see NICE's interventional procedure outcomes audit tool).

1.3 Patient selection should be done by a multidisciplinary team with experience in the assessment and management of women with stress urinary incontinence.

1.4 This procedure should only be done by clinicians with specific training in transobturator surgical techniques. Removal of a short sling mesh should only be done by people with expertise in this specialised surgery.

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1.5 NICE encourages further research into single-incision short sling mesh insertion for stress urinary incontinence in women and may update the guidance on publication of further evidence. Studies should include details of patient selection, and should measure long-term outcomes including effects on quality of life and other patient-reported outcomes.

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2 Indications and current treatments

2.1 Stress urinary incontinence is the involuntary leakage of urine during exercise or certain movements such as coughing, sneezing and laughing. In women, it is most commonly associated with previous pregnancy, with or without recognised obstetric trauma. Previous urogynaecological surgery may also result in stress urinary incontinence.

2.2 Conventional treatment is conservative, and includes lifestyle changes such as weight loss and pelvic floor muscle training. Surgery is considered if these conservative measures do not help. Different types of surgery may be used, including intramural bulking procedures, insertion of a synthetic tension-free vaginal tape, insertion of a transobturator tape or other sling procedures, colposuspension or insertion of an artificial urinary sphincter.

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3 The procedure

3.1 Single-incision short sling mesh insertion aims to reduce the risk of urinary leakage in women with stress urinary incontinence. It is considered when conservative options (see section 2.2) have been tried but incontinence persists. The procedure aims to minimise the risk of major adverse events such as bladder, vaginal, urethral and vascular perforations or erosions, and chronic pain that are associated with minimally-invasive sling procedures. The single-incision short slings have shorter tape lengths and different fixation systems to transobturator minimally-invasive slings. These fixation systems do not enter the retropubic space (minimising the risk of major vessel or visceral injury) or the lateral half of the obturator foramen (potentially reducing the risk of groin pain), but they are anchored in the obturator membrane or in the obturator muscles.

3.2 With the patient under local (with or without sedation), regional or general anaesthesia, a small incision is made in the vaginal wall, under the urethra. The sling, which is typically 8–14 cm long, is inserted using a delivery needle through the obturator foramen and retracted to deploy the sling into the obturator internus muscle. This is repeated with a second sling on the contralateral side. A special tip anchors the sling in place behind the mid urethra. Sling tension is then controlled using the delivery device until the appropriate tension is achieved. The delivery device is then removed and the incision is closed. The slings are permanent implants. Cystoscopy is used to check that bladder perforation has not occurred during the procedure.

3.3 Single-incision short sling systems may differ in the length of the sling, the fixation method, the fixation location and the method of tension adjustment or control.

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4 Efficacy

This section describes efficacy outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

4.1 In a systematic review and meta-analysis of 3,308 women from 26 randomised controlled trials (RCTs) comparing single-incision mini sling (SIMS, n=1,735) procedures with standard midurethral sling (SMUS, n=1,573) procedures in women with stress urinary incontinence, there was no statistically significant difference in objective cure rates at a mean follow-up of 18.6 months between SIMS (tension-free vaginal tape [TVT] 'Secur' trials excluded) and SMUS (risk ratio [RR] 0.98; 95% confidence interval [CI] 0.94 to 1.01, n=11, I^2=7%). There were similar results when SIMS was compared with transobturator tension-free vaginal tape (TOT, RR 0.98; 95% CI 0.94 to 1.01, n=10, I^2=11%) and with retropubic tension-free vaginal tape (r-TVT, RR 0.81; 95% CI 0.48 to 1.40, n=1).

4.2 In the systematic review and meta-analysis of 3,308 women, there was no statistically significant difference in patient-reported cure rates at a mean follow-up of 18.6 months between SIMS ('TVT Secur' trials excluded) and SMUS (RR 0.94; 95% CI 0.88 to 1.00, n=11, I^2=57%). There were similar results when SIMS was compared with TOT (RR 0.96; 95% CI 0.92 to 1.00, n=9, I^2=20%) and with r-TVT (RR 0.71; 95% CI 0.42 to 1.20, n=2, I^2=75%).

4.3 In a Cochrane systematic review and meta-analysis of 3,290 women with stress urinary incontinence from 31 randomised or quasi-randomised trials, women were more likely to remain incontinent after surgery with SIMS (41% [121/292]) than with r-TVT (26% [72/281]; RR 2.08, 95% CI 1.04 to 4.14). Four out of 5 studies in the comparison included 'TVT Secur', which has been withdrawn from use as a single-incision sling. In the same study, incontinence rates were also higher with SIMS than with inside-out TOT (30% versus 11%; RR 2.55, 95% CI 1.93 to 3.36). However, if the trials in which 'TVT Secur' was not used were excluded, it showed that a high risk of incontinence was mainly associated with use of this device (RR 2.65, 95% CI 1.98 to 3.54). The evidence was insufficient to show a difference in incontinence rates with other SIMS ('TVT Secur' trials excluded) compared with inside-out or outside-in TOT.

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4.4 In an RCT of 80 women (40 SIMS versus 40 TOT), there were no statistically significant differences between groups for the cough stress pad test (CSPT) values before and after the procedure. However, there were statistically significant differences within groups in CSPT values before and after the procedure (mean±standard deviation, grams: 71±18 versus 0.66±0.8 in the SIMS group, p=0.0001, and 73±27 versus 0.41±0.4 in the TOT group, p=0.0002).

4.5 In a prospective case series of 120 women treated by SIMS, the mean daily pad use decreased statistically significantly from 2.4 before the procedure to 0.1 at 1 month and 0.2 at 12 months ($p<0.01$ versus baseline).

4.6 In a prospective comparative study of 240 women treated by SIMS (n=120) or r-TVT (n=120), detrusor instability scores did not change statistically significantly in the SIMS group from baseline (2.1±1.3 versus 2.2±1.3 at 24 months after the procedure). In the r-TVT group, the scores statistically significantly worsened from baseline (2.4±1.5 versus 2.9±1.9 at 24 months, $p<0.05$).

4.7 In the prospective case series of 120 women, the mean urogenital distress inventory scores (a 6-item questionnaire) decreased statistically significantly from 65% before the procedure to 3% at 1 month and 13% at 12 months ($p<0.01$ versus baseline).

4.8 In the prospective case series of 120 women, the mean Incontinence impact scores (a 7-item short-form questionnaire) decreased statistically significantly from 87% before the procedure to 3% at 1 month and 13% at 12 months ($p<0.01$ versus baseline).

4.9 In an RCT of 225 women treated by SIMS (n=112) or TOT (n=113), the proportion of women using antimuscarinics 12 months after the procedure was statistically significantly lower in the SIMS group than in the TOT group (6% [5/87] versus 16% [15/95], p=0.034).

4.10 In the systematic review and meta-analysis of 3,308 women, women with SIMS ('TVT Secur' trials excluded) returned to normal activities statistically significantly earlier (weighted means difference [WMD] 5.08 days; 95% CI −9.59 to −0.56, n=2, I^2=63%) and to work statistically significantly earlier (WMD −7.20 days; 95% CI −12.43 to −1.98, n=2, I^2=38%).

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4.11 In the systematic review and meta-analysis of 3,308 women, there was no statistically significant difference in quality-of-life scores (measured with the Incontinence Impact Questionnaire–Short Form IIQ7 and King's Health Questionnaire 7) between SIMS ('TVT Secur' trials excluded) and SMUS (WMD 1.23; 95% CI −2.76 to 5.21, n=3, I^2=56%). All 3 RCTs included in the analysis reported improvement in quality-of-life scores at follow-up compared with baseline, with no statistically significant differences between SIMS and SMUS.

4.12 In the prospective comparative study of 240 women treated by SIMS (n=120) or r-TVT (n=120), patient satisfaction (assessed using a visual analogue scale [0 to 10, from low to high satisfaction]) was 7.5±2.6 in the SIMS group compared with 7.4±1.7 in the r-TVT group (level of significance not stated).

4.13 In the systematic review and meta-analysis of 3,308 women, there was no statistically significant difference in Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ12) scores between SIMS ('TVT Secur' trials excluded) and SMUS at a mean 18-month follow-up (WMD 0.39; 95% CI −0.89 to 1.67, n=2, I^2=17%).

4.14 The specialist advisers listed the following key efficacy outcomes: objective and subjective cure of stress urinary incontinence, reduction in stress urinary leakage and reduction in stress incontinence episodes for more than 1 year.

4.15 Twenty two commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

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5 Safety

This section describes safety outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

5.1 Pain after the procedure was statistically significantly lower in the single-incision mini sling (SIMS) group (tension-free vaginal tape [TVT] 'Secur' trials excluded) than in the standard midurethral sling (SMUS) group (weighted means difference [WMD] −3.13; 95% confidence interval [CI] −4.89 to −1.36, n=4, I^2=93%, p<0.0005), and groin pain was also statistically significantly lower (risk ratio [RR] 0.30; 95% CI 0.18 to 0.49, n=10, I^2=19%, p<0.00001) in a systematic review and meta-analysis of 3,308 women from 26 randomised controlled trials (RCTs) comparing SIMS procedures (n=1,735) with SMUS (n=1,573) procedures in women with stress urinary incontinence.

5.2 Haemorrhage during the procedure was reported in 2% (2/120) of women in the SIMS group (including treatment with 'TVT Secur' slings) and in 1% (1/120) of women in the retropubic TVT (r-TVT) group in a prospective comparative study of 240 women. In the same study, haemoglobin drop within 30 days of the procedure was reported in 1% (1/120) of women in the SIMS group and in none of the women in the r-TVT group (p value not significant). Pelvic haematoma was reported in 1 woman in a prospective case series of 116 women treated by SIMS; it developed after revision surgery needed because of urinary outlet obstruction.

5.3 Vaginal tape erosion rates were not statistically significantly different between the SIMS group ('TVT Secur' trials excluded) and the SMUS group in the systematic review and meta-analysis of 3,308 women (RR 1.43; 95% CI 0.61 to 3.35, n=11, I^2=0%, p=0.41). Vaginal mesh exposure rate was statistically significantly greater in the SIMS group ('TVT Secur' trials included) than in the transobturator sling (TOT) group in a Cochrane systematic review and meta-analysis of 3,290 women with stress urinary incontinence from 31 randomised or quasi-randomised trials (RR 2.59, 95% CI 1.21 to 5.56, n=9, I^2=4%, p=0.015). In the same systematic review, bladder or urethral erosion rate was statistically significantly greater in the SIMS group ('TVT Secur' trials included) than in the TOT group (RR 17.79, 95% CI 1.06 to 298.88, n=2, I^2=0%, p=0.046). Mesh

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extrusion was reported in 4% (4/113) of women in the prospective case series of 116 women with stress urinary incontinence treated with SIMS, within 12 months of the procedure. Three of the 4 mesh extrusions were treated by revision surgery that included trimming and excision; 1 mesh extrusion was asymptomatic and successfully treated with oestrogen cream. Erosion-free rates 5 years after the procedures were not statistically significantly different between the single-incision sling group and the transobturator vaginal tape group in a comparative study of 381 women (99% versus 96%, p=0.15).

5.4 Urethrovaginal fistula was reported in 1 women treated by SIMS in a single case report. The same patient had also bladder mesh erosion and vaginal mesh exposure. She was treated by excision of midurethral mesh, urethroplasty, Martius flap tissue transfer and cystourethroscopy but continued to have mild stress urinary incontinence.

5.5 De novo urgency or worsening of pre-existing surgery rates were not statistically significantly different between the SIMS group ('TVT Secur' trials excluded) and the SMUS group in the systematic review and meta-analysis of 3,308 women (RR 1.09; 95% CI 0.78 to 1.54, n=12, I^2=0%, p=0.61). Rates of de novo overactive bladder symptoms 5 years after the procedure were statistically significantly higher in the single-incision sling group compared with the transobturator vaginal tape group in the comparative study of 381 women (9% versus 3%, p=0.012).

5.6 Repeat continence surgery rates were not statistically significantly different between the SIMS group ('TVT Secur' trials excluded) and the SMUS group in the systematic review and meta-analysis of 3,308 women (RR 2.00; 95% CI 0.93 to 4.31, n=10, I^2=0%, p=0.08).

5.7 Lower urinary tract injury rates were not statistically significantly different between the SIMS group ('TVT Secur' trials excluded) and the SMUS group in the systematic review and meta-analysis of 3,308 women (RR 0.99; 95% CI 0.38 to 2.56, n=13, I^2=0%, p=0.99). Bladder perforation was reported in 3% (3/120) of women in a prospective case series of 120 women. The patients were treated with a Foley catheter overnight, which was removed 1 day after the procedure.

5.8 Vaginal wall perforation was reported in 1% of women in the SIMS group, in 3% of women in the TVT group and in 4% of women in the TOT group in a retrospective

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comparative study of 531 women (relative number of women not reported).

5.9 Voiding difficulties after the procedure rates were not statistically significantly different between the SIMS group ('TVT Secur' trials excluded) and the SMUS group in the systematic review and meta-analysis of 3,308 women (RR 0.58; 95% CI 0.26 to 1.31, n=11, I^2=31%, p=0.19).

5.10 Urinary tract infection within 30 days of the procedure was reported in 3% (3/120) of women in the SIMS group and in 4% (5/120) of women in the r-TVT group in the prospective comparative study of 240 women (p value not statistically significant).

5.11 A bladder stone was reported in 1 woman 3 years after the procedure in a second case report. It was treated by excision of mesh transvaginally, separation of the stone from the eroded mucosal mesh and subsequent transurethral stone removal. The patient continued to have persistent stress urinary incontinence that had worsened after SIMS removal. She was subsequently treated with periurethral bulking and her symptoms of stress urinary incontinence improved.

5.12 Dyspareunia was reported in 1 woman in the prospective case series of 116 women, within 12 months of the procedure.

5.13 Delayed wound healing was reported in 1 woman in the prospective case series of 116 women, within 12 months of the procedure.

5.14 Anchor displacement was reported in 1 woman at the 1-year follow-up visit in the RCT of 80 women (40 SIMS versus 40 TOT). The anchor was removed with the patient under local anaesthesia and the patient remained continent.

5.15 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers did not list any new anecdotal adverse event. They considered that the following were theoretical adverse events: reaction to tape and poor anchoring of tape leading to failure in the short or long term.

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6 Committee comments

6.1 The committee noted there are a number of different devices in use.

6.2 The committee was advised that the mesh slings are intended to be permanent implants, and that the presence of anchors makes removal of an implant, if necessary, particularly difficult.

6.3 The committee noted that, despite the existence of 2 registries, data collection had been poor and previous recommendations had not been followed.

6.4 The committee encouraged the reporting of all device-related adverse events to the Medicines and Healthcare products Regulatory Agency.

6.5 The committee was advised that a national standard consent form is being developed.

6.6 The committee noted the work of NHS England's Mesh Working Group and the Scottish Government's independent review of the use, safety and efficacy of transvaginal mesh implants in the treatment of stress urinary incontinence and pelvic organ prolapse in women.

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Update information

Minor changes after publication

January 2026: Interventional procedures guidance 566 has been migrated to HealthTech guidance 419. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

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