NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of single-incision short sling (mesh) insertion for stress urinary incontinence in women

Stress urinary incontinence is when urine leaks out during exercise or certain movements such as coughing, sneezing and laughing. It usually happens because the muscles and tissue that make up the pelvic floor have become weakened or damaged, most commonly associated with pregnancy.
Single-incision short sling (mesh) insertion involves placing a short synthetic sling under the urethra (the tube that carries urine from the bladder) through an incision in the vagina. The aim of the sling is to support the urethra to reduce the chance of urine leaking when the bladder is put under pressure.

Introduction

The National Institute for Health and Care Excellence (NICE) has prepared this interventional procedure (IP) overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This IP overview was prepared in September 2015.

Procedure name

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

Specialist societies

- British Association of Urological Surgeons – (section of female and reconstructive urology)

- British Society of Urogynaecology
- Royal College of Obstetricians and Gynaecologists.

Description

Indications and current treatment

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.

Conventional treatment is conservative, and includes lifestyle changes such as weight loss and pelvic floor muscle training. If the condition does not improve, 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.

What the procedure involves

Single-incision short sling (mesh) insertion aims to reduce the risk of urinary leakage in women with stress urinary incontinence. The procedure also 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 minimally-invasive slings. These fixation systems do not enter the obturator fossa (potentially minimising the risk of groin pain) or the retropubic space (minimising the risk of major vessel or visceral injury).

With the patient under local (with or without sedation), spinal 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.

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.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to single-incision short sling (mesh) insertion for stress urinary incontinence in women. The following databases were searched, covering the period from their start to 3 September 2015: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Female patients with stress urinary incontinence
Intervention/test	Single-incision short sling (mesh) insertion
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on 8,590 women from 3 systematic reviews and meta-analyses, 2 randomised controlled trials (RCTs), 2 non-randomised comparative studies, 2 case series and 2 case reports.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on single-incision short sling (mesh) insertion for stress urinary incontinence in women

Study 1 Mostafa A (2014)

Details

Study type	**Systematic review and meta-analysis**
Country	UK
Recruitment period	Not reported
Study population and number	n=**3,308 women from 26 RCTs (1,735 SIMS versus 1,573 SMUS)** with stress urinary incontinence
Age and sex	Mean age (SIMS: 51 versus SMUS: 55); 100% (3,308/3,308) female.
Patient selection criteria	All RCTs and quasi-RCTs comparing SIMS with either TO-TVT or RP-TVT in the surgical treatment of women with stress urinary incontinence with a minimum of 12-month follow-up.
Technique	The SIMS assessed were: MiniArc (7 RCTs; n=759), SIMS-Ajust (3 RCTs; n=350), Ophira (1 RCT; n=130), Contasure-Needleless (1 RCT; n=257), SIMS-TFS (1 RCT; n=80), Solyx (1 RCT; n=30), and TVTSecur (12 RCTs; n=1606). The SIMS were compared with RP-TVT in 4 RCTs and TO-TVT in 22 RCTs.
Follow-up	**12 to 36 months**
Conflict of interest/source of funding	The only financial disclosure was that 1 of the authors had received travel honorariums for attending medical conferences and paid consultancy for Bard, AMS, Pfizer, and Astellas.

Analysis

Follow-up issues:

- Ten out of 26 RCTs had complete outcomes data and/or reported the reasons for the loss of follow-up.
- All authors were contacted, and supplementary data were provided by 17 authors; a number of authors provided the 24-month data for their published longer or shorter follow-up reports.
- Overall, 8% (259/3,308) of women were lost to follow-up (SIMS: n=142 versus SMUS: n=117).

Study design issues:

- Two RCTs were translated, from Dutch and from Russian; 32 studies were exclude
- Reviews and Meta-analysis (PRISMA) statement guidance.
- The literature search was last updated on 2 May 2013.
- Risk of bias: Most RCTs had good sequence generation and allocation concealment; however, reporting of blinding methods and rates of incomplete outcome data in most RCTs were generally poor. Two studies used a quasi-randomised method.

Study population issues: Women with urodynamic or clinical diagnosis of stress urinary incontinence with or without symptoms of overactive bladder and with or without concomitant prolapse surgery were included.
Other issues: This paper is an updated systematic review and meta-analysis of a paper published in 2011.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **3,308 women from 26 RCTs (1,735 SIMS versus 1,573 SMUS)** **Patient-reported cure rate at mean follow-up of 18.6 months (RCTs with TVT-Secur excluded)** SIMS versus SMUS: RR: 0.94; 95% CI, 0.88–1.00 (n=11), I^2=57% SIMS versus TO-TVT: RR: 0.96; 95% CI, 0.92–1.00 (n=9), I^2=20% SIMS versus RP-TVT: RR: 0.71; 95% CI, 0.42–1.20 (n=2), I^2=75% SIMS (Ajust and TFS) versus SMUS: RR: 1.09; 95%CI, 0.91–1.31 (n=4) **Objective cure rate at mean follow-up of 18.6 months (RCTs with TVT-Secur excluded)** SIMS versus SMUS: RR: 0.98; 95% CI, 0.94–1.01 (n=11), I^2=7% SIMS versus TO-TVT**:** RR: 0.98; 95% CI, 0.94–1.01 (n=10), I^2=11% SIMS versus RP-TVT: RR: 0.81; 95% CI, 0.48–1.40 (n=1) SIMS (Ajust and TFS) versus SMUS: RR: 1.01; 95% CI, 0.92–1.10 (n=4) The authors reported that 'these results also pertained to sensitivity analysis including high-quality RCTs only'. **Quality-of-life changes (Incontinence Impact Questionnaire–Short Form IIQ-7 and King's Health Questionnaire-7, RCTs with TVT-Secur excluded)** SIMS versus SMUS: WMD: 1.23; 95% CI, -2.76 to 5.21 (n=3), I^2=56% All RCTs reported improvement in QoL scores at the follow-up compared with baseline with no significant differences between SIMS versus SMUS. **Impact on sexual function (PISQ-12 score, RCTs with TVT-Secur excluded)** SIMS versus SMUS: WMD 0.39; 95% CI, -0.89 to 1.67 (n=2), I^2=17% No evidence of significant differences in total PISQ-12 scores between both groups. **Time to return to normal activities (RCTs with TVT-Secur excluded)** SIMS versus SMUS: WMD: -5.08; 95% CI, -9.59 to -0.56 (n=2), I^2=63% **Time to return to work (RCTs with TVT-Secur excluded)** SIMS versus SMUS: WMD: -7.20; 95% CI, -12.43 to -1.98 (n=2), I^2=38%	**Postoperative pain** SIMS (TVT-Secur excluded) versus SMUS: WMD: -3.13; 95% CI, -4.89 to -1.36 (n=4), I^2=93% (p=0.0005) After excluding trials with TVT-Secur, there was no statistically significant difference in the rate of **lower urinary tract injury, postoperative voiding difficulties, vaginal tape erosions, de novo urgency, and/or worsening of pre-existing urgency**, I^2<25%. **Lower urinary tract injury** SIMS (TVT-Secur excluded) versus SMUS: RR: 0.99; 95% CI, 0.38–2.56 (n=13), I^2=0%, p=0.99. **Postoperative voiding difficulties** SIMS (TVT-Secur excluded) versus SMUS: RR: 0.58; 95% CI, 0.26–1.31 (n=11), I^2=31%, p=0.19. **Vaginal tape erosion** SIMS (TVT-Secur excluded) versus SMUS: RR: 1.43; 95% CI, 0.61–3.35 (n=11), I^2=0%, p=0.41. **De novo urgency and/or worsening of pre-existing surgery** SIMS (TVT-Secur excluded) versus SMUS: RR: 1.09; 95% CI, 0.78–1.54 (n=12), I^2=0%, p=0.61. Also the **groin pain** rate was significantly lower in the SIMS group (RR: 0.30; 95% CI, 0.18–0.49 (n=10), I^2=19% (p<0.00001). **Repeat continence surgery** SIMS (TVT-Secur excluded) versus SMUS: RR: 2.00; 95% CI, 0.93–4.31 (n=10), I^2=0% (p=0.08).
Abbreviations used: CI, confidence interval; PISQ-12: Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire; QoL, quality of life; RCT, randomised controlled trial; RP-TVT, retropubic tension-free vaginal tape; RR, risk ratio; SIMS, single-incision mini-sling; SMUS, standard midurethral sling; TO-TVT, transobturator tension-free vaginal tape; WMD, weighted means difference.	

Study 2 Nambiar A (2014)

Details

Study type	**Cochrane systematic review and meta-analysis**
Country	UK
Recruitment period	Not reported
Study population and number	n=**3,290 women from 31 trials** with urodynamic stress incontinence, symptoms of stress incontinence or stress-predominant mixed urinary incontinence.
Age and sex	100% female (3,290/3,290)
Patient selection criteria	Randomised and quasi-randomised trials in which at least one trial arm involves one of the new single-incision slings. Studies were excluded if they were not randomised or quasi-randomised controlled trials for women with stress incontinence or stress-predominant mixed incontinence.
Technique	The types of single-incision slings included in this review were TVT-Secur (Gynecare), MiniArc (American Medical Systems), Ajust (C.R. Bard), Needleless (Mayumana Healthcare), Ophira (Promedon), Tissue Fixation System (TFS PTY Ltd) and CureMesh (D.Med. Co.).
Follow-up	**Not reported**
Conflict of interest/source of funding	One of the authors has received travel and educational grants from Pfizer, Astellas and GSK. Another author is a speaker for Johnson and Johnson (Women's Health and Urology) and Bard Medical and is part of a randomised trial on Contasure Needleless. He has received honoraria and travel and educational grants from Bard, Johnson and Johnson and Boston Scientific.

Analysis

Follow-up issues:

- Ranges of follow-up varied considerably between trials, and sometimes trials with significantly different mean durations of follow-up were included in the same comparison.
- The risk of bias was considered high for 8 trials as the result of high dropout rates.

Study design issues:

- The meta-analysis was done as per the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) statement guidance.
- Data were independently checked by three review authors.
- The risk of bias was considered to be low for random sequence generation for 14 trials, in which the sequence was generated most often by using a computer. The risk of bias was considered high for three trials, in which allocation was based on medical record number, participants were allocated alternately or the method of randomisation was inadequately described. The risk of bias was considered unclear in the remaining 14 trials, in which no description was given in the report.
- Eleven trials used an adequate allocation concealment method (most often opaque envelopes). The other 20 trials failed to describe any method of allocation concealment.
- Only five trials carried out some kind of blinding of participants. The other trials made no mention of blinding or stated that it was not possible.
- Six trials mentioned methods of reducing risk of bias through blinded outcome assessment. Three were considered to be at high risk of bias owing to unblinded outcome assessment or inadequate information for assessment.

Study population issues: None.

Other issues: Some studies included used the TVT-Secur device that has been withdrawn from use.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **3,290 women from 31 trials** **Urinary incontinence** • Women were more likely to remain incontinent after surgery with single-incision slings than with retropubic slings: 121/292, 41% versus 72/281, 26%; RR=2.08, 95% CI 1.04 to 4.14 (4/5 studies in the comparison included TVT-Secur as the single-incision sling). • Single-incision slings resulted in higher incontinence rates compared with inside-out transobturator slings: 30% versus 11%; RR=2.55, 95% CI 1.93 to 3.36 ○ Excluding the trials in which TVT-Secur was not used showed that high risk of incontinence was principally associated with use of this device (RR=2.65, 95% CI 1.98 to 3.54). • Evidence was insufficient to reveal a difference in incontinence rates with other single-incision slings (excluding TVT-Secur trials) compared with inside-out or outside in transobturator slings. Overall results show that TVT-Secur is considerably inferior to retropubic and inside-out transobturator slings, but additional evidence is required to allow any reasonable comparison of other single-incision slings versus transobturator slings. When one single-incision sling was compared with another, evidence was insufficient to suggest a significant difference between any of the slings in any of the comparisons made.	**De novo urgency** Single-incision slings versus retropubic slings: RR=2.39, 95% CI 1.25 to 4.56, I^2=0%, n=3, p=0.0083 (including TVT Secur trials). **Vaginal mesh exposure** Single-incision slings versus trans-obturator slings: RR=2.59, 95% CI 1.21 to 5.56, I^2=4%, n=9, p=0.015 (including TVT Secur trials) **Bladder/urethral erosion** Single-incision slings versus trans-obturator slings: RR=17.79, 95% CI 1.06 to 298.88, I^2=0%, n=2, p=0.046 (including TVT Secur trials) **Operative blood loss** (ml) Single-incision slings versus inside-out transobturator slings: mean difference 18.79, 95% CI 3.70 to 33.88, I^2=0%, n=2, p=0.015) **Pain** Single-incision slings versus obturator minimally invasive slings **Postoperative pain or discomfort** was less common with single-incision slings (RR=0.26, 95% CI 0.19 to 0.37, I^2=0%, n=10, p<0.00001) **Rates of long-term groin/thigh pain or discomfort** were lower with single-incision slings (RR=0.14, 95% CI 0.04 to 0.54, I^2=0%, n=5, p=0.0043).
Abbreviations used: CI, confidence interval; RR, risk ratio.	

Study 3 Zhang P (2015)

Details

Study type	**Systematic review and meta-analysis**
Country	China
Recruitment period	Not reported
Study population and number	n=**678 women from 5 RCTs (361 SIMS-Ajust versus 317 TVT-O/TOT)** with stress urinary incontinence
Age and sex	Not reported
Patient selection criteria	Inclusion criteria: RCTs of studies on the efficacy of surgeries for female stress urinary incontinence, prospective studies, trials of studies on the comparison of Ajust methods versus the TVT-O method or versus the TOT method, similar baseline characteristics of the patient population, observed indicators include the cure rate and perioperative complications, with or without allocation concealment or with blind treatment. Exclusion criteria: unclear sample data and intervention means, inappropriate statistical method, high rate of loss to follow-up, not uniform assessment criteria.
Technique	Device used for single-incision short sling insertion: Ajust.
Follow-up	**Not reported**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: A total of 13 people were lost to follow-up (SIMS-Ajust: n =3, TVT-O/TOT: n =10).

Study design issues:

- Two urologists extracted the relevant data and assessed their quality independently.
- The literature search was done from 2009 to August 2014.

Study population issues: None.

Other issues: A total of five (<10) RCTs were included in this study, so funnel plot analysis was not done to detect publication bias.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: n=**678 women from 5 RCTs (361 SIMS-Ajust versus 317 TVT-O/TOT**) **Objective cure rate (235 SIMS-Ajust versus 200 TVT-O/TOT , n=3 studies, I^2=0%, p>0.1)** RR=0.97, 95 % CI (0.90 to 1.05), p=NS **Patient-reported cure rate (261 SIMS-Ajust versus 261 TVT-O/TOT , n=4 studies, I^2=0%, p>0.1)** RR=0.95, 95 % CI (0.87 to 1.04), p=NS	**Postoperative groin pain (235 SIMS-Ajust versus 192 TVT-O/TOT , n=3 studies, I^2=25%, p=0.26)** RR=0.30, 95 % CI (0.11 to 0.85), p=0.02 **Postoperative pain (154 SIMS-Ajust versus 154 TVT-O/TOT , n=2 studies, I^2=0%, p>0.1)** RR=0.50, 95 % CI (0.18 to 1.43), p=NS **Lower urinary tract injuries (361 SIMS-Ajust versus 317 TVT-O/TOT , n=5 studies)** RR=2.82, 95 % CI (0.14 to 57.76), p=NS **Postoperative voiding difficulties (304 SIMS-Ajust versus 260 TVT-O/TOT , n=4 studies, I^2=0%, p=0.42)** RR=0.64, 95 % CI (0.28 to 1.45), p=NS **De novo urgency and/or worsening of pre-existing surgery (311 SIMS-Ajust versus 267 TVT-O/TOT , n=4 studies, I^2=0%, p=0.76)** RR=1.06, 95 % CI (0.66 to 1.71), p=NS **Vaginal tape erosion (361 SIMS-Ajust versus 317 TVT-O/TOT , n=5 studies, I^2=0%, p=0.67)** RR=1.04, 95 % CI (0.24 to 4.45), p=NS **Repeat of continence surgery (169 SIMS-Ajust versus 124 TVT-O/TOT, n=2 studies)** RR=1.64, 95 % CI (0.41 to 6.61), p=NS
Abbreviations used: NS, not significant; RCT, randomised controlled trial; RR, risk ratio; SIMS, single-incision mini-sling; TVT-O/TOT, transobturator tension-free vaginal tape.	

Study 4 Lee J K (2015)

Details

Study type	**RCT**
Country	Australia
Recruitment period	2009-2011
Study population and number	n=**225 (112 MiniArc versus 113 Monarc)** women with stress urinary incontinence
Age and sex	Mean 52 years; 100% (225/225) female
Patient selection criteria	Inclusion criteria: women with stress urinary incontinence or urodynamic stress incontinence for whom conservative treatments had failed and who needed surgery. Exclusion criteria: women with intrinsic sphincter deficiency, previous mid-urethral slings, untreated detrusor overactivity or significant voiding dysfunction.
Technique	Single incision sling: MiniArc Outside-in transobturator midurethral sling: Monarc Surgeries were done by surgeons who were already proficient with Monarc and who had already done at least 10 MiniArc procedures. All patients were treated under general anaesthetic. Cystourethroscopy was routinely done for all patients. Postoperative analgesia (for patients treated by Monarc only) and voiding assessment were standardised for both groups.
Follow-up	**12 months**
Conflict of interest/source of funding	An external research grant was received by 4 of the authors from American Medical Systems.

Analysis

Follow-up issues:

- Patients were seen at 6 weeks, 6 and 12 months for a clinical examination.
- Urodynamic studies were done before the procedure and 6 months after the procedure except when the patient declined, in which case a clinical cough stress test was done.
- At 6-month follow-up, 110 patients in the MiniArc group and 107 patients in the Monarc group were available for analysis.
- At 12-month follow-up, 103 patients in the MiniArc group and 103 patients in the Monarc group were available for analysis.

Study design issues:

- Computer-generated random allocation was concealed and stratified by centre.
- Surgeons or patients were not blinded once allocation was revealed.
- Operative data including operative time, estimated blood loss and analgesia usage in the first 24 hours were collected on a subset of women who had sling surgery only, without concomitant prolapse surgery.
- The RCT was powered (80%) to detect a clinical difference of 15% and allow for an attrition of 15% with a sample size of 220.

Study population issues:

- Women with concomitant prolapse or mixed urinary incontinence were included.
- Baseline characteristics of patients in both groups showed no statistically significant difference between groups except for the Patient Global Impression of Severity outcome.

Other issues: None.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **225 (112 MiniArc versus 113 Monarc)**

Subjective and objective SUI cure rates

	MiniArc (n=112)		Monarc (n=113)		p value	
Cure rates	**6 months**	**12 Months**	**6 months**	**12 Months**	**6 m versus 6 m**	**12 m versus 12 m**
Subjective	95% (105/110)	92% (95/103)	93% (99/107)	94% (97/103)	0.40	0.78
ITT population	94% (105/112)	85% (95/112)	88% (99/113)	86% (97/113)		
Objective	81% (77/95)	94% (84/89)	86% (82/95)	97% (87/90)	0.43	0.50
ITT population	69% (77/112)	75% (84/112)	73% (82/113)	77% (87/113)		
	Sling only		**Sling only**			
Subjective	95% (63/66)	92% (57/62)	93% (52/56)	91% (49/57)	0.70	>0.99
Objective	81% (47/58)	92% (47/51)	84% (43/51)	93% (42/45)	0.80	>0.99

Subjective cure rate was defined as an absence of recorded leakage with coughing and exercise on questions 3 and 5 of the International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form.

Objective cure rate was defined as a negative urodynamic stress or cough stress test at 6 months and a negative cough stress test at 12 months.

Functional outcomes

	MiniArc (n=112)			Monarc (n=113)			p value	
Outcome	**Baseline**	**6 m**	**12 m**	**Baseline**	**6 m**	**12 m**	**6 m versus 6 m**	**12 m versus 12 m**
ICIQ UI SF[a]	13 (10-16)	4 (0-7)	4 (0-6)	14 (10-16)	3 (0-6)	3 (0-6)	0.77	0.61
Total number incomplete data		9	14		10	18		
ICIQ OAB[a]	5 (3-8)	3 (2-5)	3 (1-4)	5 (3-8)	3 (2-5)	3 (2-5)	0.57	0.48
Total number incomplete data		8	10		11	17		
OAB medications (antimuscarinics)		11% (10/92)	6% (5/87)		15% (14/96)	16% (15/95)	0.52	0.034
Total number incomplete data		20	25		17	18		
PISQ12[a]	33 (28-37)	36 (33-40)	37 (34-41)	33 (29-38)	39 (33-41)	38 (33-41)	0.06	0.91
Total number incomplete data		34	43		39	40		
NSA	19% (21/112)	24% (25/103)	27% (26/95)	21% (23/113)	28% (29/103)	23% (22/95)	0.64	0.62
Total number incomplete data		9	17		10	18		
IIQ7[a]	9 (5-13)	0 (0-4)	0 (0-3)	9 (5-12)	0 (0-3)	0 (0-3)	0.70	0.88
Total number incomplete data		10	14		10	20		

Safety

Operative characteristics (intraoperative and postoperative data to 6 weeks)

Sling only	**MiniArc (n=68)**	**Monarc (n=59)**	**p value**
Catheter longer than 1 day	1% (1/68)	7% (4/59)	0.170
Panadeine use[a]	0.5 (0.0 to 2.0)	2.0 (0.3 to 6.0)	0.002
Groin pain	15% (10/68)	58% (34/59)	<0.001
Duration 1-3 days	3% (2/68)	34% (20/59)	
Duration 4-7 days	7% (5/68)	12% (7/59)	
Duration 2-4 weeks	4% (3/68)	12% (7/59)	
Concomitant pelvic organ prolapse	**MiniArc (n=44)**	**Monarc (n=54)**	**p value**
Catheter 1-2 days	5% (2/44)	35% (19/54)	0.0003
Catheter 3-4 days	2% (1/44)	2% (1/54)	
Catheter 7 days	2% (1/44)	2% (1/54)	

[a]Paracetamol 500mg and codeine phosphate 8mg. Median (interquartile range, 25-75%). Panadeine use reflects usage in 24 hours.

Voiding dysfunction

Miniarc: 1/112

Monarc: 1/113

Both had low maximum flow of 10-11 ml/s, postvoid residual of more than 100 ml, but none necessitated sling release.

Need for repeat surgery

Miniarc: 3% (3/112)

Monarc: 2% (2/113)

p=0.68

Groin pain beyond 6 months

Miniarc: 0%

Monarc: 6%

p=0.014

Paraurethral prominence

Miniarc: 0% (0/112)

PGII[a]		1 (1-2)	1 (1-2)		1 (1-2)	1 (1-2)	0.90	0.46
Total number incomplete data		10	14		11	19		
24-hour pad	21.1 (mean)	4 (0-8) (median)		28.5 (mean)	2 (2-6) (median)		0.89	
Total number incomplete data		46			54			

[a]Median (interquartile range, 25-75%)

Monarc: 3% (3/113)

Mesh exposure

Miniarc: 1/112

Monarc: 0/113

The authors said: ‘’There was 1 mesh exposure because of the mesh kit in the Miniarc arm, in a patient who also had an elevate anterior.‘’

Abbreviations used: ICIQ, International consultation on incontinence questionnaire; ICIQ OAB, ICIQ overactive bladder; IIQ, incontinence impact questionnaire; ITT, intention-to-treat; NSA, not sexually active; PGII, patient global impression of improvement; PISQ 12, pelvic organ prolapse/urinary incontinence sexual questionnaire; SUI, stress urinary incontinence; UI SF, urinary incontinence short form.

Study 5 Sivaslioglu A A (2012)

Details

Study type	**Single blind prospective RCT**
Country	Turkey
Recruitment period	2005-2006
Study population and number	n=**80 (40 TFS versus 40 transobturator tape [TOT])** women with urodynamic stress urinary incontinence
Age and sex	TFS group: mean 50 years; TOT group: mean 52 years 100% (80/80) female
Patient selection criteria	Inclusion criteria: Female patients with urodynamic stress urinary incontinence Exclusion criteria: Patients with overflow incontinence , those with overactive bladder and those who had previous anti-incontinence surgery.
Technique	Mini-sling used: TFS (TFS Surgical) TOT: I-stop (CL Medical). All procedures used spinal anaesthesia.
Follow-up	**64 months (range 58 to 70)**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues:

- The patients had follow-up at 1, 3 and 6 months, and annually thereafter.
- 10% (8/80) of patients (4 in each arm) were lost to follow-up at 5 years because they moved to another location.

Study design issues:

- Patients were randomly allocated by computer program.
- All procedures were done by the same surgeon.
- The postoperative assessment was done by another senior surgeon who did not participate in the procedures.

Study population issues: None

Other issues: The study was included in the 2 meta-analyses from Abdel-Fattah (2014) and Nambiar (2014) which are included in table 2.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **72 (36 TFS versus 36 transobturator tape [TOT])**

Cough stress pad test assessment

	TFS	TOT	p value
Preoperative CSPT (mean ± SD gm)	71±18	73±27	0.3
Postoperative CSPT (mean ± SD gm)	0.66±0.8	0.41±0.4	0.5
p value	0.0001	0.0002	

Cure rates at 5 years

	TFS	TOT	p value
Objective cure*	83% (30/36)	75% (27/36)	0.029
Subjective cure**	6% (2/36)	3% (1/36)	0.80
Failure***	11% (4/36) 2 patients did not want any further intervention and 2 patients were treated with oral anti-muscarinic treatment.	22% (8/36) 3 patients did not want any further intervention, 3 were treated with oral anti muscarinic treatment, 1 was treated by abdominal hysterectomy plus bilateral salpingo-oophorectomy plus Burch colposuspension and 1 had suburethral mesh cutting plus retropubic TVT insertion (for urgency).	0.04

***Objective cure was defined as CSPT negative after the operation and patient-reported restauration of urinary continence.

**Subjective cure was defined as patient-reported restauration of urinary continence but positive CSPT.

***Failure was defined as no change in incontinence after the procedure.

Decrease in cure rates from 3 to 5 years

TFS: 7% (from 90% to 83%)

TOT: 9% (from 84% to 75%)

p=0.16

Quality of life** before and after the procedure

	TFS	TOT
Preoperative quality-of-life score (mean ± SD)	15±4	16±5
Postoperative quality-of-life score (mean ± SD)	4±1	3±2
p value	0.003	0.002

****Simplified quality-of-life score with grades from 1 to 5 to describe the limitation of normal activities by incontinence, with higher scores indicating problems.

Safety

No intraoperative complications were reported in either group.

Postoperative complications

	TFS	TOT	p value
Urinary retention	0	6% (2/36)	0.4
Groin pain	0	33% (12/36)	0.03
Mesh extrusion	0	3% (1/36)	0.7
Anchor displacement	3% (1/36)	0	NA

The anchor displacement was observed in 1 patient at the 1-year follow-up visit. The anchor was removed with the patient under local anaesthesia and the patient remained continent.

Abnormal urination was reported by 1 patient at the 4-year follow-up visit. Poor stream and staying in the toilet for longer durations were noted, and uroflowmetry revealed outflow obstruction. The suburethral mini-sling was cut lateral to the urethra and symptoms persisted through the early postoperative period. Six months after urethrolysis the symptoms subsided and the patient remained continent.

Abbreviations used: CSPT, cough stress pad test; NA, not applicable; SD, standard deviation; TFS, Tissue Fixation mini sling; TOT, transobturator tape;

Study 6 Palomba S (2013)

Details

Study type	**Prospective comparative study**
Country	Italy
Recruitment period	2008-2010
Study population and number	n=**240 (120 SIMS versus 120 r-TVT)** women with stress urinary incontinence or mixed urinary incontinence
Age and sex	Mean age (SIMS: 64 versus r-TVT: 64); 100% (240/240) female
Patient selection criteria	Inclusion criteria: Patients who were incontinent after conservative management and, in the presence of mixed urinary incontinence, only patients with persistent, clinically significant stress urinary incontinence under oral antimuscarinic therapy. Exclusion criteria: postvoidal residual urine greater than 100 ml, intrinsic sphincteric insufficiency, detrusor instability score greater than 7, history of previous incontinence surgery, lower urinary tract anomaly, current UTI or more than 3 UTI episodes in the last year, Baden-Walker pelvic organ prolapse of second degree or more, body mass index greater than 35, neurogenic disease and/or drugs affecting bladder function, desired future childbearing, pregnancy, less than 12 months postpartum, concurrent genitourinary disease, previous pelvic surgery or radiotherapy, previous or active malignancies, contraindications for surgery, unable to understand the purpose of the trial, sexually inactive, or immobility.
Technique	For each centre, the procedures were done by 1 experienced operator expert in both surgical techniques, under local anaesthesia, with light conscious sedation. The same intravenous prophylactic antibiotic therapy (1.5 mg cefuroxime or 500 mg metronidazole) was administered for each procedure. SIMS: Ajust (Bard), MiniArc (Tegea for TMS) or TVT Secur System (Johnson & Johnson). r-TVT: SPARC system (Tegea for TMS) Postoperative pain was self-controlled by each patient using intravenous tramadol (100 mg). Tramadol tablets were prescribed to all patients and taken when necessary.
Follow-up	**24 months**
Conflict of interest/source of funding	None

Analysis

Follow-up issues:

- All treated patients completed the 30-day follow-up. At the 6-month follow-up, 2% (2/120) of SIMS patients and 3% (3/120) of r-TVT patients were lost to follow-up. At the 12-month follow-up, they were 6% (7/120) and 4% (5/120) respectively. At the 18-month follow-up, they were 10% (12/120) and 8% (9/120) respectively. At the 24-month follow-up, they were 14% (17/120) and 12% (14/120).

Study design issues:

- The treatment allocation was based on the patient's choice.
- The data assessors were masked to the SIMS or r-TVT procedure.
- No pelvic organ prolapse concomitant surgery was done.
- Multi centre design.

Study population issues: None.

Other issues: The SIMS group included use of the TVT-Secur device.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **240 (120 SIMS versus 120 r-TVT)**

Patient satisfaction (mean±SD)

	SIMS (n=120)	r-TVT (n=120)
Patient satisfaction	7.5±2.6	7.4±1.7

Patient satisfaction was assessed using a visual analogue scale (0-10, from low to high).

Detrusor instability score (mean ± SD)

	Baseline	6 months	12 months	18 months	24 months
SIMS	2.1±1.3	2.3±1.7	2.2±1.4	2.2±1.3	2.2±1.3
r-TVT	2.4±1.5	2.8±2.0*	2.7±2.0*	2.8±1.9*	2.9±1.9*

*Scores significantly worse versus baseline (p<0.05).

Quality of life (SF-36)

	Baseline	6 months	12 months	18 months	24 months
SIMS	68.9±8.8	76.9±8.0*	76.1±7.8*	76.8±8.5*	77.3±8.7*
r-TVT	69.6±9.7	75.9±8.4*	75.3±8.3*	76.5±9.0*	76.7±9.4*

*Significant improvement versus baseline (p<0.05).

Impact of the urinary incontinence on quality of life

King's Health Questionnaire (mean ± SD)

	Baseline	6 months	12 months	18 months	24 months
SIMS	284.0±96.2	160.1±82.3*	182.1±86.2*	202.0±93.1*	235.7±113.9*
r-TVT	278.1±93.4	128.4±52.1*	133.9±62.8*	138.1±66.1*	146.0±77.4*

*Significant improvement versus baseline (p<0.05).

Patient global impression of severity (mean ± SD)

	Baseline	6 months	12 months	18 months	24 months
SIMS	2.8±1.1	1.7±1.0*	1.9±1.0*	1.9±1.0*	2.3±1.2*
r-TVT	2.4±1.9	1.3±0.6*	1.5±0.8*	1.5±0.8*	1.4±0.8*

*Significant improvement versus baseline (p<0.05).

Patient global impression of improvement (mean ± SD)

	Baseline	6 months	12 months	18 months	24 months
SIMS	-	2.3±1.5	2.7±1.6*	2.7±1.7*	3.1±1.9*
r-TVT	-	1.9±1.1	1.9±1.4	2.0±1.3	1.8±1.4

*Significant improvement versus 6-month follow-up (p<0.05).

Safety

Surgical data (mean±SD)

	SIMS (n=120)	r-TVT (n=120)	P value
Intraoperative blood loss (ml)	33.8±21.6	30.3±9.0	NS
Decrease in haemoglobin (g/dl)	0.5±0.3	0.4±0.3	NS
Analgesic vials (n)	1.5±1.1	1.1±1.0	NS
Postoperative pain	5.4±3.4	4.7±1.6	NS
Users of analgesic tablets	53% (63/120)	30% (36/120)	<0.05
Analgesic tablets (n)	15.4±9.6	2.9±3.2	<0.05

Postoperative pain was assessed using the Wong-Baker FACES Pain Scale (0-10, from best to worst).

Complications (intra - and postoperative [30 days after surgery])

	SIMS (n=120)	r-TVT (n=
Total complications	17% (20/120)	25% (30
Intraoperative complications	2% (2/120)	3% (3/
Bladder perforations	0	2% (2/
Intraoperative haemorrhages	2% (2/120)	1% (1/
Postoperative complications	15% (18/120)	23% (27
Pain	4% (5/120)	-
Haemoglobin drop	1% (1/120)	-
UTIs	3% (3/120)	4% (5/
Voiding dysfunctions	3% (4/120)	8% (10/
Surgical revisions	0	3% (3/
De novo or worse urge urinary incontinence	4% (5/120)	8% (9/

All comparisons were not statistically significant.

Complication rate after 24-month follow-up

- 16% (19/120) versus 25% (30/120), p=NS
- RR (r-TVT versus SIMS)=1.58; 95% CI 0.94-2.65, p=0.083
- NNH for complications caused by SIMS: 11 (95% CI, 2 harm-17 harm)

Female sexual function index

	Baseline	6 months	12 months	18 months	24 months
SIMS	22.4±9.5	22.7±9.4	22.9±9.4	23.1±9.6	23.1±9.5
r-TVT	21.3±9.9	23.7±8.9*	23.9±9.4*	24.1±9.3*	24.2±9.5*

*Significant improvement versus baseline (p<0.05).

Subjective cure rate

	SIMS	r-TVT
6 months	91% (107/118)	95% (111/117)
12 months	64% (72/113)*	83% (96/115)
18 months	56% (61/108)*	83% (92/111)
24 months	55% (57/103)*	84% (89/106)

*p<0.05 versus the r-TVT arm

RR (SIMS versus r-TVT at 24 months)=0.66; 95% CI 0.54-0.80, p<0.001

Objective cure rate

	SIMS	r-TVT
6 months	81% (96/118)	90% (105/117)
12 months	64% (72/113)*	86% (99/115)
18 months	53% (57/108)*	80% (89/111)
24 months	51% (52/103)*	77% (82/106)

*p<0.05 versus the r-TVT arm

NNH for recurrence for the SIMS procedure: 2.7 (95% CI, 1 harm-8 harm)

The proportion of patients who reported ‘’worse’’ incontinence at the follow-up visits was significantly higher among the patients treated by SIMS compared with those treated by r-TVT: 4.9% (5/103) versus 0% (0/106), p=0.001. In all other patients, incontinence was reported to be ‘’ unchanged’’.

Retreatment (24-month follow-up)

35% (37/103) versus 11% (12/106), p<0.001

Abbreviations used: CI, confidence interval; NNH, number needed to harm; NS< not significant; RR, relative risk; r-TVT, retropubic tension-free vaginal tape; SD, standard deviation; SIMS, single-incision mini-sling; UTI, urinary tract infection

Study 7 Stavros C (2012)

Details

Study type	**Retrospective comparative study**
Country	Greece
Recruitment period	1999-2011
Study population and number	n=**531 (73 SIMS versus 265 TVT versus 193 TVT-O/TOT)** women with stress urinary incontinence
Age and sex	SIMS: mean 58.4 years TVT: mean 56.2 years TVT-O/TOT: mean 58.8 years 100% (531/531) female
Patient selection criteria	Inclusion criteria: women with pure stress urinary incontinence or mixed urinary incontinence with prominent stress urinary incontinence features. Exclusion criteria: patients admitted for second operation due to failed mid-urethral sling or who had previous pelvic floor surgery and those who were treated by open surgery for stress urinary incontinence or had pelvic prolapse of 2 grade or more.
Technique	SIMS: 37% (27/73) MiniArc, 19% (14/73) TVT-Secur, 22% (16/73) Contasure Needless and 22% (16/73) TFS. Spinal anaesthesia was used in all the groups.
Follow-up	**At least 30 months**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues:

- All patients had urine analysis, urine bacterial cultures, uroflowmetry, post void urine residual (PVR), stress cough test (SCT) and vaginal examination 7 days after the procedure.
- Patients had 1-hour pad test and filling cystometry 3 months after the procedure.
- At annual follow-up, SCT and PVR were examined.
- 48 months after the procedure, 158 patients were available for follow-up (19 SIMS, 102 TVT and 37 TVT-O/TOT).

Study design issues:

- Postoperative pain was quantified by the pain point system scale. Each dose of paracetamol 600 mg was scored by 1 point, each dose of non-steroidal-anti-inflammatory-drugs or codeine by 3 and each dose of opioids by 7.

Study population issues:

- Duration of stress urinary incontinence (mean ± standard deviation [SD])
    - SIMS: mean 31±7.4 months
    - TVT: mean 54±12.2 months
    - TVT-O/TOT: mean 49±5.8 months
- Mixed urinary incontinence: SIMS, 27% (20/73); TVT, 20% (53/265); TVT-O/TVT, 13% (25/193).
- Grade of stress urinary incontinence
    - SIMS: I, 12% (9/73); II, 58% (42/73); III, 30% (22/73)
    - TVT: I, 6% (17/265); II, 55% (146/265); III, 38% (102/265)
    - TVT-O/TOT: I, 10% (19/193); II, 64% (123/193); III, 26% (51/193)

Other issues: The SIMS group included use of the TVT-Secur device.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **531 (73 SIMS versus 265 TVT versus 193 TVT-O/TOT)**

Overall improvement and success rates 3, 12 and 30 months after the procedure

	SIMS (n=73)	TVT (n=265)	TVT-O/TOT (n=193)	p value*
3-month follow-up				
Cured	96%	94%	97%	-
Improved	3%	4%	1%	-
Failed	1%	2%	2%	-
Success rate	99%	98%	98%	-
12-month follow-up				
Cured	90%	91%	96%	-
Improved	2%	3%	1%	-
Failed	8%	6%	3%	-
Success rate	92%	94%	97%	-
30-month follow-up				
Cured	90%	86%	92%	0.01; 0.02; 0.014
Improved	2%	3%	1%	0.009; 0.01; 0.005
Failed	8%	11%	7%	0.001; 0.03; 0.01
Success rate	92%	89%	93%	0.01; 0.03; 0.005
After 48 months	**SIMS (n=19)**	**TVT (n=102)**	**TVT-O/TOT (n=37)**	**p value***
Cured	84% (16/19)	84% (86/102)	89% (33/37)	0.01; NS; 0.01
Improved	5% (1/19)	2% (2/102)	3% (1/37)	NS; 0.005; 0.01
Failed	11% (2/19)	12% (12/102)	8% (3/37)	0.01; NS; 0.01
Success rate	89% (17/19)	86% (88/102)	92% (34/37)	0.009; 0.02; 0.01

Cured was defined as negative SCT, negative 1-hour pad test, insignificant PVR, no urodynamic SUI and reported improvement of quality of life.

Improved was defined as subjective improvement.

Failed was defined as urine leakage, tape-related complications or subjective deterioration of patient continence status.

Success rate is the sum of cured and improved patients.

* TVT versus TVT-O/TOT; TVT versus SIMS; TVT-O/TOT versus SIMS

Improvement, success and failed rates, based on the tapes used, 30 months after the procedure

	SIMS (n=73)				TVT (n=265)	TVT-O/TOT (n=193)	
	MiniArc (n=27)	TVT-Secure (n=14)	Needless (n=16)	TFS (n=16)		TVT-O (n=117)	TOT (n=76)
Cured	**89%**	**90%**	**88%**	**91%**	**86%**	**92%**	**92%**
Improved	**1%**	**3%**	**2%**	**2%**	**3%**	**1%**	**2%**
Failed	**10%**	**7%**	**10%**	**7%**	**11%**	**7%**	**6%**
Success rate	**90%**	**93%**	**90%**	**93%**	**89%**	**93%**	**94%**

Safety

Perioperative complications

	SIMS (n=73)	TVT (n=265)	TVT-O/TOT (n=193)	p values*
Bladder perforation	-	10% (26/265)	-	
Vaginal wall perforation	1% (0.2% MiniArc 0.4% TVT-Secure 0.4% Needless 0.2% TFS)	3% (7/265)	4% (1% TVT-O 3% TOT)	
Urethral injury	-	2% (6/265)	-	
Bleeding				
Mild	78% (57/73)	72% (190/265)	88% (170/193)	
Moderate	21% (15/73)	26% (69/265)	12% (23/193)	
Severe	1% (1/73)	2% (6/265)	-	
Total complications	3%	17%	4%	0.012; 0.009; 0.36

***** TVT versus TVT-O/TOT; TVT versus SIMS; TVT-O/TOT versus SIMS

Postoperative care

	SIMS (n=73)	TVT (n=265)	TVT-O/TOT (n=193)	p values*
Postoperative pain[a] ± SD	4.0±2.2	12.8±3.6	4.1±1.9	0.021; 0.02; NS
Haematoma	-	1% (2/265)	-	
Large haematoma	-	1/265	-	
Hospitalisation (hours)±SD	24±2.1	48±16.4	24±9.4	0.001; 0.001; NS
Catheterisation (hours) ± SD	24±12.3	48±16	24±9	0.001; 0.001; NS

[a] Postoperative pain was quantified by the pain point system scale. Each dose of paracetamol 600 mg was scored by 1 point, each dose of non-steroidal-anti-inflammatory-drugs or codeine by 3 and each dose of opioids by 7.

* TVT versus TVT-O/TOT; TVT versus SIMS; TVT-O/TOT versus SIMS

Late postoperative complications (up to 30 months after the procedure)

Complications up to 30 months after the procedure				
	SIMS (n=73)	TVT (n=265)	TVT-O/TOT (n=193)	p values*
De Novo urgency	7% (5/73)	14% (37/265)	6% (11/193)	0.009; 0.01; NS
De Novo SUI incontinence	1% (1/73)	-	1% (2/193)	-; -; NS
Dyspareunia	-	2% (4/265)	1% (2/193)	NS; -; -
Incontinence during intercourse	1% (1/73)	1% (2/265)	-	-; NS; -
Dysuria	4% (3/73)	10%	6%	0.01;

Uroflowmetry, urodynamic parameters and UDI-6 results before the procedure, and 12 and 30 months after the procedure.

	SIMS (n=73)	TVT (n=265)	TVT-O/TOT (n=193)	p value*
Before the procedure				
Mean Qmax (ml/s)	29.1	26.9	19.4	-
Max cystometric capacity (ml)	209±168	211±82	164±82	-
Mean voided volume (ml)	179.2	194.4	148.0	-
PVR (ml)	20±6	26±9	26±7	-
Valsalva LPP (cm H_2O)	43±7	42±21	54±8	-
UDI-6 (0-100)±SD (range)	69.4±7.7 (66.7-100)	74.5±19.8 (66.7-100)	68.9±21.1 (45.3-100)	-
12-month follow-up				
Mean Qmax (ml/s)	27.7	28.2	24.5	-
Max cystometric capacity (ml)	395±117	412±103	403±120	-
Mean voided volume (ml)	300.8	349.0	354.1	-
PVR (ml)	29±11	31±17	26±15	-
Valsalva LPP (cm H_2O)	83±15	82±19	97±14	-
UDI-6 (0-100)±SD (range)	37.4±19.8 (0-100)	25.9±7.7	27.1±10 (0-50)	-
30-month follow-up				
Mean Qmax (ml/s)	28.4	27.5	22.7	0.01; NS; 0.02
Max cystometric capacity (ml)	280±140	360±101	389±82	NS; 0.005; 0.01
Mean voided volume (ml)	254.1	321.9	368.7	0.009; 0.001; 0.001
PVR (ml)	13±10	27±11	29±10	NS; 0.005; 0.005
Valsalva LPP (cm H_2O)	59±13	67±12	71±9	NS; 0.01; 0.005
UDI-6 (0-100)±SD (range)	37.2±28.8 (0-100)	36.7±19.8 (0-100)	27.4±21 (0-100)	0.007; NS; 0.001
From 48 months after the procedure				
Valsalva LPP (cm H_2O)	51±21	63±17	65±12	NS; 0.02; 0.008

* TVT versus TVT-O/TOT; TVT versus SIMS; TVT-O/TOT versus SIMS

		(27/265)	(11/193)	0.004; 0.02
Urinary tract infections	5% (4/73)	5% (12/265)	7% (14/193)	NS; 0.001; NS
Urinary retention**	1% (1/73)	1% (3/265)	-	-; NS; -
Postoperative pain***	3% (2/73)	14% (38/265)	13% (25/193)	NS; 0.001; 0.0009
Groin/thigh pain	4% (3/73)	1% (2/265)	6% (11/193)	0.006; 0.001; 0.02
Suprapubic discomfort	-	5% (12/265)	-	-
Bladder wall erosion	-	2% (4/265)	-	-
Vaginal wall erosion	-	-	2% (4/193)	-
After 48 months	**SIMS (n=19)**	**TVT (n=102)**	**TVT-O/TOT (n=37)**	**p value***
Bladder wall erosion	-	1% (1/102)	-	-
Urinary tract infections	5% (1/19)	5% (5/102)	11% (4/37)	0.01; NS; 0.009
Dysuria	10% (2/19)	12% (12/102)	16% (6/37)	0.03; NS; 0.01
De novo SUI incontinence	-	2% (2/102)	3% (1/37)	NS; -; -

* TVT versus TVT-O/TOT; TVT versus SIMS; TVT-O/TOT versus SIMS

**including patients with post void residual bladder urine volume > 80 ml

***Postoperative pain leading to seek medical consultation

Reoperation

Reoperation for specific complication					
		SIMS	**TVT**	**TVT-O/TOT**	**p values***
Up to 30-month follow-up	Bladder tape excision	-	2% (4/265)	-	-
	Vaginal tape excision	-	-	2% (4/193)	-
	evacuation	-	1/265	-	-
	Urethrolysis	-	1/265	-	-
From 48 months after the procedure	Bladder tape excision	-	1% (1/102)	-	-
Reoperation for SUI recurrence					
Up to 30-month follow-up		5% (4/73)	-	1% (2/193)	0.01
From 48 months after the procedure		11% (2/19)	-	3% (1/37)	0.005

* TVT versus TVT-O/TOT; TVT versus SIMS; TVT-O/TOT versus SIMS

Abbreviations used: LPP, leak point pressure; NS, not significant; PVR, post void urine residual; Qmax: maximum flow rate; SCT, stress cough test; SD, standard deviation; SIMS, single-incision mini-sling; SUI, stress urinary incontinence; TOT, transobturator tape outside-in; TVT, transobturator tension-free vaginal tape; TVT-O, transobturator tape inside-out.

Study 8 Pickens R B (2011)

Details

Study type	**Prospective case series**
Country	USA
Recruitment period	2007-2008
Study population and number	n=**120** women with stress urinary incontinence
Age and sex	Mean 58 years; 100% (120/120) female
Patient selection criteria	Inclusion criteria: primary stress urinary incontinence Exclusion criteria: women with concomitant pelvic organ prolapse or who had had previous surgery for stress urinary incontinence.
Technique	Miniarc mid-urethral sling placement under general anaesthesia.
Follow-up	**12 months**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: 90% (108/120) of patients completed the minimal follow-up of 12 months.
Study design issues: None.
Study population issues: 35% (42/120) of patients reported concomitant symptoms of overactivity that were confirmed on preoperative urodynamics.
Other issues: None.

Key efficacy and safety findings

<table>
<tr><th>Efficacy</th><th>Safety</th></tr>
<tr><td>
Number of patients analysed: 120

Success rate
All patients had successful Miniarc placement.
<u>1 month after the procedure</u>
• ‘’Cured’’: 94% (113/120)
• Significantly improved but not completely dry: 5% (6/120)
• Persistent SUI with demonstrable leakage: 1% (1/120)
The patient had a repeat mid-urethral sling 2 months later and was ‘’cured’’.
<u>12 months after the procedure</u>
• ‘’Cured’’: 94% (101/108)

Pad use
<table>
<tr><th></th><th>Before the procedure</th><th>1 month</th><th>12 months</th></tr>
<tr><td>Mean daily pad use</td><td>2.4</td><td>0.1*</td><td>0.2*</td></tr>
</table>
*p<0.01 versus baseline

UDI-6
<table>
<tr><th></th><th>Before the procedure</th><th>1 month</th><th>12 months</th></tr>
<tr><td>Mean UDI-6 score</td><td>65%</td><td>3%*</td><td>13%*</td></tr>
</table>
*p<0.01 versus baseline

IIQ-7
<table>
<tr><th></th><th>Before the procedure</th><th>1 month</th><th>12 months</th></tr>
<tr><td>Mean IIQ-7 score</td><td>87%</td><td>3%*</td><td>13%*</td></tr>
</table>
*p<0.01 versus baseline

Sexual function (Female sexual function index) at 12 months
• 49% of patients had no discomfort during intercourse
• 9% of patients sometimes had discomfort
• 2% of patients always had discomfort
• 40% of patients were sexually inactive
</td><td>
Mean estimated blood loss: 37 ml

Bladder perforation: 3% (3/120)
The patients were treated with a Foley catheter overnight, with removal 1 day after the procedure.

Pain
Mean oral narcotic use in the first month after the procedure: 1.6 tablets of 7.5 mg hydrocodone

Postoperative urinary retention: 2% (2/120)
One patient was treated by catheter placement and the other patient was treated by clean intermittent catheterisation with eventual sling lysis 2 months after the procedure.

De novo overactivity: 4% (5/120)

Persistent overactivity: 25% (30/120)
</td></tr>
<tr><td colspan="2">Abbreviations used: IIQ-7, incontinence impact 7-item short form questionnaire; SUI, stress urinary incontinence: UDI-6, urogenital distress inventory, 6-item questionnaire.</td></tr>
</table>

Study 9 Kocjancic E (2014)

Details

Study type	**Prospective case series**
Country	USA and Canada
Recruitment period	2010–12
Study population and number	n=**116** women with stress urinary incontinence
Age and sex	Mean 54.5 years; 100% (116/116) female
Patient selection criteria	Inclusion criteria: women at least 18 years, with SUI confirmed through the CST or urodynamic evaluation and in whom 2 non-invasive incontinence therapies have failed. Exclusion criteria: patients with neurogenic or urge predominant incontinence , active urogenital infection, pelvic organ prolapse stage II or greater, atonic bladder or postvoid residual volume consistently greater than 100 ml, prior surgical treatment for incontinence or pregnancy or a plan to become pregnant.
Technique	Insertion of the Altis sling, with the patient under general, spinal or local anaesthesia. No concomitant pelvic floor surgical procedures were allowed.
Follow-up	**12 months**
Conflict of interest/source of funding	Financial interest and/or other relationship with Coloplast.

Analysis

Follow-up issues:

- 97% (113/116) of enrolled patients were successfully implanted. Three procedures were aborted intraoperatively because of technical observation (bent introducer tip due to surgical technique), intraoperative exclusion (eroded prolapse mesh discovered during surgery needing treatment) and anatomical variation (pelvis was too wide).
- 4% (4/113) of implanted patients withdrew consent before the 6-month visit and an additional 4% (3/113) withdrew consent before the 12-month visit. Reasons for consent withdrawal were changes in family, work or health care provider status. However, 1 subject withdrew consent after having unsuccessful revision surgery for mesh extrusion.
- Median follow-up of patients withdrawn before 12 months was 7.3 months.
- 91% (103/113) of implanted patients had primary efficacy data at baseline and 6 months and 89% (101/113) had efficacy data at 12 months.

Study design issues:

- Multicentre study including 17 sites

Study population issues:

- At baseline, 63% (71/113) of implanted patients had SUI alone and 37% (42/113) had mixed incontinence.
- 70% (79/113) of patients had previously practices behavioural modification and 50% (56/113) had used physical therapy.

Other issues: None.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **113**

Urinary incontinence improvement

Clinically meaningful improvement (defined as a 50% or greater reduction in pad weight from baseline):

- 85% (88/103) of patients at 6 months (p<0.0001)
- 90% (91/101) of patients at 12 months (p<0.0001)

24-hour pad weight test (g)

	Before the procedure	6 months	12 months
Median (IQR)	21.9 (9.4, 57.0)	1.9 (0.2, 5.2)	1.1 (0.3, 4.0)
Median reduction (IQR)	-	18.4 (7.0, 46.0)	18.1 (7.2, 49.8)
% of patients dry (pad of 4g or less)	-	71% (73/103)	77% (78/101)

Negative cough stress test

- 92% (95/103) of patients at 6 months
- 90% (91/101) of patients at 12 months

Leaks per day

	Before the procedure	6 months	12 months
3-day voiding diary median leaks/day	3.7	0.0	N/A

UDI-6

	Before the procedure	1 month	12 months
Median UDI-6 score (IQR)	55.5 (38.9, 66.6)	5.6 (0.0, 16.7)	5.6 (0.0, 16.7)
Median reduction (IQR)	-	44.4 (33.3, 55.5)	44.4 (33.3, 55.5)

IIQ-7

	Before the procedure	1 month	12 months
Median IIQ-7 score (IQR)	57.0 (33.0, 71.0)	0.0 (0.0, 6.5)	0.0 (0.0, 9.0)
Median reduction (IQR)	-	47.0 (24.0, 66.0)	47.0 (24.0, 66.0)

Patient global impression of improvement (PGI-I)

	Before the procedure	1 month	12 months
Very much better	N/A	58% (61/105)	58 % (60/103)
Much better	N/A	30% (31/105)	31% (31/103)
A little better	N/A	11% (12/105)	8% (8/103)
No change	N/A	0	1% (1/103)
A little worse	N/A	0	2% (2/103)
Much worse	N/A	0	0
Very much	N/A	1% (1/105)	0

Safety

Device or procedure-related adverse events

	% of patients	Details
Other: non-pelvic pain (groin, hip or thigh pain)	8% (9/113)	
Mesh extrusion*	4% (4/113)	Includes 2 mesh extrusions categorised as serious adverse events.
Pelvic/urogenital pain	4% (4/113)	
Urinary retention	2% (2/113)	The cases of urinary retention were treated by a Foley catheter and resolved within 3 and 8 days.
Urinary tract infection	1% (1/113)	
De novo urgency	1% (1/113)	
Dyspareunia	1% (1/113)	
Inflammation	1% (1/113)	
Delayed wound healing	1% (1/113)	
Other: worsening overactive bladder	1% (1/113)	
Other: bleeding (pelvic haematoma)	1% (1/113)	The pelvic haematoma developed after revision surgery caused by urinary outlet obstruction. It was categorised as a serious adverse event.
Other: decreased urine stream	1% (1/113)	
Other: voiding dysfunction (urinary outlet obstruction)	1% (1/113)	Occurred 6 days after the procedure. The patient was treated by 2 revision surgeries and the mesh was incised on both sides of the urethra and the condition resolved.
Other: miscellaneous	2% (2/113)	Includes 1 event of nausea and 1 event of reaction to antibiotherapy.

* 3 of the 4 mesh extrusions were treated by revision surgery that included trimming and excision. It was resolved in 2 patients and the third patient withdrew from the study before the determination of resolution. 1 mesh extrusion was asymptomatic and successfully treated with oestrogen cream.

worse				

Revision procedures

6 revision procedures were done in 4 patients.

Abbreviations used: CST, cough stress test; IIQ-7, incontinence impact 7-item short form questionnaire; IQR, interquartile range; N/A, not applicable; PGI-I, patient global impression of improvement; SUI, stress urinary incontinence; UDI-6, urogenital distress inventory, 6-item questionnaire.

Study 10 Chung C (2012)

Details

Study type	**Case report**
Country	USA
Recruitment period	2011
Study population and number	n=**1** patient with stress urinary incontinence
Age and sex	57-year old woman
Patient selection criteria	Not applicable
Technique	Single-incision midurethral sling: Solyx.
Follow-up	**4 months**
Conflict of interest/source of funding	None

Key efficacy and safety findings

Bladder mesh erosion

Vaginal mesh exposure

Urethrovaginal fistula

A 57-year old multiparous woman with history of osteogenesis imperfecta type I presented to her gynaecologist with subjective symptoms of stress urinary incontinence. She had no pad requirement before the procedure. She had SIMS placement that was complicated by cystotomy. She had a Foley catheter in place for 2 weeks and a negative cystogram at the time of Foley removal. She subsequently developed constant urinary leakage requiring 6 to 12 pads. A repeat cystogram showed a fistula. The patient was referred for further treatment 3 months after her initial surgery. A cystoscopy revealed erosion of mesh at the proximal urethra; the mesh was seen protruding under the mucosa on the right side of the bladder. Vaginoscopy also revealed mesh exposure. The patient was treated by excision of midurethral mesh, urethroplasty, Martius flap tissue transfer and cystourethroscopy. The patient was discharged home 1 day after surgery. She continued to wear a Foley catheter for 1 month. After the Foley catheter was removed, the patient continued to have mild stress urinary incontinence, which required 1 pad per day.

Abbreviations used: SIMS, single-incision midurethral sling.

Study 11 Chin K (2014)

Details

Study type	**Case report**
Country	USA
Recruitment period	Not reported
Study population and number	n=**1** patient with stress urinary incontinent
Age and sex	52-year-old woman
Patient selection criteria	Not applicable
Technique	Single-incision midurethral sling: Solyx.
Follow-up	**3 years**
Conflict of interest/source of funding	None

Key efficacy and safety findings

Bladder stone

The patient presented with recurrent stress incontinence 3 years after the SIMS placement. She was found to have a 1.7-cm bladder stone that formed around the SIMS polypropylene barb. The patient had a prior surgical history of transurethral resection of the bladder neck and subsequent urethrovaginal fistula repair as a child. The bladder stone was treated by excision of mesh transvaginally, separation of the stone from the eroded mucosal mesh and subsequent transurethral stone removal. The patient was discharged home the next day with continuous urinary catheter drainage and bilateral ureteral stents. Two weeks after the procedure, the ureteral stents were removed and normal bladder mucosa and integrity was confirmed by cystourethroscopy. 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.

Abbreviations used: SIMS, single-incision midurethral sling.

Efficacy

Objective cure rate

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 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).[1]

In a systematic review and meta-analysis of 678 women with stress urinary incontinence from 5 RCTs comparing SIMS (n=361) with TVT-O/TOT (n=317) procedures, there was no significant difference in objective cure rates between SIMS and TOT (0.97, 95 % CI 0.90 to 1.05, p value not significant).[3]

In an RCT of 225 women with stress urinary incontinence treated by SIMS (n=112) or TOT (n=113), objective cure rates were 81% (47/58) in the SIMS group and 84% (43/51) in the TOT group at 6-month follow-up (p=0.80). At 12-month follow-up the objective cure rates remained not significantly different between the 2 groups: 92% (47/51) and 93% (42/45) in the SIMS and TOT group respectively (p>0.99). [4]

In an RCT of 80 women (40 SIMS versus 40 TOT) with stress urinary incontinence, the objective cure rates 5 years after the procedure were significantly different between the groups: 83% (30/36) for the SIMS and 75% (27/36) for the TOT group (p=0.029).[5]

In a prospective comparative study of 240 women with stress urinary incontinence treated by SIMS (n=120) or r-TVT (n=120), objective cure rates 24 months after the procedure were significantly lower in the SIMS group: 51% (52/103) compared with 77% (82/106) in the r-TVT group (p<0.05). [6]

Subjective cure rate

In the systematic review and meta-analysis of 3,308 women, there was no significant difference in patient-reported cure rates at a mean follow-up of 18.6 months between SIMS ('TVTSecur' 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%).[1]

In the systematic review and meta-analysis of 678 women comparing SIMS (n=361) with TVT-O/TOT (n=317) procedures, there was no significant difference in subjective cure rates between SIMS and TOT (0.95, 95 % CI 0.87 to 1.04, p value not significant).[3]

In the RCT of 225 women treated by SIMS (n=112) or TOT (n=113), subjective cure rates for the women treated by sling procedures only were 95% (63/66) in the SIMS group and 93% (52/56) in the TOT group at 6-month follow-up (p=0.70). At 12-month follow-up the subjective cure rates remained not significantly different between the 2 groups: 92% (57/62) and 91% (49/57) in the SIMS and TOT group respectively (p>0.99).[4]

In the RCT of 80 women (40 SIMS versus 40 TOT), the subjective cure rates 5 years after the procedure were not significantly different between the groups: 6% (2/36) for the TFS and 3% (1/36) for the TOT group (p=0.80).[5]

In the prospective comparative study of 240 women treated by SIMS (n=120) or r-TVT (n=120), subjective cure rates 24 months after the procedure were significantly higher in the r-TVT group: 55% (57/103) in the SIMS groups and 84% (89/106) in the r-TVT group (p<0.05).[6]

Success/failure rate

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 'TVTSecur', 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 'TVTSecur' 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 ('TVTSecur' trials excluded) compared with inside-out or outside-in TOT.[2]

In the RCT of 80 women (40 SIMS versus 40 TOT), the failure rates 5 years after the procedure were significantly different between the groups: 11% (4/36) for the SIMS and 22% (8/36) for the TOT group (p=0.04). In the SIMS group, 2 patients did not want any further intervention and 2 patients were treated with oral anti muscarinic treatment. In the TOT group, 3 patients did not want any further intervention, 3 were treated with oral anti muscarinic treatment, 1 was treated by abdominal hysterectomy plus bilateral salpingo-oophorectomy plus Burch colposuspension and 1 had suburethral mesh cutting plus retropubic TVT insertion (for urgency).[5]

In a retrospective comparative study of 531 women with stress urinary incontinence treated by SIMS (n=73), TVT (n=265) or TVT-O/TOT (n=193), the success rates at 30-month follow-up were 92% in the SIMS group, 89% in the TVT group and 93% in the TVT-O/TOT group (p=0.03 for the comparison with TVT and p=0.005 for the comparison with TVT-O/TOT). At 48-month follow-up, the success rates were 89% (17/19) in the SIMS group, 86% (88/102) in the TVT group and 92% (34/37) in the TVT-O/TOT group (p=0.02 for the comparison with TVT and p=0.01 for the comparison with TVT-O/TOT).[7]

In a prospective case series of 120 women treated by SIMS, 94% (101/108) were considered “cured” 12 months after the procedure.[8]

In a prospective case series of 116 women with stress urinary incontinence treated by SIMS, clinically meaningful improvement in urinary incontinence (defined as a 50% or greater reduction in pad weight from baseline) was reported in 85% (88/103) of women at 6 months and in 90% (91/101) of women at 12 months (p<0.0001).[9]

Cough stress pad test assessment

In the RCT of 80 women, there were no significant differences between groups for the cough stress pad test (CSPT) values before and after the procedure. However, there were 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).[5]

In the prospective case series of 120 women, 92% (95/103) of women had a negative cough stress test at 6 months and 90% (91/101) at 12 months.[8]

Pad use/24-hour pad weight test

In the prospective case series of 120 women, the mean daily pad use decreased significantly from 2.4 before the procedure to 0.1 at 1 month and 0.2 at 12 months (p<0.01 versus baseline).[8]

In the prospective case series of 116 women, median weight (IQR, g) of pads used during a 24-hour period was 21.9 g (9.4 g, 57.0 g) before the procedure and 1.1 g (0.3 g, 4.0 g) 12 months after the procedure. The proportion of women with a pad of 4 g or less was 77% (78/101).[9]

Detrusor instability score

In the prospective comparative study of 240 women treated by SIMS (n=120) or r-TVT (n=120), detrusor instability scores did not change 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 significantly worsened (2.4±1.5 versus 2.9±1.9 at 24 months, p<0.05).[6]

Urogenital distress inventory, 6-item questionnaire (UDI-6) score

In the prospective case series of 120 women, the mean urogenital distress inventory scores (a 6-item questionnaire) decreased significantly from 65% before the procedure to 3% at 1 month and 13% at 12 months ($p<0.01$ versus baseline).[8]

In the prospective case series of 116 women, the median (IQR) UDI-6 scores decreased from 55.5 (38.9, 66.6) before the procedure to 5.6 (0.0, 16.7) at 12 months and 13% at 12 months (level of statistical significance not stated).[9]

Incontinence impact 7-item short form questionnaire (IIQ-7) score

In the prospective case series of 120 women, the mean IIQ-7 scores decreased significantly from 87% before the procedure to 3% at 1 month and 13% at 12 months ($p<0.01$ versus baseline).[8]

In the prospective case series of 116 women, the median (IQR) IIQ-7 scores decreased from 57.0 (33.0, 71.0) before the procedure to 0.0 (0.0, 9.0) at 12 months (level of statistical significance not stated).[9]

Use of medications for overactive bladder

In the 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 significantly lower in the SIMS group than in the TOT group (6% [5/87] versus 16% [15/95], $p=0.034$).[4]

Time to return to normal activities

In the systematic review and meta-analysis of 3,308 women, women with SIMS ('TVT Secur' trials excluded) returned to normal activities significantly earlier (weighted means difference [WMD] 5.08 days; 95% CI, −9.59 to −0.56, n=2, I^2=63%).[1]

Time to return to work

In the systematic review and meta-analysis of 3,308 women, women with SIMS ('TVT Secur' trials excluded) returned to work significantly earlier (WMD −7.20 days; 95% CI, −12.43 to −1.98, n=2, I^2=38%).[1]

Quality of life

In the systematic review and meta-analysis of 3,308 women, there was no 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 significant differences between SIMS and SMUS.[1]

In the RCT of 80 women (40 SIMS versus 40 TOT), there were significant improvements within groups in quality-of-life scores before and after the procedure (mean±SD): 15±4 versus 4±1 in the SIMS group (p=0.003) and 16±5 versus 3±2in the TOT group (p=0.002).[5]

In the prospective comparative study of 240 women treated by SIMS (n=120) or r-TVT (n=120), quality-of-life scores measured with the SF-36 questionnaire improved significantly in both groups from baseline (mean±SD): 68.9±8.8 to 77.3±8.7 at 24 months in the SIMS group and 69.6±9.7 to 76.7±9.4 at 24 months in the r-TVT group ($p<0.05$). The King's Health Questionnaire scores and the Patient global impression of severity scores also improved significantly in both groups from baseline (mean±SD): 284.0±96.2 to 235.7±113.9 at 24 months in the SIMS group and 278.1±93.4 to 146.0±77.4 at 24 months in the r-TVT group for the King's Health Questionnaire scores, and 2.8±1.1 to 2.3±1.2 at 24 months in the SIMS group and 2.4±1.9 to 1.4±0.8 at 24 months in the r-TVT group for the patient global impression of severity scores ($p<0.05$). Patient global impression of improvement scores improved significantly in the SIMS group from 2.3±1.5 at 6 months to 3.1±1.9 at 24 months after the procedure; in the r-TVT group, the change was not significant (1.9±1.1 at 6 months to 1.8±1.4 at 24 months). [6]

In the prospective case series of 116 women, 58 % (60/103) of women reported feeling very much better, 31% (31/103) reported feeling much better, 8% (8/103) reported feeling a little better, 1% (1/103) reported no change and 2% (2/103) reported feeling a little worse on the patient global impression of improvement index 12 months after the procedure.[9]

Patient satisfaction

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).[6]

Impact on sexual function

In the systematic review and meta-analysis of 3,308 women, there was no significant difference in Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ12) scores between SIMS ('TVTSecur' 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%).[1]

In the prospective comparative study of 240 women treated by SIMS (n=120) or r-TVT (n=120), the female sexual function index scores did not statistically significantly changed 24 months after the procedure in the SIMS group (22.4±9.5

versus 23.1±9.5) but they significantly improved from baseline in the r-TVT group (21.3±9.9 versus 24.2±9.5).[6]

In the prospective case series of 120 women, using the female sexual function index, 49% of women had no discomfort during intercourse, 9% of women sometimes had discomfort, 2% of women always had discomfort and 40% of women were sexually inactive at 12-month follow-up.[8]

Safety

Pain after the procedure

Pain after the procedure was 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 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 (weighted means difference [WMD] −3.13; 95% confidence interval [CI] −4.89 to −1.36, n=4, I^2=93%, p<0.0005).[1]

Pain after the procedure or discomfort was significantly lower in the SIMS group (including 'TVTSecur' trials) than in the obturator minimally invasive sling group in a Cochrane systematic review and meta-analysis of 3,290 women with stress urinary incontinence from 31 randomised or quasi-randomised trials (risk ratio [RR] 0.26, 95% CI 0.19 to 0.37, I^2=0%, n=10, p<0.00001).[2]

Pain after the procedure did not significantly differ between groups in a systematic review and meta-analysis of 678 women with stress urinary incontinence from 5 RCTs comparing SIMS (n=361) with TVT-O/TOT (n=317) procedures (RR 0.50, 95 % CI 0.18 to 1.43, p=not significant).[3]

Groin pain 6 weeks after the procedure was significantly less common in the SIMS group of an RCT of 225 women with stress urinary incontinence treated by SIMS (n=112) or TOT (n=113): 15 % (10/68) versus 58% (34/59), p<0.001. In the same study, analgesic use (median [interquartile range] Panadeine [500 mg paracetamol and 8 mg codeine] in 24 hours) was also significantly lower in the SIMS group than in the TOT group (0.5 [0.0 to 2.0] versus 2.0 [0.3 to 6.0], p=0.002).[4]

The number of patients using analgesic tablets after the procedure was significantly higher in the SIMS group than in the r-TVT group in a prospective comparative study of 240 women with stress urinary incontinence treated by SIMS (n=120) or r-TVT (n=120): 53% (63/120) versus 30% (36/120), p<0.05. The number of analgesic tablets (tramadol) used was also significantly greater in the SIMS group (mean ± standard deviation [SD]): 15.4±9.6 versus 2.9±3.2, p<0.05.[6]

Pain scores after the procedure were significantly lower in the SIMS group (n=73) than in the TVT group (n=265) in a retrospective comparative study of 531

women with stress urinary incontinence treated by SIMS, TVT or TVT-O/TOT (mean±SD): 4.0±2.2 versus 12.8±3.6 (p=0.02). There was no significant difference in pain score between the SIMS group and the TVT-O/TOT group: 4.0±2.2 versus 4.1±1.9 (p value not significant). Pain was quantified by the pain point system scale. Each dose of paracetamol 600 mg was scored by 1 point, each dose of non-steroidal anti-inflammatory drugs or codeine by 3 and each dose of opioids by 7.[7]

Long-term pain

Groin pain was significantly lower in the SIMS group ('TVTSecur' trials excluded) than in the SMUS group in the systematic review and meta-analysis of 3,308 women (RR 0.30; 95% CI, 0.18 to 0.49 (n=10), I^2=19%, p<0.00001).[1]

Long-term groin or thigh pain or discomfort was significantly lower in the SIMS group (including 'TVTSecur' trials) than in the obturator minimally invasive sling group in the Cochrane systematic review and meta-analysis of 3,290 women with stress urinary incontinence from 31 randomised or quasi-randomised trials (RR 0.14, 95% CI 0.04 to 0.54, I2=0%, n=5, p=0.0043).[2]

Groin pain was significantly lower in the SIMS group than in the TVT-O/TOT group in the systematic review and meta-analysis of 678 women with stress urinary incontinence from 5 RCTs comparing SIMS (n=361) with TVT-O/TOT (n=317) procedures (RR 0.30, 95 % CI 0.11 to 0.85, p=0.02).[3]

Groin pain beyond 6 months was significantly lower in the SIMS group (n=112) than in the TOT group (n=113) in the RCT of 225 women with stress urinary incontinence treated by SIMS or TOT (0% versus 6%, p=0.014, number of patients not reported).[4]

Groin pain within 5 years of follow-up was reported in none of the patients in the SIMS group (n=36 at 5-year follow-up) and in 33% (12/36 at 5-year follow-up) of patients in the TOT group in an RCT of 80 women (40 SIMS versus 40 TOT) with stress urinary incontinence (p=0.03).[5]

Pain up to 30 months after the procedure for which patients sought medical consultation was reported in 3% (2/73) of patients treated by SIMS, 14% (38/265) of patients treated by TVT and 13% (25/193) of patients treated by TVT-O/TOT in the retrospective comparative study of 531 women (p=0.001 for the comparison of SIMS versus TVT and p=0.0009 for the comparison versus TVT-O/TOT). In the same study, groin or thigh pain up to 30 months after the procedure was reported in 4% (3/73) of patients in the SIMS group, in 1% (2/265) in the TVT group and in 6% (11/193) in the TVT-O/TOT group (p=0.001 for the comparison SIMS versus TVT and p=0.02 for the comparison versus TVT-O/TOT).[7]

Non-pelvic (groin, hip or thigh) pain was reported in 8% (9/113) of patients and pelvic or urogenital pain was reported in 4% (4/113) of patients in a prospective

case series of 116 women with stress urinary incontinence treated by SIMS, 12 months after the procedure.[9]

Bleeding

Operative blood loss was significantly greater in the SIMS group (including 'TVTSecur' trials) than in the transobturator minimally invasive sling group in the Cochrane systematic review and meta-analysis of 3,290 women with stress urinary incontinence from 31 randomised or quasi-randomised trials (mean difference 18.79 ml, 95% CI 3.70 to 33.88, I^2=0%, n=2, p=0.015).[2]

Haemorrhage during the procedure was reported in 2% (2/120) of women in the SIMS group (including treatment with 'TVTSecur' 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).[6]

Mild bleeding during the procedure was reported in 78% (57/73) of women treated by SIMS, 72% (190/265) of women treated by TVT and 88% (170/193) of women treated by TVT-O/TOT in the retrospective comparative study of 531 women; moderate bleeding was reported in 21% (15/73) of women treated by SIMS, 26% (69/265) of women treated by TVT and 12% (23/193) of women treated by TVT-O/TOT; severe bleeding was reported in 1% (1/73) of women treated by SIMS, in 2% (6/265) of women treated by TVT and in none of the women treated by TVT-O or TOT (p values not provided).[7]

Pelvic haematoma was reported in 1 woman in the prospective case series of 116 women; it developed after revision surgery needed because of urinary outlet obstruction.[9]

Tape erosion/extrusion/exposure

Vaginal tape erosion rates were not significantly different between the SIMS group ('TVTSecur' 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).[1]

Vaginal mesh exposure rate was significantly greater in the SIMS group ('TVTSecur' trials included) than 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).[2]

In the same systematic review, bladder or urethral erosion rate was significantly greater in the SIMS group ('TVTSecur' trials included) than in the TOT group (RR 17.79, 95% CI 1.06 to 298.88, n=2, I2=0%, p=0.046).[2]

Vaginal tape erosion rates were not significantly different between the SIMS group and the TVT-O/TOT group in the systematic review and meta-analysis of 678 women with stress urinary incontinence from 5 RCTs comparing SIMS (n=361) with TVT-O/TOT (n=317) procedures (RR=1.04, 95 % CI (0.24 to 4.45), p=not significant).[3]

Mesh exposure was reported in 1 patient in the SIMS group in the RCT of 225 women with stress urinary incontinence treated by SIMS (n=112) or TOT (n=113).[4]

Mesh 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.[9]

Urethrovaginal fistula

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.[10]

De novo urgency

De novo urgency or worsening of pre-existing surgery rates were not significantly different between the SIMS group ('TVTSecur' 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).[1]

De novo urgency rate was significantly greater in the SIMS group (including 'TVTSecur' trials) than in the retropubic sling group in the Cochrane systematic review and meta-analysis of 3,290 women with stress urinary incontinence from 31 randomised or quasi-randomised trials (RR 2.39, 95% CI 1.25 to 4.56, I^2=0%, n=3, p=0.0083).[2]

De novo urgency and/or worsening of pre-existing surgery rates were not significantly different between the SIMS group and the TVT-O/TOT group in the systematic review and meta-analysis of 678 women with stress urinary incontinence from 5 RCTs comparing SIMS (n=361) with TVT-O/TOT (n=317) procedures (RR 1.06, 95 % CI 0.66 to 1.71, p value not significant).[3]

De novo or worse urge urinary incontinence 30 days after surgery was reported in 4% (5/120) of patients in the SIMS group and in 8% (9/120) of patients in the r-TVT group in the prospective comparative study of 240 women (p value not significant).[6]

De novo urgency 30 months after the procedure was reported in 7% (5/73) of patients treated by SIMS, 14% (37/265) of patients treated by TVT and 6% (11/193) of patients treated by TVT-O/TOT in the retrospective comparative study of 531 women (p=0.01 for the comparison with TVT and p value not significant for the comparison with TVT-O/TOT). In the same study, de novo stress urinary incontinence was reported in 1% (1/73) of patients treated by SIMS, none of the patients treated by TVT and 1% (2/193) of patients treated by TVT-O/TOT (p value not significant for the comparison with TVT-O/TOT). Incontinence during intercourse was reported in 1% (1/73) of patients treated by SIMS, 1% (2/265) of patients treated by TVT and in none of the patients treated by TVT-O/TOT (p value not significant for the comparison with TVT).[7]

De novo overactivity was reported in 4% (5/120) of patients in a prospective case series of 120 women treated by SIMS. Persistent overactivity was reported in 25% (30/120) of patients.[8]

De novo urgency and worsening overactive bladder were reported in 1 patient each in the prospective case series of 116 women, 12 months after the procedure.[9]

Repeat of continence surgery

Repeat continence surgery rates were not significantly different between the SIMS group ('TVTSecur' '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).[1]

Repeat of continence surgery rates were not significantly different between the SIMS group and the TVT-O/TOT group in the systematic review and meta-analysis of 678 women with stress urinary incontinence from 5 RCTs comparing SIMS (n=361) with TVT-O/TOT (n=317) procedures (RR 1.64, 95 % CI (0.41 to 6.61), p value not significant).[3]

Need for repeat surgery was reported in 3% (3/112) of patients in the SIMS group and in 2% (2/113) of patients in the TOT group in the RCT of 225 women with stress urinary incontinence treated by SIMS or TOT(p=0.68).[4]

Retreatment was reported in 35% (37/103) of patients in the SIMS group and in 11% (12/106) of patients in the r-TVT group in the prospective comparative study of 240 women, 24 months after the procedure (p<0.001).[6]

Reoperation for stress urinary incontinence recurrence within 30 months of the procedure was reported in 5% (4/73) of patients treated by SIMS, in none of the patients treated by TVT and in 1% (2/193) of patients treated by TVT-O/TOT in the retrospective comparative study of 531 women (p=0.01 for the comparison with TVT-O/TOT). Reoperation for stress urinary incontinence recurrence from 48 months after the procedure was reported in 11% (2/19) of patients treated by

SIMS, in none of the patients treated by TVT and in 3% (1/37) of patients treated by TVT-O/TOT (p=0.005 for the comparison with TVT-O/TOT).[7]

Lower urinary tract injury

Lower urinary tract injury rates were not significantly different between the SIMS group ('TVTSecur' 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).[1]

Lower urinary tract injury rates were not significantly different between the SIMS group and the TVT-O/TOT group in the systematic review and meta-analysis of 678 women with stress urinary incontinence from 5 RCTs comparing SIMS (n=361) with TVT-O/TOT (n=317) procedures (RR 2.82, 95 % CI (0.14 to 57.76), p value not significant).[3]

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.[8]

Vaginal wall perforation

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 comparative study of 531 women (relative number of women not reported).[7]

Voiding dysfunction after the procedure

Voiding difficulties after the procedure rates were not significantly different between the SIMS group ('TVTSecur' 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).[1]

Voiding difficulties after the procedure rates were not significantly different between the SIMS group and the TVT-O/TOT group in the systematic review and meta-analysis of 678 women with stress urinary incontinence from 5 RCTs comparing SIMS (n=361) with TVT-O/TOT (n=317) procedures (RR 0.64, 95 % CI 0.28 to 1.45, p value not significant).[3]

Voiding dysfunction was reported in 1 patient in each group in the RCT of 225 women treated by SIMS (n=112) or TOT (n=113). Both had low maximum flow of 10–11 ml/s, postvoid residual of more than 100 ml, but none necessitated sling release.[4]

Abnormal urination was reported in 1 patient in the SIMS group at the 4-year follow-up visit in the RCT of 80 women (40 SIMS versus 40 TOT). Poor stream and staying in the toilet for longer durations were noted, and uroflowmetry

revealed outflow obstruction. The suburethral mini-sling was cut lateral to the urethra and symptoms persisted through the early postoperative period. Six months after urethrolysis the symptoms subsided and the patient remained continent.[5]

Voiding dysfunction 30 days after the procedure was reported in 3% (4/120) of patients in the SIMS group and in 8% (10/120) of patients in the r-TVT group in the prospective comparative study of 240 women (p value not significant).[6]

Dysuria was reported in 4% (3/73) of patients treated by SIMS, in 10% (27/265) of patients treated by TVT and in 6% (11/193) of patients treated by TVT-O/TOT 30 months after the procedure, in the retrospective comparative study of 531 women (p=0.004 for the comparison with TVT and p=0.02 for the comparison with TVT-O/TOT). From 48 months after the procedure, dysuria was reported in 10% (2/19) of patients treated by SIMS, in 12% (12/102) of patients treated by TVT and in 16% (6/37) of patients treated by TVT-O/TOT (p value not significant for the comparison with TVT and p=0.01 for the comparison with TVT-O/TOT). In the same study, urinary retention was reported in 1% (1/73) of patients treated by SIMS, in 1 % (3/265) of patients treated by TVT and in none of the patients treated by TVT-O/TOT (p value not significant for the comparison with TVT).[7]

Urinary retention was reported in 2% (2/113) of patients in the prospective case series of 116 women, 12 months after the procedure. The patients were treated by a Foley catheter and their condition resolved within 3 and 8 days. In the same study, decreased urine stream was reported in 1 patient out of 113. Urinary outlet obstruction was reported in another patient 6 days after the procedure. The patient was treated successfully by 2 revision surgeries and the mesh was incised on both sides of the urethra.[9]

Urinary tract infection

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 significant).[6]

Urinary tract infection was reported in 5% (4/73) of patients treated by SIMS, in 5% (12/265) of patients treated by TVT and in 7% (14/193) of patients treated by TVT-O/TOT 30 months after the procedure, in the retrospective comparative study of 531 women (p=0.001 for the comparison with TVT and p value not significant for the comparison with TVT-O/TOT). From 48 months after the procedure, the urinary tract infection rates were 5% (1/19) in the SIMS group, 5% (5/102) in the TVT group and 11% (4/37) (p value not significant for the comparison with TVT and p=0.009 for the comparison with TVT-O/TOT).[7]

Urinary tract infection was reported in 1 patient in the prospective case series of 116 women, 12 months after the procedure.[9]

Bladder stone

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.[11]

Dyspareunia

Dyspareunia was reported in 1 woman in the prospective case series of 116 women, within 12 months of the procedure.[9]

Inflammation

Inflammation was reported 1 woman in the prospective case series of 116 women, within 12 months of the procedure.[9]

Delayed wound healing

Delayed wound healing was reported 1 woman in the prospective case series of 116 women, within 12 months of the procedure.[9]

Anchor displacement

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]

Nausea

Nausea was reported in 1 woman in the prospective case series of 116 women, 12 months after the procedure.[9]

Reaction to antibiotherapy

Reaction to antibiotherapy was reported in 1 patient in the prospective case series of 116 women, 12 months after the procedure.[9]

Validity and generalisability of the studies

- There are different devices available for single-incision short sling insertion and they are likely to have different safety and efficacy profiles.
- Two of the 3 systematic reviews and meta-analyses[1,2] included in Table 2 include studies where the TVT Secur device was used.

- The longest follow-up is 5 years[5].
- 2 case series et 2 case reports were included in Table 2 for safety data.[9-12]

Existing assessments of this procedure

A summary of the evidence on the benefits and risks of vaginal mesh implants was published in October 2014 by the MHRA[12]. It stated: '' *In considering the overall risk–benefit balance of vaginal mesh implants for SUI, no single conclusion is given as to how successful the treatment option is, as this depends on different surgical approaches. Data from literature in the National Institute for health and Care Excellence (NICE) guideline CG171 (see Section 5.3.3) show that up to one year post-operation for procedures involving vaginal mesh implants for SUI, peri-operative complications can be in the range of 1-12%, depending upon the surgical approach. More limited data at 10 years post-operation indicate that significant long-term benefits are achieved in the majority of women undergoing these procedures, which denominator data indicates to be currently around 13,500 women per year in England. Thus the overall benefit outweighs the relatively low rate of complications.''*

A mesh working group interim report was published in December 2015 by NHS England. [13]

A Scottish 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 interim report was published in October 2015 by The Scottish Government. [14]

An opinion on the safety of surgical meshes used in urogynaecological surgery was published in December 2015 by the Scientific Committee on Emerging and Newly Identified Health Risks. It stated: '' *In sling surgery, there is evidence that absorbable biological materials have a high failure rate while sling surgery with non-absorbable synthetic mesh was effective with an approximately mesh exposure rate of 4% (Brubaker et al., 2011). Autologous slings are a more invasive alternative (because of the need to harvest native tissue), but they also can be inserted using a minimally invasive approach. The traditional surgical approach of colposuspension is associated with greater morbidity compared to sling surgery with mesh.*

However, synthetic sling SUI surgery is an accepted procedure with proven efficacy and safety in the majority of patients with moderate to severe SUI, when used by an experienced and appropriately trained surgeon. Therefore, the SCENIHR supports continuing synthetic sling use for SUI, but emphasises the importance of appropriately trained surgeons and detailed counselling of patients about the associated risk/benefits.

Based on the available scientific evidence, the SCENIHR recommends

• the implantation of any mesh for the treatment of POP via the vaginal route should be only considered in complex cases in particular after failed primary repair surgery,

• that due to increased risks associated with the use of synthetic mesh for POP repair via a trans-vaginal route, this option should only be used when other surgical procedures have already failed or are expected to fail.

• limiting the amount of mesh for all procedures where possible. However, there is a need for further improvement in the composition and design of synthetic meshes, in particular for POP surgery.

• the introduction of a certification system for surgeons based on existing international guidelines and established in cooperation with the relevant European Surgical Associations.

• appropriate patient selection and counselling, which is of paramount importance for the optimal outcome for all surgical procedures, particularly for the indications discussed. This should be based on the results of further clinical evidence, which should be collected in a systematic fashion for all of these devices."[15]

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Interventional procedures

- Insertion of biological slings for stress urinary incontinence. NICE interventional procedure guidance 154 (2006). Available from https://www.nice.org.uk/guidance/ipg154
- Intramural urethral bulking procedures for stress urinary incontinence. NICE interventional procedure guidance 138 (2005). Available from https://www.nice.org.uk/guidance/ipg138
- Insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women. NICE interventional procedure guidance 133 (2005). Available from https://www.nice.org.uk/guidance/ipg133
- Sacral nerve stimulation for urge incontinence and urgency-frequency. NICE interventional procedure guidance 64 (2004). Available from https://www.nice.org.uk/guidance/ipg64

- Bone-anchored cystourethropexy. NICE interventional procedure guidance 18 (2003). Available from https://www.nice.org.uk/guidance/ipg18

NICE guidelines

- Urinary incontinence in women: management. NICE clinical guideline 171 (2013). Available from http://www.nice.org.uk/guidance/CG171
- Urinary incontinence in neurological disease: assessment and management. NICE clinical guideline 148 (2012). Available from http://www.nice.org.uk/guidance/CG148

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by Specialist Advisers, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. Three Specialist Advisor Questionnaires for single-incision short sling (mesh) insertion for stress urinary incontinence in women were submitted and can be found on the NICE website.

Patient commentators' opinions

NICE's Public Involvement Programme sent xxx questionnaires to xxx NHS trusts for distribution to patients who had the procedure (or their carers). NICE received xxx completed questionnaires.

Section to be inserted if there is no patient commentary

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

Section to be inserted if patient commentators raised no new issues

The patient commentators' views on the procedure were consistent with the published evidence and the opinions of the specialist advisers.

Section to be inserted if patient commentators raised new issues

The patient commentators raised the following issues about the safety/efficacy of the procedure, which did not feature in the published evidence or the opinions of specialist advisers, and which the committee considered to be particularly relevant:

- [insert additional efficacy and safety issues raised by patient commentators and highlighted by IPAC, add extra rows as necessary].
- [Last item in list].

Issues for consideration by IPAC

- In June 2012, Ethicon voluntarily withdrew the GYNECARE TVT-SECUR system from the market. Therefore, the studies in which only the TVT-Secur device was used for the procedure were excluded.
- Ongoing studies:
  - MHRA report: The use of polypropylene mesh in stress urinary incontinence and pelvic floor reconstructive surgery: a review of biocompatibility (anticipated publication date: early 2016).
  - HTA - 12/127/157: Adjustable Anchored Single-Incision Mini-Slings Versus Standard Tension-Free Mid-Urethral Slings in the Surgical Management Of Female Stress Urinary Incontinence; A Pragmatic Multicentre Non Inferiority Randomised Controlled Trial: The SIMS Trial. Anticipated publication date: December 2019.
  - NCT02049840 The European Study of Altis Single Incision Sling System for Female Stress Urinary Incontinence (EASY). Location: Europe. Prospective single arm multicenter study. Recruiting. Estimated enrolment: 136 patients. Estimated Completion Date: December 2018.
  - NCT02348112 Altis® 522 Trial - Treatment of Female Stress Urinary Incontinence. Location: US, Canada. Non-randomised comparative study.

Recruiting. Estimated enrolment: 356 patients. Estimated Completion Date: January 2020.

References

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2. Nambiar A, Cody JD, and Jeffery ST. (2014) Single-incision sling operations for urinary incontinence in women. Cochrane Database of Systematic Reviews.
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4. Lee JK, Rosamilia A, Dwyer PL et al. (2015) Randomized trial of a single incision versus an outside-in transobturator midurethral sling in women with stress urinary incontinence: 12 month results. American Journal of Obstetrics & Gynecology 213:35-39.
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7. Stavros C, Ioannis V, Vasileios SI et al. (2012) Comparison of TVT, TVT-O/TOT and mini slings for the treatment of female stress urinary incontinence: 30 Months follow up in 531 patients. Archivio Italiano di Urologia e Andrologia.84 (3) 129-136.
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11. Chin K, Ripperda CM, Schaffer JI et al. (2014) Cystolith formation complicating single-incision sling. Female Pelvic Medicine & Reconstructive Surgery 20:177-179.

12. MHRA report. A summary of the evidence on the benefits and risks of vaginal mesh implants. Published on 28 October 2014. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/402162/Summary_of_the_evidence_on_the_benefits_and_risks_of_vaginal_mesh_implants.pdf

13. NHS England, Acute Care Policy and Strategy Unit. Mesh working group interim report. Published on 3 December 2015. https://www.england.nhs.uk/wp-content/uploads/2015/12/mesh-wg-interim-rep.pdf

14. The Scottish Government. The Scottish 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 interim report. Published on 2 October 2015. http://www.gov.scot/resource/0048/00486661.pdf

15. SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), The safety of surgical meshes used in urogynecological surgery, 3 December 2015.

Appendix A: Additional papers on single-incision short sling (mesh) insertion for stress urinary incontinence in women

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies. Case series with fewer than 120 patients were excluded.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Abdel-Fattah M, Ford JA, Lim CP et al. (2011) Single-incision mini-slings versus standard midurethral slings in surgical management of female stress urinary incontinence: a meta-analysis of effectiveness and complications. [Review]. European Urology 60:468-480.	Systematic review and meta-analysis Single-incision mini-slings (SIMS) versus standard midurethral slings (SMUS) n=758 patients from 9 RCTs FU=mean 9.5 months	SIMS are associated with inferior patient-reported and objective cure rates on the short-term follow-up, as well as higher reoperation rates for SUI when compared with SMUS.	An updated systematic review and meta-analysis (the Mostafa 2014 paper) is already included in Table 2.
Barber MD, Weidner AC, Sokol AI et al. (2012) Single-incision mini-sling compared with tension-free vaginal tape for the treatment of stress urinary incontinence: a randomized controlled trial. Obstetrics & Gynecology 119:t-37.	Non-inferiority RCT n=263 (136 TVT Secur versus 127 TVT) FU=1 year	The mini-sling placed in the "U" position results in similar subjective cure rates to TVT 1 year after surgery but postoperative incontinence severity is greater with the mini-sling than with TVT.	The mini-sling group only included patients treated by TVT Secur.
Basu M and Duckett J. (2013) Three-year results from a randomised trial of a retropubic mid-urethral sling versus the Miniarc single incision sling for stress urinary incontinence. International Urogynecology Journal 24:2059-2064.	RCT n=71 (38 Miniarc single-incision sling versus 33 Advantage retropubic mid-urethral sling) FU=3 years	In this study, there was a significantly higher 3-year failure rate for the single-incision sling versus the retropubic mid-urethral sling. Both procedures had reduced efficacy over time	This RCT is included in the Mostafa (2014) systematic review and meta-analysis.
Bianchi-Ferraro AM, Jarmy-Di Bella ZI, Castro RA et al. (2013) Single-incision sling compared with transobturator sling for treating stress urinary incontinence: a randomized controlled trial. International Urogynecology Journal 24:1459-1465.	Non-inferiority RCT n=122 (66 TVT-Secur versus 56 TVT-O) FU=1 year	TVT-S was not inferior to TVT-O for treating SUI at 12-month follow-up.	The SIMS group only included patients treated by TVT Secur.
Blewniewski M, Markowski M, Klis R et al. (2015) Mini-slings - an option in stress urinary incontinence treatment. Case studies. Central European Journal of Urology 68:68-71.	Case series n=140 (65 TVT-Secur, 70 Adjust and 5 Miniarc) FU=1 year	The implantation of mini-slings is a low invasive, relatively safe and effective procedure for the treatment of SUI even in cases of recurrence. Almost full recovery was achieved in all the cases of this study. The mini-sling has become an important element in modern urogynaecology.	Larger studies with longer follow-up are included. No new safety event reported.
Chen YQ, Pei HH, Liang YY et al. (2014) Efficacy of	Retrospective comparative study	Both tension-free vaginal tape obturator	The SIMS group only included patients treated

tension-free vaginal tape obturator and single-incision tension-free vaginal tape-Secur, hammock approach, in the treatment of stress urinary incontinence. Minerva Urologica e Nefrologica 66:165-173.	n=60 (32 TVT-Secur versus 28 TVT-O) FU=31 months	and tension-free vaginal tape-Secur can achieve a cure rate over 80% while with little complications, showing both methods are reliable to treat stress urinary incontinence.	by TVT Secur.
De Ridder D, Berkers J, Deprest J et al. (2010) Single incision mini-sling versus a transobturator sling: a comparative study on MiniArc and Monarc slings. International Urogynecology Journal 21:773-778.	Retrospective comparative study n=131 (75 Miniarc versus 56 Monarc) FU=1 year	These results suggest that MiniArc sling and Monarc sling are equally effective in the treatment of stress incontinence at 1 year follow-up.	More recent RCTs are included.
Djehdian LM, Araujo MP, Takano CC et al. (2014) Transobturator sling compared with single-incision mini-sling for the treatment of stress urinary incontinence: A randomized controlled trial. Obstetrics and Gynecology.123 (3) 553-561	Non-inferiority RCT n=130 (69 SIMS [Ophira] versus 61 TO-TVT) FU=1 year	The non-inferiority of the mini-sling could not be demonstrated in this study at the 12-month follow-up. The mini-sling was associated with shorter operative time and less postoperative thigh pain.	This RCT is included in the Mostafa (2014) systematic review and meta-analysis.
Foote A. (2014) Randomized prospective study comparing Monarc and Miniarc suburethral slings. Journal of Obstetrics and Gynaecology Research.41 (1) 127-131.	RCT n=50 (25 Miniarc versus 25 Monarc) FU=6 months	The only significant intraoperative difference was a shorter operation time for the Miniarc. The success rates were similar at 6 weeks and 6 months.	Larger RCTs with longer follow-up are already included in table 2. No new safety event reported.
Grigoriadis C, Bakas P, Derpapas A et al. (2013) Tension-free vaginal tape obturator versus Ajust adjustable single incision sling procedure in women with urodynamic stress urinary incontinence. European Journal of Obstetrics, Gynecology, & Reproductive Biology 170:563-566.	Prospective matched controlled study n=171 (Ajust versus TVT-O) FU=22 months	The Ajust sling procedure presents success rates, at 22 months' mean follow up, comparable to the TVT-O method. Both techniques seem to be safe and effective for the treatment of urodynamic stress urinary.	Larger RCTs are included.
Grimsby GM, Tyson MD, and Wolter CE. (2013) Comparison of midurethral sling outcomes with and without prolapse repair. Canadian Journal of Urology 20:6927-6932.	Retrospective comparative study n=89 45 single incision slings (27 slings only and 18 sling + pelvic organ prolapse repair) versus 44 retropubic slings (28 slings only and 16 sling + pelvic organ prolapse repair)	There was a higher incidence of single incision mid-urethral sling failure when done at the same time as repair of pelvic organ prolapse in comparison to sling placement alone. There is no difference in the success of retropubic slings when done with or without concomitant prolapse repair.	Larger studies with longer follow-up are included.

	FU=180 days		
Hwang E, Shin JH, Lim JS et al. (2012) Predictive factors that influence treatment outcomes of innovative single incision sling: Comparing TVT-Secur to an established transobturator sling for female stress urinary incontinence. International Urogynecology Journal and Pelvic Floor Dysfunction.23 (7) 907-912.	Comparative study n=175 (89 TVT-S versus 86 TOT) FU=32 months	TVT-S could be done for selected patients, but conventional TOT procedures are still superior to the novel TVT-S device.	The SIMS group only included patients treated by TVT Secur.
Jeong MY, Kim SJ, Kim HS et al. (2010) Comparison of efficacy and satisfaction between the TVT-SECUR and MONARC procedures for the treatment of female stress urinary incontinence. Korean Journal of Urology.51 (11) 767-770.	Comparative study n=64 (31 TVT-S versus 33 Monarc) FU=1 year	The TVT-S and MONARC procedures may be comparable in terms of cure rate and patient satisfaction after more than 1 year of follow-up.	The SIMS group only included patients treated by TVT Secur.
Jimenez-Calvo J, Montesino-Semper M, Hualde-Alfaro A et al. (2015) Stress urinary incontinence surgery with sling MiniArc: a 4-year results. Actas Urologicas Espanolas 39:47-52.	Retrospective case series n=135 Miniarc FU=mean 59 months	87% of patients showed objective cured (81% with MUI and 89% with SUI). The ICIQ-SF decreased average of 12.7 points, 86% patients were very or fairly satisfied.	Studies with more patients or longer follow-up are already included. No new safety event reported.
Joo YM, Choe JH, and Seo JT. (2010) One-year surgical outcomes and quality of life after minimally invasive sling procedures for the treatment of female stress urinary incontinence: TVT SECUR versus. CureMesh. Korean Journal of Urology.51 (5) 337-343.	Prospective non-randomised comparative study n=60 (38 TVT-S versus 22 CureMesh) FU=1 year	The TVT SECUR and CureMesh procedures are both safe and simple to do and have no significant differences in efficacy. Comparative studies with long-term follow-up are warranted to determine the true efficacy of these procedures.	The SIMS group only included patients treated by TVT Secur.
Kennelly MJ, Moore R, Nguyen JN et al. (2012) Miniarc single-incision sling for treatment of stress urinary incontinence: 2-year clinical outcomes. International Urogynecology Journal 23:1285-1291.	Prospective case series n=180 Miniarc FU=2 years	MiniArc is a safe and effective surgical procedure for the treatment of SUI in women with follow-up through 2 years.	Studies with more patients or longer follow up are already included. No new safety event reported.
Kennelly MJ, Moore R, Nguyen JN et al. (2010) Prospective evaluation of a single incision sling for stress urinary incontinence. Journal of Urology 184:604-609.	Prospective case series n=188 Miniarc FU=1 year	The MiniArc single incision sling is a safe and effective first line surgical procedure for the treatment of female SUI. It demonstrated excellent patient tolerability with minimal pain, early return to normal activity and low	Studies with more patients or longer follow up are already included. No new safety event reported.

		morbidity. Patients experienced a significant improvement in quality of life.	
Leanza V, Intagliata E, Leanza A et al. (2014) Comparison between three mini-sling surgical procedures and the traditional transobturator vaginal tape technique for female stress urinary incontinence. [Review]. Giornale di Chirurgia 35:80-84.	Systematic review SIMS (TVT-Secur, Monarc and Miniarc) versus TOT FU=1 year	In term of objective cure rate at 12 month after surgery, TOT at first, and MiniArc are the most effective procedures. The incidence of postoperative urgency and UTI was lower in TOT technique, while vaginal perforation was described in equal frequency both in TOT and in MiniArc procedures. The advantages of the three above described mini-invasive techniques seem to consist into lower cases of urinary retention, pain and bleeding. Furthermore, bladder perforation and bleeding are not described in the literature for TVT-Secur and Monarc systems.	Review without a meta-analysis.
Lo TS, Tan YL, Wu PY et al. (2014) Ultrasonography and clinical outcomes following surgical anti-incontinence procedures (Monarc versus Miniarc). European Journal of Obstetrics, Gynecology, & Reproductive Biology 182:91-97.	Prospective comparative study. n=140 (85 Miniarc versus 55 Monarc) FU=1 year	Miniarc and Monarc exhibit similar mechanism of action with comparable subjective and objective clinical outcomes. Majority of urethral impingement was noted in the Miniarc group. A higher maximum urethral closure pressure (MUCP), longer resting Ul, and shorter resting Us suggested these observations. Postoperative ultrasonographic evaluation may give a promising future perspective for the evaluation of sling tension.	Studies with more patients or longer follow up are already included. No new safety event reported.
Madsen AM, El-Nashar SA, Woelk JL et al. (2014) A cohort study comparing a single-incision sling with a retropubic midurethral sling. International Urogynecology Journal 25:351-358.	Comparative study. n=202 (93 Miniarc versus 109 retropubic Align slings)	Compared with retropubic ALIGN Slings, MiniArc Single-Incision Slings are less effective, with more postoperative incontinence, less	Studies with more patients or longer follow up are already included. No new safety event reported.

	FU=18-23 months	patient-reported improvement, satisfaction, and higher reoperation rates for SUI.	
Martinez Franco E. (2015) Contasure-NeedlelessÃ‚Â® single incision sling compared with transobturator TVT-O Ã‚Â® for the treatment of stress urinary incontinence: long-term results. International Urogynecology Journal 26:213-218.	Non-inferiority prospective quasi-randomised trial n=257 (131 Contasure-Needleless [C-NDL] versus 108 TVT-O) FU=at least 3 years	The outcomes of the C-NDL group were similar to those of the TVT-O group.	Higher quality studies are included in table 2. No new safety events reported.
Masata J, Svabik K, Zvara K et al. (2012) Randomized trial of a comparison of the efficacy of TVT-O and single-incision tape TVT SECUR systems in the treatment of stress urinary incontinent women--2-year follow-up. International Urogynecology Journal 23:1403-1412.	RCT n=197 (64 TVT Secur H and 65 TVT Secur U versus 68 TVT-O) FU=median 2 years	There was a significantly lower subjective and objective cure rate in the single-incision TVT group compared to the TVT-O group.	The SIMS group only included patients treated by TVT Secur.
Meschia M, Rossi G, Bertini S et al. (2013) Single incision mid-urethral slings: impact of obesity on outcomes. European Journal of Obstetrics, Gynecology, & Reproductive Biology 170:571-574.	Case series n=206 (95 TVT-Secur and 111 Ajust) FU=1 year	Single incision slings seem to be an effective treatment regardless of BMI, but obese women had nearly 4 times the odds of objective failure as compared to normal weight women.	Studies with more patients or longer follow up are already included. No new safety event reported.
Moore RD, De RD, and Kennelly MJ. (2013) Two-year evaluation of the MiniArc in obese versus non-obese patients for treatment of stress urinary incontinence. International Journal of Urology 20:434-440.	Prospective comparative study n=188 Miniarc (62 obese patients versus 126 non obese patients) FU=2 years	The Miniarc sling represents a safe and effective treatment option for both obese and non-obese patients with stress incontinence. Comparable outcomes at 2 years can be obtained in terms of cure rates using the cough stress test or questionnaires, as well as complication rates.	Comparison of outcomes in obese patients versus non obese patients.
Mostafa A, Agur W, Abdel-All M et al. (2013) Multicenter prospective randomized study of single-incision mini-sling versus tension-free vaginal tape-obturator in management of female stress urinary incontinence: A minimum of 1-year follow-up. Urology 82 (3) 552-559.	RCT n=137 (69 SIMS [Ajust] versus 68 TVT-O) FU=1 year	Adjustable-anchored SIMS (Ajust) is associated with comparable patient-reported and objective success rates when compared to standard midurethral sling (SMUS, TVT-O) at a minimum of 1-year follow-up. The results	This RCT is included in the Mostafa (2014) systematic review and meta-analysis.

		should be interpreted with caution due to the relatively small cohort size. Long-term follow-up of this RCT is required to ascertain the durability of these results.	
Mostafa A, Agur W, Abdel-All M et al. (2012) A multicentre prospective randomised study of single-incision mini-sling (Ajust) versus tension-free vaginal tape-obturator (TVT-OTM) in the management of female stress urinary incontinence: Pain profile and short-term outcomes. European Journal of Obstetrics Gynecology and Reproductive Biology.165 (1) 115-121.	RCT n=137 (69 SIMS [Ajust] versus 68 TVT-O) FU=6 months	Ajust is associated with a significantly improved postoperative pain profile and earlier return to work when compared to standard mid-urethral slings (TVT-OTM), with encouraging results in patient-reported and objective success rates at short-term follow-up.	Same study as in Mostafa (2013) paper above. This RCT is included in the Mostafa (2014) systematic review and meta-analysis.
Naumann G, Steetskamp J, Meyer M et al. (2013) Sexual function and quality of life following retropubic TVT and single-incision sling in women with stress urinary incontinence: results of a prospective study. Archives of Gynecology & Obstetrics 287:959-966.	Prospective comparative study n=150 (75 Miniarc versus 75 r-TVT) FU=6 months	The SIS procedure appears to be as effective in improving incontinence-related quality of life and sexual function as the TVT through 6 months of postoperative follow-up. No differences in complications and sexual function were demonstrated between the groups.	Studies with more patients or longer follow up are already included. No new safety event reported.
Naumann G, Hagemeier H, Albrich SB et al. (2012) Patient goals after incontinence procedures: does the single-incision sling satisfy them? European Journal of Obstetrics, Gynecology, & Reproductive Biology 163:234-237.	Prospective comparative study n=180 (57 Miniarc versus 51 TVT) FU=8 weeks	Self-reported achievement of preoperative goals of patients submitted to single-incision slings are comparable at the first follow-up with patients who have had the classic mid-urethral sling.	Studies with more patients or longer follow up are already included. No new safety event reported.
Neuman M, Sosnovski V, Kais M et al. (2011) Transobturator versus single-incision suburethral mini-slings for treatment of female stress urinary incontinence: early postoperative pain and 3-year follow-up. Journal of Minimally Invasive Gynecology 18:769-773.	Prospective non-randomised comparative study n=162 (82 TVT-Secur versus 80 TVT-O) FU=36 months	Both procedures were effective, with few adverse effects. In sexually inactive patients, the TVT-SECUR procedure may be preferable because thigh and vaginal pain is largely averted with this procedure. Sexually active patients might be better referred for the TVT-O procedure because it was not	The SIMS group only included patients treated by TVT Secur.

		followed by dyspareunia in our series. Patient choice of surgical method rather than randomization weakened the strength of this study.	
Oliveira R, Botelho F, Silva P et al. (2011) Exploratory study assessing efficacy and complications of TVT-O, TVT-Secur, and Mini-Arc: results at 12-month follow-up. European Urology 59:940-944.	RCT n=90 (30 Miniarc versus 30 TVT-S versus 30 TVT-O) FU=12 months	Mini-Arc offers cure and improvement rates similar to TVT-O, whereas TVT-Secur may yield an inferior outcome. These findings recommend the urgent launch of large randomised phase 3 studies comparing conventional MUS with SIS, with Mini-Arc the advised option.	The study is included in the Nambiar (2014) systematic review and meta-analysis included in table 2.
Palma P, Riccetto C, Bronzatto E et al. (2014) What is the best indication for single-incision Ophira Mini Sling? Insights from a 2-year follow-up international multicentric study. International Urogynecology Journal 25:637-643.	Case series n=124 Ophira FU=2 years	The Ophira procedure is an effective option for SUI treatment, with durable good results. Previous surgeries were identified as the only significant risk factor, though previously operated patients showed an acceptable success rate.	Studies with more patients or longer follow-up are already included in table 2. No new safety event reported.
Palomba S, Falbo A, Oppedisano R et al. (2014) A randomized controlled trial comparing three single-incision minislings for stress urinary incontinence. International Urogynecology Journal 25:1333-1341.	RCT n=120 (40 Ajust versus 40 Miniarc versus 40 TVT-Secur) FU=24 months minimum	The long-term efficacy of SIMS does not differ between the vaginal kits examined.	Study comparing 3 different SIMS. The group of patients is the same as in the Palomba (2013) paper that is included in table 2.
Palomba S, Oppedisano R, Torella M et al. (2012) A randomized controlled trial comparing three vaginal kits of single-incision mini-slings for stress urinary incontinence: surgical data. European Journal of Obstetrics, Gynecology, & Reproductive Biology 163:108-112.	RCT n=120 (40 Ajust versus 40 Miniarc versus 40 TVT-Secur) FU=2 years	MiniArc is simpler to insert under local anaesthesia and in an ambulatory setting. It is safer than the TVT Secur System, and is related to higher patient satisfaction.	Study comparing 3 different SIMS. The group of patients is the same as in the Palomba (2013) paper that is included in table 2.
Ross S, Tang S, Schulz J et al. (2014) Single incision device (TVT Secur) versus retropubic tension-free vaginal tape device (TVT) for the management of stress urinary incontinence in women: a randomized clinical trial. BMC Research	RCT n=74 (40 TVT-S versus 34 TVT-r) FU=1 year	No statistically significant differences in outcomes between women allocated to the TVT Secur device versus those allocated to the TVT device for stress urinary incontinence.	The SIMS group only included patients treated by TVT Secur.

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Schellart RP, Oude RK, Van der Aa F et al. (2014) A randomized comparison of a single-incision midurethral sling and a transobturator midurethral sling in women with stress urinary incontinence: results of 12-mo follow-up. European Urology 66:1179-1185.	RCT n=193 (97 MIniarc versus 96 Monarc) FU=1 year	At 1-yr follow-up, MiniArc was non-inferior to Monarc with respect to subjective and objective cure and superior with respect to postoperative pain.	This RCT is included in the Mostafa (2014) systematic review and meta-analysis.
Schweitzer KJ, Milani AL, van Eijndhoven HW et al. (2015) Postoperative pain after adjustable single-incision or transobturator sling for incontinence: a randomized controlled trial. Obstetrics & Gynecology 125:27-34.	RCT n=156 (100 adjustable single-incision sling versus 56 TOT) FU=1 year	An adjustable single-incision sling for the treatment of SUI is associated with lower early postoperative pain scores but shows comparable cure rates with a transobturator at 12 months of follow-up.	Studies with more patients or longer follow up are already included. No new safety event reported.
Sun M-J, Sun R, and Li Y-I. (2013) A comparative study of a single-incision sling and a transobturator sling: Clinical efficacy and urodynamic changes. International Urogynecology Journal and Pelvic Floor Dysfunction.24 (5) 823-829.	Retrospective non-randomised comparative study n=85 (43 Miniarc versus 42 TOT) FU=1 year	These results suggest that the single-incision sling and the transobturator sling are equally as effective and safe for the treatment of stress incontinence, as evaluated during the 1-year follow-up. The insertion of a single-incision sling seems to be less painful than that of a conventional sling. One year after surgery, the MUCP and mean flow rate of the transobturator sling group had significantly decreased compared with that of the single-incision sling group.	Studies with more patients or longer follow up are already included. No new safety event reported.
Tardiu L, Franco EM, and Vicens JML. (2011) Contasure-Needleless compared with transobturator-TVT for the treatment of stress urinary incontinence. International Urogynecology Journal and Pelvic Floor Dysfunction.22 (7) (pp 827-833), 2011.Date of Publication: July 2011. 827-833.	Quasi-randomised prospective study n=132 (72 Contasure-Needleless versus 60 TVT-O) FU=1 year	C-NDL provides similar outcomes as TVT-O after 1-year follow-up. It is necessary that long-term data confirm our results.	Studies with more patients or longer follow up are already included. No new safety event reported.
Tincello DG, Botha T, Grier D et al. (2011) The TVT Worldwide Observational Registry for Long-Term Data: safety and efficacy of suburethral sling insertion approaches for stress	Registry data n=1334 (49% TVT-S, 33% TVT and 18% TVT-O)	This registry demonstrates the high effectiveness of all 3 approaches. The single incision sling (TVT-S) appeared to have objective and subjective	The SIMS group only included patients treated by TVT Secur.

urinary incontinence in women. Journal of Urology 186:2310-2315.	FU=1 year	efficacy similar to that of the retropubic sling and it can be done under local anaesthesia in an office environment.	
Tommaselli GA, D'Afiero A, Di CC et al. (2013) Tension-free vaginal tape-O and -Secur for the treatment of stress urinary incontinence: a thirty-six-month follow-up single-blind, double-arm, randomized study. Journal of Minimally Invasive Gynecology 20:198-204.	RCT n=154 (77 TVT-S versus 77 TVT-O) FU=36 months	TVT-Secur seems not to be inferior to TVT-O in the surgical treatment of stress urinary incontinence and causes less postoperative pain. The possibility of severe blood loss cannot be ruled out when TVT-Secur is used.	The SIMS group only included patients treated by TVT Secur.
Tommaselli GA, Di CC, Gargano V et al. (2010) Efficacy and safety of TVT-O and TVT-Secur in the treatment of female stress urinary incontinence: 1-Year follow-up. International Urogynecology Journal and Pelvic Floor Dysfunction.21 (10) 1211-1217.	Prospective comparative study n=75 (37 TVT-S versus 38 TVT-O) FU=1 year	Both techniques seem to be effective and safe, with a low incidence of complications in both groups.	The SIMS group only included patients treated by TVT Secur.
Tommaselli GA, D'Afiero A, Di CC et al. (2015) Tension-free vaginal tape-obturator and tension-free vaginal tape-Secur for the treatment of stress urinary incontinence: a 5-year follow-up randomized study. European Journal of Obstetrics, Gynecology, & Reproductive Biology 185:151-155.	RCT n=154 (77 TVT-S versus 77 TVT-O) FU=5 years	TVT-Secur did not show an inferior subjective success rate in comparison with TVT-O five year after the original procedure, even though displaying a clear trend toward a lower efficacy. Considering that the long-term safety profile is similar between the two procedures, there are no advantages in using TVT-Secur.	The SIMS group only included patients treated by TVT Secur.
Walsh CA. (2011) TVT-Secur mini-sling for stress urinary incontinence: a review of outcomes at 12 months. [Review]. BJU International 108:652-657.	Review n=1178 patients from 10 studies	Longer-term studies and randomized comparisons with more established MUSs are required before TVT-S should be routinely used in the surgical treatment of stress urinary incontinence.	The SIMS group only included patients treated by TVT Secur.
Yuksel MB, Kose O, Karakose A et al. (2013) The comparison of short term results of transobturator tape and single incision midurethral sling procedures. International Journal of Women's Health and Reproduction Sciences.1	Comparative study n=32 (15 SIMS [Ophira] versus 17 TOT [Promedon]) FU=1 year	SIMS procedure is safe and as effective as TOT with shorter operation time in the surgical treatment of female SUI.	Studies with more patients or longer follow up are already included. No new safety event reported.

(3) 80-87.			

Appendix B: Related NICE guidance for single-incision short sling (mesh) insertion for stress urinary incontinence in women

Guidance	Recommendations
Interventional procedures	**Single-incision sub-urethral short tape insertion for stress urinary incontinence in women (current guidance). NICE interventional procedure guidance 262 (2008)** 1.1 Current evidence on the safety and efficacy of single-incision sub-urethral short tape insertion for stress urinary incontinence in women is inadequate in quality and quantity. Therefore this procedure should be carried out only in the context of research studies or through submission of data to a national register (at the British Society of Urogynaecology or the Female and Reconstructive Urology Section of the British Association of Urological Surgeons). 1.2 This procedure should only be carried out by a clinician with specific training in this technique. 1.3Systematic long-term follow-up is essential. The Institute may review the procedure upon publication of further evidence. **Insertion of biological slings for stress urinary incontinence. NICE interventional procedure guidance 154 (2006).** 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.

	Intramural urethral bulking procedures for stress urinary incontinence. NICE interventional procedure guidance 138 (2005). 1.1 Current evidence on the safety and short-term efficacy of intramural urethral bulking procedures for stress urinary incontinence is adequate to support the use of these procedures provided that normal arrangements are in place for clinical governance and for audit or research. 1.2 Clinicians should ensure that patients understand that the benefits of the procedures diminish in the long term and provide them with clear written information. In addition, use of the Institute's information for the public is recommended. 1.3 Further publication of longer-term efficacy outcomes will be useful. Clinicians should submit data to the British Association of Urological Surgeons registry, or the British Society of Urogynaecologists registry (for further information contact the British Society of Urogynaecologists). **Insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women. NICE interventional procedure guidance 133 (2005).** 1.1 Current evidence on the safety and efficacy of insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research. 1.2 Clinicians wishing to undertake insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of the Institute's information for the public is recommended. • Audit and review clinical outcomes of all patients having insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence. 1.3 Publication of safety and efficacy outcomes will be useful. The Institute may review the procedure upon publication of further evidence.

	Sacral nerve stimulation for urge incontinence and urgency-frequency. NICE interventional procedure guidance 64 (2004). 1.1 Current evidence on the safety and efficacy of sacral nerve stimulation for urge incontinence and urgency-frequency appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance. 1.2 Patient selection is important. The diagnosis should be defined as clearly as possible and the procedure limited to patients who have not responded to conservative treatments such as lifestyle modifications, behavioural techniques and drug therapy. Patients should be selected on the basis of their response to peripheral nerve evaluation **Bone-anchored cystourethropexy. NICE interventional procedure guidance 18 (2003).** 1.1 Current evidence of the safety and efficacy of bone-anchored cystourethropexy does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians wishing to undertake bone-anchored cystourethropexy should inform the clinical governance leads in their Trusts. They should ensure that patients offered it understand the uncertainty about the procedure's safety and efficacy and should provide them with clear written information. In particular patients should be informed that the long-term efficacy of the procedure appears to be poor. Use of the Institute's information for the public is recommended. Clinicians should ensure that appropriate arrangements are in place for audit or research. Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. NICE is not undertaking further investigation at present.

NICE guidelines	**Urinary incontinence in women: management. NICE clinical guideline 171 (2013).** 1.10 Surgical approaches for SUI 1.10.1 When offering a surgical procedure discuss with the woman the risks and benefits of the different treatment options for SUI using the information in Information to facilitate discussion of risks and benefits of treatments for women with stress urinary incontinence. **[new 2013]** 1.10.2 If conservative management for SUI has failed, offer: • synthetic mid-urethral tape (see recommendations 1.10.3–8), **or** • open colposuspension (see also recommendation 1.10.9), **or** • autologous rectus fascial sling (see also recommendation 1.10.10). **[new 2013]** **Synthetic tapes** 1.10.3 When offering a synthetic mid-urethral tape procedure, surgeons should: • use procedures and devices for which there is current high quality evidence of efficacy and safety • only use a device that they have been trained to use (see recommendations in section 1.11) • use a device manufactured from type 1 macroporous polypropylene tape • consider using a tape coloured for high visibility, for ease of insertion and revision. **[new 2013]** 1.10.4 If women are offered a procedure involving the transobturator approach, make them aware of the lack of long-term outcome data. **[new 2013]** 1.10.5 Refer women to an alternative surgeon if their chosen procedure is not available from the consulting surgeon. **[new 2013]** 1.10.6 Use 'top-down' retropubic tape approach only as part of a clinical trial. **[new 2013]** 1.10.7 Refer to single-incision sub-urethral short tape insertion for stress urinary incontinence (NICE interventional procedure guidance 262) for guidance on single-incision procedures. **[new 2013]** 1.10.8 Offer a follow-up appointment (including vaginal examination to exclude erosion) within 6 months to all women who have had continence surgery. **[new 2013]** **Colposuspension** 1.10.9 Do not offer laparoscopic colposuspension as a routine procedure for the treatment of stress UI in women. Only an experienced laparoscopic surgeon working in an MDT with expertise in the assessment and treatment of UI should

	perform the procedure. **[2006]** **Biological slings** 1.10.10 Do not offer anterior colporrhaphy, needle suspensions, paravaginal defect repair and the Marshall–Marchetti–Krantz procedure for the treatment of stress UI. **[2006]** **Intramural bulking agents** 1.10.11 Consider intramural bulking agents (silicone, carbon-coated zirconium beads or hyaluronic acid/dextran copolymer) for the management of stress UI if conservative management has failed. Women should be made aware that: • repeat injections may be needed to achieve efficacy • efficacy diminishes with time • efficacy is inferior to that of synthetic tapes or autologous rectus fascial slings. **[2006, amended 2013]** 1.10.12 Do not offer autologous fat and polytetrafluoroethylene used as intramural bulking agents for the treatment of stress UI. **[2006]** **Artificial urinary sphincter** 1.10.13 In view of the associated morbidity, the use of an artificial urinary sphincter should be considered for the management of stress UI in women only if previous surgery has failed. Life-long follow-up is recommended. **[2006]** **Considerations following unsuccessful invasive SUI procedures or recurrence of symptoms** 1.10.14 Women whose primary surgical procedure for SUI has failed (including women whose symptoms have returned) should be: • referred to tertiary care for assessment (such as repeat urodynamic testing including additional tests such as imaging and urethral function studies) and discussion of treatment options by the MDT, **or** • offered advice as described in recommendation 1.6.9 if the woman does not want continued invasive SUI procedures. **[new 2013]** **Urinary incontinence in neurological disease: assessment and management. NICE clinical guideline 148 (2012).** 1.4 Treatment for stress incontinence **Pelvic floor muscle training** 1.4.1 Consider pelvic floor muscle training for people with: • lower urinary tract dysfunction due to multiple sclerosis or stroke **or** • other neurological conditions where the potential to voluntarily contract the pelvic floor is preserved.

	Select patients for this training after specialist pelvic floor assessment and consider combining treatment with biofeedback and/or electrical stimulation of the pelvic floor. **Urethral tape and sling surgery** 1.4.2 Consider autologous fascial sling surgery for people with neurogenic stress incontinence. 1.4.3 Do not routinely use synthetic tapes and slings in people with neurogenic stress incontinence because of the risk of urethral erosion. **Artificial urinary sphincter** 1.4.4 Consider surgery to insert an artificial urinary sphincter for people with neurogenic stress incontinence only if an alternative procedure, such as insertion of an autologous fascial sling, is less likely to control incontinence. 1.4.5 When considering inserting an artificial urinary sphincter: • discuss with the person and/or their family members and carers the risks associated with the device, the possible need for repeat operations and alternative procedures • ensure that the bladder has adequate low-pressure storage capacity. 1.4.6 Monitor the upper urinary tract after artificial urinary sphincter surgery (for example, using annual ultrasound scans), as bladder storage function can deteriorate in some people after treatment of their neurogenic stress incontinence.

If this is a review of existing guidance, include 'current guidance' in brackets after the title and before the recommendations. These recommendations (i.e. the 'old' recommendations) should be deleted from the overview after IPAC II before the final overview us published with the guidance.

If including guidance being reviewed, include both the draft and existing recommendations in appendix B.

[delete any rows that do not apply]

Appendix C: Literature search for single-incision short sling (mesh) insertion for stress urinary incontinence in women

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane)	03/09/2015	Issue 9 of 12, September 2015
HTA database (Cochrane)	03/09/2015	Issue 3 of 4, July 2015
Cochrane Central Register of Controlled Trials (Cochrane)	03/09/2015	Issue 8 of 12, August 2015
MEDLINE (Ovid)	03/09/2015	1946 to August Week 4 2015
MEDLINE In-Process (Ovid)	03/09/2015	September 02, 2015
EMBASE (Ovid)	03/09/2015	1974 to 2015 week 35
PubMed	04/09/2015	n/a
BLIC (British Library)	07/09/2015	n/a

Trial sources searched on 04/09/2015

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

Websites searched on 04/09/2015-07/09/2015

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- EuroScan
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

Strategy used:
Database: Ovid MEDLINE(R) <1946 to August Week 4 2015>
Search Strategy:
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1 exp Suburethral slings/
2 ((subureth$ or sub-ureth* or midurethral or mid-urethral* or vagin*) adj4 (sling$ or tape* or mesh*)).tw.
3 tension-free vaginal tape.tw.
4 (tension adj4 vagin$).tw.
5 TVT.tw.
6 or/1-5
7 exp urogenital Surgical procedures/
8 exp Urologic Surgical Procedures/
9 (ur$ adj4 (surg$ or proced$ or operat$)).tw.
10 ((urethra$ or vagina$ or bladder$) adj4 surger$).tw.
11 or/7-10
12 exp Minimally Invasive Surgical Procedures/
13 (minim$ adj4 invasiv$).tw.
14 ((sing$ or one or once) adj4 (incision$ or cut or entr$)).tw.
15 or/12-14
16 11 and 15
17 6 and 16
18 exp Urinary Incontinence, Stress/
19 (SUI or (incont$ adj4 (urin$ or stress$))).tw.
20 (sphincter adj4 (defic$ or dysfunct$)).tw.
21 exp Urethra/
22 (urethra$ adj4 hypermob$).tw.
23 or/18-22
24 17 and 23
25 (Miniarc or "mini arc" or mini-arc).tw.
26 (minitape or "mini tape" or mini-tape).tw.
27 25 or 26
28 24 or 27
29 Animals/ not humans/
30 28 not 29
31 limit 30 to ed=20080131-20150930