NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women

Stress urinary incontinence is when urine leaks out during exercise or when 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 because of pregnancy. This procedure involves placing 2 small silicone balloons under the bladder, through a cut in the skin behind the vagina. The balloons are placed on either side of the urethra (the tube that carries urine from the bladder). The balloons are filled with fluid and they support the bladder, reducing leaks but allowing the normal passage of urine. After the procedure, fluid can be added or removed from the balloons to get the best effect for the individual person.

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 July 2016.

Procedure name

- Extraurethral (non-circumferential) retropubic adjustable compression devices 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.

A NICE guideline describes recommendations for the management of urinary incontinence in women. Conventional treatment is conservative, and includes lifestyle changes such as weight loss and pelvic floor muscle training. Surgery is considered if these conservative measures do not help. Different types of surgery may be used, including intramural bulking procedures, insertion of a synthetic tension-free vaginal tape, insertion of a transobturator tape or other sling procedures and colposuspension. When previous surgery has failed, insertion of an artificial urinary sphincter may be needed.

What the procedure involves

Extraurethral (non-circumferential) retropubic adjustable compression device insertion aims to prevent stress urinary incontinence by increasing urethral resistance and providing support to the bladder neck.

With the patient under local, regional or general anaesthesia, an incision is made in the perineum. Specially designed introducers are used to insert 2 small silicone balloons. Under radiological guidance the balloons are positioned on either side of the urethra, close to the bladder neck. The balloons are filled with a mixture of water and radiocontrast to enable the positioning to be confirmed. Each balloon is then attached to a subcutaneous port sited in the labia major. These ports can be used to add or remove fluid to the balloon postoperatively, thereby achieving the best balance between voiding and leakage.

Outcome measures

The severity of stress incontinence can be classified by the Stamey score:

Grade 1: loss of urine with sudden increases of abdominal pressure, for example with coughing, sneezing or laughing.

Grade 2: loss of urine with lesser degrees of stress, for example when walking or standing up.

Grade 3: loss of urine without any relation to physical activity or position, for example while lying in bed.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women. The following databases were searched, covering the period from their start to 19 July 2016: 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	Women with stress urinary incontinence.
Intervention/test	Extraurethral (non-circumferential) retropubic adjustable compression devices.
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 approximately 600 patients from 1 systematic review and 6 case series (4 of which were also included in the systematic review; 3 case series appear to be reporting results from the same study)[1–7].

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 extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women

Study 1 Phé V (2014)

Details

Study type	**Systematic review**
Country	Study countries not reported
Recruitment period	Search date: 2007–13
Study population and number	**n=8 studies (approximately 520 patients)** Women with isolated or mixed stress urinary incontinence
Age	Mean age ranged from 62–73 years
Patient selection criteria	The PubMed database was searched using the following terms: ACT balloons, female urinary incontinence, and female continence. All peer-reviewed studies published in English or French were included, regardless of methodology.
Technique	Device: Adjustable continence therapy (ACT) balloon (Uromedica, US)
Follow-up	**Range 1–6 years**
Conflict of interest/source of funding	Not reported

Analysis

Study design issues: The paper gives limited information about how the review was done. There were no randomised controlled trials identified. All studies except 1 were prospective and all were open label. Patients were evaluated by validated questionnaires (I-QOL, Urinary Symptom Profile, Urinary Distress Inventory), the number of pads per day, a urinary incontinence test (short pad test), and patient impression of improvement of incontinence at the end of follow-up. Efficacy endpoints were heterogeneous and differed from one study to another.

Study population issues: Between 38% and 100% of patients included in the studies had previous surgical treatment for stress urinary incontinence (suburethral sling, Burch colposuspension, artificial urinary sphincter).

Other issues: The authors note that continence is only achieved after repeated outpatient inflation of the balloons and results should be analysed at the end of the adjustment period, ideally after 3–6 months. The review included 3 studies that were published in a French-language journal.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **8 studies** Mean number of adjustments range 1 to 3.8 Mean final balloon volume range 1.97 ml to 3.45 ml (not reported in all studies) Mean I-QOL score range (higher scores indicate better quality of life) • Baseline=30 to 40 • 1-year follow-up=65.5 to 70 • 2-year follow-up=70.4 to 75 Mean number of pads used per day range • Baseline=4.1 to 5.4 • 1-year follow-up=1.2 to 2.5 • 2-year follow-up=1.1 to 1.2 Pad test improved from 49.6 g to 77.3 g at baseline to 11.2g to 25.7 g after the procedure. On intention-to-treat analysis at the end of follow-up, considering only those patients with a balloon still in place, 15% to 44% of patients considered that they were cured and 66% to 78.4% of patients were satisfied with the result and felt improved.	No major complications were reported. **Intraoperative complications** • Urethral or bladder perforation=3% to 17% of patients (The 17% perforation rate was reported in a study published in 2007, which included the early experience of this procedure. The most recent studies have reported intraoperative perforation rates between 3.7 and 4.5%). **Postoperative complications during the first year** • Urethral erosion=2% to 15% • Cutaneous erosion of the port=3% to 7.5% • Balloon migration=6.5% to 17.5% • Device infection=0.6% to 8.9% • Balloon dysfunction=0.6% to 6% • Inefficacy of treatment or worsening of incontinence=2.5% to 11.7% • Dysuria or acute urinary retention=1.5% to 6.8% • De novo urgency=10.5% (in 1 study) Explantation rate ranged from 18.7% to 30.8% (in 2 studies, the reimplantation rate in these patients was 50%).
Abbreviations used: I-QOL, incontinence quality of life questionnaire	

Study 2 Billault C (2015)

Details

Study type	**Case series**
Country	France
Recruitment period	2000–13
Study population and number	**n=52** Women aged >80 years with stress urinary incontinence (SUI) caused by intrinsic sphincter deficiency
Age	Median 83 years (Interquartile range 81 to 85)
Patient selection criteria	Women without neurological disease aged >80 years with SUI caused by intrinsic sphincter deficiency. Preoperative assessment of SUI consisted of clinical examination, urodynamics, 1 hour pad test and the number of pads used per day.
Technique	Device: Adjustable continence therapy (ACT) balloons. The procedure was done under general or local anaesthesia, with concomitant prophylactic antibiotic treatment. The first balloon inflation was scheduled at 4 weeks after the procedure. Evaluations and inflations were scheduled every 4 weeks until the patient was free from leakage. Implantations were repeated if necessary (for example, if the balloons had to be removed because of erosion, infection or migration). Nine patients had a second implantation, 5 had a third, and 1 patient had a fourth implantation. Two patients had a concomitant pelvic floor prolapse repair.
Follow-up	**Median 10.5 months (interquartile range 3 to 24)**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: 21% (11/52) of patients were lost to follow-up.

Study design issues: Single centre, retrospective study. Early postoperative complications (<30 days) were reported according to Clavien–Dindo classification. Continence was assessed subjectively by the patients.

Study population issues: 44% (23/52) of patients had 1 previous operation for SUI, 15% (8/52) had 2 previous operations and 8% (4/52) had 3 or more previous operations; 33% (17/52) of patients had had no previous surgery for SUI. Two patients had a history of pelvic radiation therapy.

Other issues: The authors noted that when explantation is necessary, it is a simple procedure that can be done in an outpatient setting and subsequent balloon implantation can be done a few weeks later, with minimal additional difficulties.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **52** Mean number of successive balloon inflations=3 (IQR 2 to 5) Median volume in each balloon=3.5 ml (IQR 2.4 to 6) **Procedural success (at last follow-up)** • Fully continent=13.5% (7/52) • >80% improvement=25.0% (13/52) • Partial results (patients still having successive balloon inflations)=19.2% (10/52) • Unsuccessful even after several consecutive implantations=7.7% (4/52) • Unsuccessful because of complications=13.5% (7/52) • Lost to follow-up=21.1% (11/52) In intention-to-treat analysis, the failure rate was 42.3% **Mean number of pads used by patients per day (postoperative data only available for 11 patients):** • Baseline=3 (IQR 3 to 4) • Last follow-up=0.5 (IQR 0 to 1)	**Early postoperative complications (<30 days) after first implantation (n=52)** • Acute urinary retention=3.9% (2/52) (Grade II complication according to Calvien–Dindo classification; treated by bladder catheterisation and deflation of the balloons) • Haematoma=1.9% (1/52) (Grade II complication according to Calvien–Dindo classification; treated by deflation of the balloons) **Early postoperative complications (<30 days) after second implantation (n=9)** • Haematoma, n=1 (Grade I complication according to Calvien–Dindo classification; no treatment necessary) **Early postoperative complications (<30 days) after third implantation (n=5)** • Acute urinary retention, n=1 (Grade II complication according to Calvien–Dindo classification; treated by bladder catheterisation) **Late postoperative complications – first implantation (n=52)** • Erosion=13.5% (7/52) (balloons removed) • Infection=3.9% (2/52) (balloons removed) • Migration with loss of efficacy=9.6% (5/52) (balloons removed) **Late postoperative complications – second implantation (n=9)** • Erosion, n=2 (balloons removed) • Infection, n=2 (balloons removed) • Migration with loss of efficacy, n=1 (balloons removed) **Late postoperative complications – third implantation (n=5)** • Erosion, n=2 (balloons removed) **Late postoperative complications – fourth implantation (n=1)** • Erosion, n=1 (balloons removed) In total, explantation occurred in 22 patients, because of infection, erosion or balloon migration.
Abbreviations used: IQR, interquartile range	

Study 3 Aboseif SR (2009)

Details

Study type	**Case series**
Country	US (10 sites) and Canada (2 sites)
Recruitment period	2001–07
Study population and number	**n=162** Women with recurrent stress urinary incontinence (SUI). Mean time from diagnosis of SUI to implantation=56 months
Age	Mean 67.4 years (range 31 to 94)
Patient selection criteria	Women with SUI in whom at least 6 months of prior treatment (surgical and nonsurgical) failed. Exclusion criteria included insulin dependent diabetes mellitus, autoimmune disease, pregnancy, urinary tract infection, prior pelvic radiotherapy, detrusor dysfunction, untreated bladder pathology and untreated grade 3 or 4 pelvic prolapse. Baseline preoperative tests included urinalysis, urodynamics, cystourethroscopy, provocative pad weight, 3-day voiding diary, Stamey score, direct visual stress test and validated questionnaires.
Technique	Device: Adjustable continence therapy (ACT) balloon (Uromedica, US). Most of the procedures were done with the patient under general anaesthetic. Balloon adjustments started 6 weeks after implantation.
Follow-up	**1 year**
Conflict of interest/source of funding	The study was supported by Uromedica Inc. Three of the 10 authors have a financial interest and/or other relationship with 1 or more of the following companies: Pfizer, GSK, Novartis, Astellas, Sanofi, AMS, Uromedica and Allergan.

Analysis

Follow-up issues: Follow-up data for 1 year were available for 86% (140/162) of patients; 8 patients were lost to follow-up, 6 missed follow-up and 1 patient died (the paper does not state what happened to the remaining 7 patients).

Study design issues: Prospective, multicentre study. Outcomes were assessed using the following subjective and objective measures: urinalysis, urodynamics, provocative pad weight, 3-day voiding diary, Stamey score (direct visual stress test and validated questionnaires: Incontinence Quality of Life [IQOL], Incontinence Impact Questionnaire [IIQ] and the Urogenital Distress Inventory [UDI].

Study population issues: 84% (136/162) of patients had at least 1 unsuccessful previous surgical procedure for SUI and 44% (71/162) had more than 1 prior unsuccessful operation (including Burch colposuspension, suburethral slings, needle suspension, tension-free vaginal tape, periurethral bulking agents and artificial urinary sphincter). Nonoperative management had failed in 16% (26/162) of patients (including pharmacotherapy, biofeedback, electrostimulation, and behavioural modification).Of the 162 treated patients, 85 (53%) had associated urethral hypermobility.

Other issues: There is some discrepancy between figures reported in the abstract and those in the main text. The figures reported in the main text have been used in the summary table below. This study is included in the systematic review by Phé V et al. (2014).

Key efficacy and safety findings

<table>
<tr><th>Efficacy</th><th>Safety</th></tr>
<tr><td>
Number of patients analysed: 162 (140 at 1 year)

Difficulty of device placement
• Mild=62%
• Moderate=30%
• Severe=9%

Mean number of balloon volume adjustments per device before 1 year follow-up=2.3 (range 0 to 9). The majority of adjustments were done in the outpatient setting within 9 months of implantation.
Mean volume in each balloon at 1 year=3.45 ml (range 1.0 to 10.0)

Improvement at 1-year follow-up
The Stamey score improved by at least 1 grade in 76.4% (107/140) of patients.

Mean provocative pad weight decreased in 84.9% (107/126) of patients, with a mean improvement from 49.6 g to 11.2 g (p<0.001).

81% (102/126) of patients had a greater than 50% reduction in provocative pad weight and 52% (67/130) met the definition of dry (<2 g).

Questionnaire scores at baseline and follow-up
<table>
<tr><th></th><th>IQOL (higher scores better)</th><th>UDI (lower scores better)</th><th>IIQ (lower scores better)</th></tr>
<tr><td>Mean score at baseline</td><td>36.8</td><td>59.6</td><td>54.1</td></tr>
<tr><td>Mean score at 1-year follow-up</td><td>71.1</td><td>32.0</td><td>23.3</td></tr>
<tr><td>p value</td><td><0.001</td><td><0.001</td><td><0.001</td></tr>
<tr><td>Proportion of patients with improvement</td><td>84.4% (114/135)</td><td>82.5% (113/137)</td><td>78.3% (108/138)</td></tr>
</table>
</td><td>
Complications within 1 year=24.4% (38/156) of patients (96% were considered to be mild or moderate)

Complication rate (n=162, actual numbers not reported, figures estimated from graphical presentation)
• Port erosion=7.5%
• Retention=6.2%
• Balloon erosion=5.6%
• Balloon migration=5.6%
• Perforation=3.8%
• Worsened incontinence=2.5%
• Urinary tract infection=1.9%
• Device failure=0.5%
• Infected device=0.5%
• Pain=0.5%
• Port migration=0.5%
• Miscellaneous (pelvic)=0.5%

The device was explanted in 18.3% (28/153) of patients during the first year of follow-up. Of these, 50% (14/28) were reimplanted within 12 months.
Reasons for explantation:
• Port erosion, n=11
• Balloon migration, n=9
• Balloon erosion, n=8
• Worsening incontinence, n=2
• Pain, n=1
• Device failure, n=1
• Infected device, n=1
• Port migration, n=1
• Other pelvic, n=1

Patients who did not have any previous surgery for incontinence had fewer complications than those with previous surgical procedures (7.7% [2/26] versus 27.7% [36/130]).

The authors noted that the majority of complications occurred early in the study period, suggesting a technical related learning curve.
</td></tr>
<tr><td colspan="2">Abbreviations used: IIQ, Incontinence Impact Questionnaire; IQOL, Incontinence Quality of Life; UDI, Urogenital Distress Inventory</td></tr>
</table>

Study 4 Galloway NT (2013)

Details

Study type	**Case series**
Country	US and Canada
Recruitment period	2002–07
Study population and number	**n=162** Women with recurrent symptomatic stress urinary incontinence (SUI).
Age	Mean 67.6 years (range 31 to 94)
Patient selection criteria	Adult female patients with symptomatic SUI with urethral hypermobility or intrinsic sphincter deficiency, in whom previous treatment over at least 6 months had failed. Exclusion criteria: neurogenic bladder or detrusor dysfunction, prior pelvic radiation therapy, insulin dependent diabetes, and uncorrected moderate or severe pelvic organ prolapse. Assessment of urethral mobility and urodynamics were done, including baseline Valsalva leak point pressure and maximum urethral closure pressure.
Technique	Device: Adjustable continence therapy (ACT) balloon (Uromedica, US). The first balloon adjustment was done 6 weeks after implantation and further adjustments were made every 4 weeks afterwards (maximum of 1 ml per balloon per adjustment) until adequate continence was achieved.
Follow-up	**up to 5 years**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: 88% (142/162) of patients were followed up to 1 year; 8 patients were lost to follow-up, 4 patients missed the follow-up visit, 1 patient died and 7 patients had the device permanently explanted. Patient visit compliance was 56%, 49%, 35% and 19% at 2, 3, 4 and 5 years respectively. At 5 years, 31 patients completed follow-up and 48 patients were lost to follow-up; 33 patients had the device permanently explanted.

Study design issues: Prospective, multi-centre study. Outcomes included subjective and objective measures of incontinence: Stamey score, provocative pad weight test, daily pad count, incontinence quality of life questionnaire (IQoL) and a visual analogue scale. Both an 'intent to treat' (including all patients) and an 'as followed' (including only those patients who complied with the protocol and interval follow-up) analysis were done. An independent reviewer scored Stamey grades to validate the primary endpoint.

Study population issues: 83% (134/162) of patients had previously been treated by surgery, including slings, suspensions and bulking agents, which was unsuccessful.

Other issues: This appears to be the same study that was reported by Aboseif SR et al. (2009), but with longer follow-up.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **162**

Improvement in investigator Stamey score of >1 grade at 1 year

- Intent to treat (n=162)=66.7% (p=0.029)
- As followed (n=142)=75.4% (p=0.0001)

Mean reduction in investigator Stamey score (as followed data)

Follow-up period	Number of patients	Mean reduction in Stamey score	p value
6 months	136	1.18	<0.001
1 year	142	1.32	<0.001
2 years	84	1.19	<0.001
3 years	56	1.29	<0.001
4 years	29	1.41	<0.001
5 years	30	1.37	<0.001

One hour provocative pad test

	Mean pad weight (g)	
Follow-up	Intent to treat	As followed
Baseline	53.7 (n=162)	53.8 (n=148)
6 months	24.1 (n=162)	19.1 (n=128)
12 months	22.7 (n=162)	11.1 (n=128)

Pad weight reduction of 50% of more at 1-year follow-up

- Intent to treat (n=162)=64.2%
- As followed (n=128)=79.7%

Dry rate (provocative pad weight <2 g)

- 1 year=51%
- 2 years=62%
- 3 years=76%
- 4 years=76%
- 5 years=76%

Questionnaire scores at baseline and follow-up, mean scores

Follow-up period	IQOL (higher scores better)	UDI (lower scores better)
Baseline	36.8	60
1 year	71.1	37
2 years	70.9	44
3 years	74.8	44
4 years	77.8	48
5 years	74.3	51

The mean number of balloon adjustments per year dropped from 2.1 at 12 months to 0.17 at 4 to 5 years.

Safety

The report states that 'there were no serious complications reported and no serious risks associated with the device'.

Complication rate=25% (38/155) at 12 months

Complications included bladder perforation, erosion, migration, pain and urinary retention.

At 5 years, 33 patients had had permanent explants of the balloons.

Abbreviations used: IQOL, Incontinence Quality of Life; UDI, Urogenital Distress Inventory

Study 5 Kocjancic E (2010)

Details

Study type	**Case series**
Country	Italy
Recruitment period	2001–06
Study population and number	**n=57** Women with severe stress urinary incontinence (SUI).
Age	Mean 63 years (range 18–86)
Patient selection criteria	Women with urodynamically proven severe degree of intrinsic sphincter deficiency with a fixed urethra, who had previously been treated by pelvic surgery. Selection criteria included age ≥18 years, low Valsalva leak point pressure (defined as 60 cm H_2O or less) and/or mean urethral closure pressure <30 cm H_2O.
Technique	Device: Adjustable continence therapy (ACT) balloon (Uromedica, US). The procedure was done under local anaesthesia in 14 patients (24.6%), spinal anaesthesia in 37 (64.9%) and general anaesthesia in 6 patients (10.5%). The first balloon adjustment was done 4–6 weeks after implantation and further adjustments were made at a minimum of 4-week intervals (maximum of 1 ml per balloon per adjustment) until adequate continence was achieved.
Follow-up	**Mean 72 months (median 58, range 12 to 84)**
Conflict of interest/source of funding	Three of the 6 authors reported a financial interest or other relationship with Uromedica and/or Medtronic.

Analysis

Follow-up issues: Data at 6-year follow-up are presented for only 51% (29/57) of patients.

Study design issues: Single centre, prospective study. Patient subjective outcome measures were evaluated using daily pad count, an incontinence quality of life questionnaire, and a visual analogue scale score. Objective outcomes were measured at 1-year follow-up using urodynamics, including measurement of uroflowmetry, Valsalva leak point pressure, and mean urethral closure pressure in willing patients.

Study population issues: All patients had been treated by at least 1 previous pelvic surgery procedure, including 1 or more anti-incontinence surgical procedures in 27 patients with no prolapse repair and prolapse repair in 23 with a concomitant retropubic or tension-free tape continence procedure. Previous anti-incontinence surgery included Burch colposuspension in 15 patients, injectable bulking agents in 16, a pubovaginal sling in 8 and tension-free tape in 22. Seven patients had various pelvic surgical procedures, including urethral reconstruction for bladder exstrophy. Coexistent grade I prolapse in 19 patients (33%) did not need concomitant surgical intervention. The mean incontinence duration since failed previous surgery was 1.7 years (range 1–5).

Other issues: This study is included in the systematic review by Phé V et al. (2014).

Key efficacy and safety findings

Efficacy

Number of patients analysed: **57**

Quality of life and pad count

Follow-up period	Number of patients	Mean±sd Incontinence Quality of life*	Mean±sd Pads (no./day)	Mean±sd Patient Global Impression Index
Baseline	57	27.2±15	5.6±2.3	-
12 months	52	65.9±17	1.6±2.1	2.3±1.0
24 months	52	70.4±16	1.2±1.5	2.0±0.9
36 months	51	70.4±16	1.1±1.8	1.8±0.9
48 months	41	76.1±17	1.0±1.7	1.9±1.3
60 months	34	78.4±17	0.7±1.1	1.8±1.0
72 months	29	78.6±18	0.4±0.8	1.6±0.9

*p<0.001 for each evaluation point compared with baseline

Pad count 'significantly decreased' from baseline – p value not reported.

Patient self-perception reported on a visual analogue scale improved by 50% within 3 months and continued to improve with time as further adjustments improved continence.

Patient overall impression of postoperative symptoms at last follow-up

- Dry=62%
- Improved more than 50%=30%
- Unchanged or improved less than 50%=8%

Mean Valsalva leak point pressure (cm H_2O), n=30

- Baseline=51.1±24.4
- 12-month follow-up=86.0±21.4 (p<0.01)

Mean urethral closure pressure (cm H_2O), n=30

- Baseline=47.4±24.4
- 12-month follow-up=51.1±19.3 (p=not significant)

Safety

Complications

- Intraoperative bladder perforation=3.5% (2/57) (As visualised by contrast leakage from the bladder; the trocar and cannula were removed and repositioned and balloons were inserted with a urethral catheter retained for 48 hours.)

All patients were discharged home within 24 hours of surgery.

Early complications (<3 months)

- Labial haematoma=5.3% (3/57) (no treatment needed)
- Migration=17.5% (10/57) (all devices removed, reimplantation in 5 patients)
- Urethral erosion=3.5% (2/57) (devices removed, further treatment refused)
- Port erosion=3.5% (2/57) (cleaned with antibiotics and resutured)
- De novo urgency=10.5% (6/57) (resolved without treatment)
- Device failure, n=3 (all devices were removed; reimplantion was successful)

2 devices failed after 3 years or more: the balloons were retained and patients became dry with the single remaining balloon.

13.2% (15/114) of balloons were removed in 21.1% (12/57) of patients (3 needed bilateral removal and 9 needed unilateral removal).

Balloon removal was done on an outpatient basis using topical anaesthesia only.

Abbreviations used: sd, standard deviation

Study 6 Aboseif SR (2011)

Details

Study type	**Case series**
Country	US and Canada
Recruitment period	2001–07
Study population and number	**n=89** Women with moderate to severe stress urinary incontinence (SUI).
Age	Mean 68 years (range 40 to 86)
Patient selection criteria	Women with moderate to severe SUI who have had previous surgical treatment (sling, Burch, suspension, artificial urinary sphincter). Moderate and severe SUI were defined as 11 to 50 and >50 g of urine loss during a provocative pad test, respectively. Mean preoperative Valsalva leak point pressure was 44.6 cm H_2O. Exclusion criteria: insulin dependent diabetes mellitus, autoimmune disease, pregnancy, urinary tract infection, prior pelvic radiotherapy, detrusor dysfunction, untreated bladder pathology, and untreated grade 3 and grade 4 pelvic prolapse.
Technique	Device: Adjustable continence therapy (ACT) balloon (Uromedica, US).
Follow-up	**1 year**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: Follow-up data at 1 year were available for 87% (77/89) of patients: 5 patients were lost to follow-up, 4 patients had the balloons permanently removed within the first year, 2 patients missed their follow-up appointment and 1 patient died because of an unrelated health issue.

Study design issues: Prospective, multicentre study. Efficacy outcomes were measured using the Stamey score (primary endpoint), provocative pad weight, 3-day voiding diaries, and validated questionnaires (Incontinence Quality of Life [IQOL], Incontinence Impact Questionnaire [IIQ] and the Urogenital Distress Inventory [UDI]). Data were analysed both on an 'as followed' basis and on an 'intent to treat' basis. For the intent to treat analysis, all patients who had an implant and were not available at the 12-month visit were treated as failures and baseline scores were used at the 12-month endpoint.

Study population issues: At baseline, 12% of patients were taking medication to control urge incontinence. All patients had at least 1 previous surgical procedure to treat SUI and 47% of patients had 2 or more (including bulking agents, sling, suspension, Burch, and artificial urinary sphincter). One patient had an artificial urinary sphincter, which was removed before implanting the ACT device.

Other issues: This paper appears to be based on a subsection of the patient population that was reported by Aboseif SR et al. (2009), but restricted to patients with moderate to severe SUI. This study is included in the systematic review by Phé V et al. (2014).

Key efficacy and safety findings

<table>
<tr><td>Efficacy</td><td>Safety</td></tr>
<tr><td>Number of patients analysed: 89

Mean number of adjustments in first year=2.03±1.6

Provocative pad weight test results at 1-year follow-up
• Dry (<2 g)=47% (as followed) or 39.3% (intent to treat)
• Improved (50% or more reduction)=92% (as followed) or 77.5% (intent to treat)

Baseline and 1-year endpoints, using the ‘as followed’ and ‘intent to treat’ analyses
<table>
<tr><td></td><td>Baseline</td><td colspan="2">1-year follow-up</td><td>Baseline</td><td colspan="2">1-year follow-up</td></tr>
<tr><td></td><td></td><td>as followed</td><td>p value</td><td></td><td>intent to treat</td><td>p value</td></tr>
<tr><td>Mean pad weight (g)</td><td>72.2</td><td>10.9</td><td><0.001</td><td>77.3</td><td>25.7</td><td><0.001</td></tr>
<tr><td>Mean Stamey score</td><td>2.2</td><td>0.9</td><td><0.001</td><td>2.2</td><td>1.1</td><td><0.001</td></tr>
<tr><td>Mean IIQ score</td><td>57.0</td><td>21.6</td><td><0.001</td><td>56.2</td><td>26.0</td><td><0.001</td></tr>
<tr><td>Mean UDI score</td><td>60.7</td><td>33.3</td><td><0.001</td><td>59.8</td><td>37.1</td><td><0.001</td></tr>
<tr><td>Mean IQOL score</td><td>33.9</td><td>71.6</td><td><0.001</td><td>33.9</td><td>65.5</td><td><0.001</td></tr>
<tr><td>Diary incontinent episodes</td><td>8.2</td><td>3.9</td><td><0.001</td><td>7.7</td><td>4.8</td><td><0.001</td></tr>
<tr><td>Diary wet pads used</td><td>4.3</td><td>1.9</td><td><0.001</td><td>4.1</td><td>2.5</td><td><0.001</td></tr>
</table></td><td>Complications
Complication rate within first year=30.2% (26/86)

• Port erosion=10.1%
• Balloon migration=7.9%
• Balloon erosion=4.5%
• Perforation at implant=4.5%
• Worsening incontinence or no change=3.4%
• Procedure failure=2.2%
• Pain or discomfort=1.1%
• Device failure=1.1%
• Device infection=1.1%

Explantation, which was done under local anaesthesia in the office, was needed in 21.7% (18/83) of patients; 50% of these patients were reimplanted before 1 year, 28% (n=5) of patients were awaiting reimplantation and 22% (n=4) had been explanted permanently.</td></tr>
<tr><td colspan="2">Abbreviations used: IIQ, Incontinence Impact Questionnaire; IQOL, Incontinence Quality of Life; UDI, Urogenital Distress Inventory</td></tr>
</table>

Study 7 Wachter J (2008)

Details

Study type	**Case series**
Country	Austria
Recruitment period	2000–05
Study population and number	**n=41** Women with stress (74%) or mixed urinary incontinence (26%). Mean duration of urinary incontinence=5.6 years (range 0.5 to 30)
Age	Mean 73 years (range 42 to 93)
Patient selection criteria	Women with stress or mixed urinary incontinence in whom conventional incontinence procedures (in particular, suburethral slings) were considered to be problematic (for example, because of previous pelvic or abdominal surgery, irradiation, high postvoid residual volume, or detrusor underactivity), less likely to succeed or in whom previous incontinence surgery had failed.
Technique	Device: Adjustable continence therapy (ACT) balloon (Uromedica, US). All procedures were done under general or spinal anaesthesia. The first balloon adjustment was done 6 weeks after implantation and further adjustments were made at 4-week intervals (maximum of 2 ml per balloon per adjustment) until adequate continence was achieved.
Follow-up	**Mean 25 months (range 5 to 60)**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: There were no losses to follow-up.

Study design issues: Retrospective, single-centre study. Efficacy was assessed by a non-validated semi-quantitative scale completed by the patients (cured: no incontinence, no pad use; significantly improved: reduction of pad use by more than 50%; slightly improved: reduction of pad use by more than 25% but less than 50%; no change: no or less than 25% improvement of incontinence). The first 2 categories were classed as a successful outcome of the procedure.

Study population issues: 83% of patients had previous pelvic surgery and 38% had previous incontinence surgery, including colposuspension, tension-free vaginal tape and collagen injection. 17.5% (7/41) of patients had 1 failed incontinence procedure, 15% (6/41) had 1 failed procedure and 5% (2/41) had 3 or more previous failed procedures. Three women had previous pelvic irradiation.

Other issues: This study is included in the systematic review by Phé V et al. (2014).

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **41** **Outcome at follow-up (mean 25 months)** • Fully continent=44% • Significant improvement=15% • Slight improvement=29% • No change=12% Overall success rate=59% The overall success rate was slightly higher in women with mixed urinary incontinence than in those with pure stress urinary incontinence (68% versus 54%). The failure rate was 20% in women with previous incontinence surgery compared with 8% in women without previous surgery. The success rate of the procedure was not correlated (all p values greater than 0.05) to the following parameters: age, duration of urinary incontinence, number of pads at baseline, bladder capacity, postvoid residual volume, pure stress versus mixed urinary incontinence, stable versus unstable detrusor. The authors note that the lack of statistical significance is most likely because of the small sample size. Explantation because of non-response was done in 14.6% (6/41) of women (3 had tension-free mid-urethral slings of whom 2 were improved but not fully continent; the third woman had urinary diversion because of multiple previous unsuccessful treatments. The remaining 3 women refused further surgical interventions.)	**Device and procedural-related complications=39.0% (16/41)** • Migration=12.2% (5/41) • Transient urinary retention=9.8% (4/41) Balloon failure occurred in 3 of the 'first few cases'. One woman with acontractile detrusor function and stress urinary incontinence developed prolonged urinary retention after implantation. The balloons were deflated to 0.5 ml each, which enabled the woman to void spontaneously.

Efficacy

Procedural success

In a case series of 52 patients, 14% (7/52) of patients were fully continent and 25% (13/52) of patients had more than 80% improvement at last follow-up (median 10.5 months); 19% (10/52) of patients were still having successive balloon inflations[2]. In a case series of 57 patients (also included in the systematic review), 62% of patients reported they were dry at last follow-up (mean 72 months), 30% had improved by more than 50% and 8% of patients had no change or improved less than 50%[5]. In a case series of 41 patients, 44% of patients were fully continent, 15% had significant improvement, 29% had slight improvement and 12% had no change at follow-up (mean 25 months)[7].

Pad usage

In a systematic review of 8 studies, the mean number of pads reduced from 4.1 to 5.4 at baseline to 1.1 to 1.2 at 2-year follow-up[1]. In the case series of 57 patients, the mean number of pads per day reduced from 5.6±2.3 at baseline (n=57) to 0.4±0.8 at 72-month follow-up (n=29; $p<0.001$)[5].

Provocative pad test

In a case series of 162 patients (also included in the systematic review), 51% and 76% of patients met the definition of dry (<2 g on a provocative pad test) at 1- and 5-year follow-up respectively[4]. The mean provocative pad weight decreased in 85% (107/126) of patients, with a mean improvement from 49.6 to 11.2 g ($p<0.001$) at 1-year follow-up[3].

Stamey score

In the case series of 162 patients, the mean reduction in Stamey score was 1.32 at 1-year follow up (n=142) and 1.37 at 5-year follow-up (n=30; $p<0.001$ for both); 67% of patients had an improvement of more than 1 grade at 1-year follow-up ($p=0.029$, intent to treat analysis)[4].

Questionnaires

In the case series of 162 patients, the mean Incontinence Quality of Life (IQOL) score improved from 36.8 at baseline to 71.1 at 1-year and 74.3 at 5-year follow-up (p value not reported). In the same study, the mean Urogenital Distress Inventory (UDI) score improved from 60 at baseline to 37 at 1-year and 51 at 5-year follow-up[4]. In the case series of 57 patients, the mean IQOL score improved from 27.2 at baseline to 65.9 at 1-year and 78.6 at 72-month follow-up ($p<0.001$ for both)[5].

Valsalva leak point pressure and urethral closure pressure

In the case series of 57 patients, the mean Valsalva leak point pressure increased from 51 cm H_2O at baseline to 86 cm H_2O at 12-month follow-up (n=30; p<0.01)[5]. The mean urethral closure pressure increased from 47 cm H_2O at baseline to 51 cm H_2O at 12-month follow-up (n=30; p=not significant)[5].

Explantation for inefficacy

In the case series of 41 patients, explantation because of non-response was done in 15% (6/41) of women (3 had tension-free mid-urethral slings of whom 2 were improved but not fully continent; the third woman had urinary diversion because of multiple previous unsuccessful treatments. The remaining 3 women refused further surgical interventions)[7].

Safety

Operative complications

Intraoperative urethral or bladder perforation was reported in 3% to 17% of patients in a systematic review of 8 studies[1]. Haematoma within 30 days of the procedure (first implantation) was reported in 1 patient in a case series of 52 patients; this was treated by deflation of the balloons[2].

Balloon related complications

Urethral erosion and cutaneous erosion of the port during the first year was reported in 2% to 15% and 3% to 8% of patients respectively in the systematic review of 8 studies[1]. Balloon migration during the first year was reported in 7% to 18% of patients in the same study and balloon dysfunction during the first year was reported in 0.6% to 6% of patients[1].

Infection

Device infection during the first year was reported in 0.6% to 9% of patients in the systematic review of 8 studies[1]. Urinary tract infection was reported in 2% of patients in a case series of 162 patients[3].

Bladder function

Dysuria or acute urinary retention was reported in 2% to 7% of patients in the systematic review of 8 studies[1]. De novo urgency during the first year was reported in 11% of patients in 1 study included in the systematic review of 8 studies[1].

Device explantation because of adverse events

The device was explanted in 18% (28/153) of patients during the first year of follow-up in the case series of 162 patients[3]. Of these, 50% (14/28) were reimplanted within 12 months. Reasons for explantation included port erosion,

balloon migration, balloon erosion, worsening incontinence, pain, device failure, infection, and port migration. 13% (15/114) of balloons were removed in 21% (12/57) of patients (3 needed bilateral removal and 9 needed unilateral removal) in a case series of 57 patients[5].

Validity and generalisability of the studies

- None of the studies were based in the UK.
- No comparative studies were identified. The systematic review included only 8 case series, most of which were relatively small[1].
- Several reports were from the same multicentre study based in the US and Canada. There is, therefore, considerable patient overlap between the studies.
- The patient populations were heterogeneous with regard to underlying pathology.
- One study only included women aged 80 or over[2]. Two studies only included women with moderate to severe stress urinary incontinence[5,6]. Most studies only included women who had recurrent stress urinary incontinence after other treatments had failed and a high proportion of women had been previously treated by surgery.
- Some of the studies only reported subjective outcomes rather than standardised pad testing, validated quality of life measures or urodynamic evaluation[2,7].

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

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 extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women. NICE interventional procedure guidance 133 (2005). This guidance is currently

under review and is expected to be updated in 2017. For more information, see https://www.nice.org.uk/guidance/indevelopment/gid-ipg10020

- Single-incision short sling mesh insertion for stress urinary incontinence in women. NICE interventional procedure guidance 566 (2016). Available from http://www.nice.org.uk/guidance/IPG566
- Insertion of biological slings for stress urinary incontinence. NICE interventional procedure guidance 154 (2006). Available from http://www.nice.org.uk/guidance/IPG154
- Intramural urethral bulking procedures for stress urinary incontinence. NICE interventional procedure guidance 138 (2005). Available from http://www.nice.org.uk/guidance/IPG138
- Sacral nerve stimulation for urge incontinence and urgency-frequency. NICE interventional procedure guidance 64 (2004). Available from http://www.nice.org.uk/guidance/IPG64
- Bone-anchored cystourethropexy (using data from In-Tac and Vesica as specified by SERNIP). NICE interventional procedure guidance 18 (2003). Available from http://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 extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women were submitted and can be found on the NICE website.

Patient commentators' opinions

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

Company engagement

A structured information request was sent to 1 company who manufactures a potentially relevant device for use in this procedure. NICE did not receive any completed submissions.

Issues for consideration by IPAC

Ongoing trials:

Randomised Comparative Prospective Study of the Treatment of Female Stress Urinary Incontinence Due to Intrinsic Sphincter Deficiency: ACT Balloon Versus Artificial Urinary Sphincter (AMS800) (NCT02490917); France; estimated enrolment 300; estimated study completion date December 2019.

References

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2. Billault C, Chartier-Kastler E, Roupret M et al. (2015) Functional outcomes of adjustable continence therapy (ACTTM) balloons in women aged >80 years and suffering from stress urinary incontinence caused by intrinsic sphincter deficiency. World Journal of Urology 33: 1897–903
3. Aboseif SR, Franke EI, Nash SD et al. (2009) The adjustable continence therapy system for recurrent female stress urinary incontinence: 1-year results of the North America Clinical Study Group. Journal of Urology 181: 2187–91
4. Galloway NT, Aboseif SR, Sassani P et al. (2013) Five years follow-up of adjustable continence therapy (ACT) in the treatment of recurrent female SUI. Open Journal of Urology 3: 132–7
5. Kocjancic E, Crivellaro S, Ranzoni S et al. (2010) Adjustable continence therapy for severe intrinsic sphincter deficiency and recurrent female stress urinary incontinence: long-term experience. Journal of Urology 184: 1017–21
6. Aboseif SR, Sassani P, Franke EI et al. (2011) Treatment of moderate to severe female stress urinary incontinence with the adjustable continence therapy (ACT) device after failed surgical repair. World Journal of Urology 29: 249–53
7. Wachter J, Henning A, Roehlich M et al. (2008) Adjustable continence therapy for female urinary incontinence: a minimally invasive option for difficult cases. Urologia Internationalis 81: 160–6

Appendix A: Additional papers on extraurethral (non-circumferential) retropubic adjustable compression devices 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.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Crivellaro S, Smith JJ 3rd (2009) Minimally invasive therapies for female stress urinary incontinence: the current status of bioinjectables/new devices (adjustable continence therapy, urethral submucosal collagen denaturation by radiofrequency). The scientific world journal 9: 466-78	Review 3 articles (n=254)	The adjustable continence therapy device and technique provide a good outcome in a difficult group of patients, and seems an appropriate second- or third-line therapy best suited for women seeking continence after other procedures have failed.	Review without a meta-analysis. A more recent systematic review is included (Phé V et al., 2014).
Kocjancic E, Crivellaro S, Smith JJ et al. (2008) Adjustable continence therapy for treatment of recurrent female urinary incontinence. Journal of Endourology 22: 1403–7	Case series n=49 Follow-up=1 year	68% of patients reported being dry and 16% were improved. Complications included migration (12%), balloon failure (3.6%), and erosion (4%).	A more recent paper by the same author is included. This study is included in the systematic review by Phé V et al. (2014).
Mehnert U, Bastien L, Denys P et al. (2012) Treatment of neurogenic stress urinary incontinence using an adjustable continence device: 4-year followup. Journal of Urology 188: 2274-80	Case series n=37 (including 13 men) Follow-up=48 months	Implantation of the adjustable continence therapy device in patients with neurogenic stress urinary incontinence is minimally invasive and safe. It can significantly improve neurogenic stress urinary incontinence in the long term. Thus, it might be a reasonable option for patients who are not willing, not suitable or not yet ready for more invasive surgery, such as artificial urinary sphincter or fascial suspension sling placement.	Study includes both men and women, and results are not reported separately.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Nimeh T, Mufarreh N, Wadhwa H et al. (2015) Review of Adjustable Continence Devices for the Treatment of Stress Urinary Incontinence with Neurogenic Etiology. Current Bladder Dysfunction Reports 10: 346-349	Review	Adjustable continence devices allow clinicians to adjust urethral tension post-operatively if necessary without secondary procedures and general anesthesia. Adjustable devices are particularly well-suited to SUI with a neurogenic aetiology as these devices allow for post-operative adjustments to sphincter pressure from a clinical setting.	Review without a meta-analysis and all included papers have been identified.
Stecco A, Saponaro A, Crivellaro S et al. (2006) Can MRI predict which patients are most likely to benefit from percutaneous positioning of volume-adjustable balloon devices? Urologia Internationalis 76: 240-6	Case series n=25 Follow-up=1 year	21/25 (84%) patients were improved; 16 (64%) of these patients were dry and 5 (20%) significantly improved. Before treatment, the mean pubococcygeal line distance was significantly different ($p<0.01$) between the responsive and the non-responsive groups. MRI provides an effective radiological method to predict the efficacy of the procedure.	Small case series, focusing on the usefulness of MRI.

Appendix B: Related NICE guidance for extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women

Guidance	Recommendations
Interventional procedures	**Insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women. NICE interventional procedure guidance 133 (2005) *(current guidance)***
	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.

Single-incision short sling mesh insertion for stress urinary incontinence in women. NICE interventional procedure guidance 566 (2016)

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

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

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy, including that there is the potential for the procedure to fail and for serious long-term complications from the device, and that the mesh implant is intended to be permanent so removal, if needed, may be difficult or impossible. Provide patients with clear written information. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having single-incision short sling mesh insertion for stress urinary incontinence in women (see section 7.1).

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

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

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

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). **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 (using data from In-Tac and Vesica as specified by SERNIP). 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)** **1.8 The multidisciplinary team (MDT)** 1.8.1 Inform any woman wishing to consider surgical treatment for UI about: • the benefits and risks of surgical and non-surgical options • their provisional treatment plan. Include consideration of the woman's child-bearing wishes in the counselling. **[2006, amended 2013]** 1.8.2 Offer invasive therapy for OAB and/or SUI symptoms only after an MDT review. **[new 2013]** 1.8.3 When recommending optimal management the MDT should take into account: • the woman's preference • past management • comorbidities • treatment options (including further conservative management such as OAB drug therapy). **[new 2013]** 1.8.4 The MDT for urinary incontinence should include: • a urogynaecologist • a urologist with a sub-specialist interest in female urology • a specialist nurse • a specialist physiotherapist • a colorectal surgeon with a sub-specialist interest in functional bowel problems, for women with coexisting bowel problems • a member of the care of the elderly team and/or occupational therapist, for women with functional impairment. **[new 2013]** 1.8.5 Inform the woman of the outcome of the MDT review if it alters the provisional treatment plan. **[new 2013]** 1.8.6 All MDTs should work within an established regional clinical network to ensure all women are offered the appropriate treatment options and high quality care. **[new 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]**

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.

Appendix C: Literature search for extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane)	19/07/2016	Issue 7 of 12, July 2016
HTA database (Cochrane)	19/07/2016	Issue 2 of 4, April 2016
Cochrane Central Register of Controlled Trials (Cochrane)	19/07/2016	Issue 6 of 12, June 2016
MEDLINE (Ovid)	19/07/2016	1946 to July Week 1 2016
MEDLINE In-Process (Ovid)	19/07/2016	July 18, 2016
EMBASE (Ovid)	19/07/2016	1974 to 2016 Week 29
PubMed	19/07/2016	n/a
BLIC (British Library)	19/07/2016	n/a

Trial sources searched on 20/07/2016

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

Websites searched on 19-20/07/2016

- 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.

1	exp Urinary Incontinence, Stress/
2	(SUI or (incont$ adj4 (urin$ or stress$))).tw.
3	(sphincter adj4 (defic$ or dysfunct$)).tw.
4	exp Urethra/
5	(urethra$ adj4 hypermob$).tw.
6	or/1-5
7	(extraurethra* or extra-urethra* or "extra urethra*").tw.
8	balloon*.tw.
9	(adjust* adj4 continen* adj4 (therap* or treat*)).tw.
10	(adjust* adj4 compres*).tw.
11	ACT.tw.
12	or/7-11
13	6 and 12
14	animals/ not humans/
15	13 not 14
16	limit 15 to ed=20041101-20160731
17	male/ not female/
18	16 not 17