Application 1369 Insertion of a synthetic sling for the treatment of male stress urinary incontinence

Evidence for Medical Services Advisory Committee (MSAC)

Table of contents

EXECUTIVE SUMMARY

A request for MBS listing of insertion, adjustment and removal of synthetic slings for the treatment of male stress urinary incontinence was received from American Medical Systems Australia Pty Ltd by the Department of Health in September 2013.

The application was considered by PASC in August and December 2014. A decision was made to do a fit for purpose assessment within the Department of Health rather than a contracted assessment.

Proposal for MBS funding

The applicant is of the view that synthetic sling insertion is currently being funded through claims under MBS item 37042. The application does not state which MBS item (if any) is currently claimed for adjustment or removal of the synthetic sling, however, MBS item 37341 may apply.

The current MBS items that may be used for synthetic sling procedures are:

Table 1: Current MBS item descriptor for insertion of urinary autologous slings

Category 3 – Therapeutic procedures
MBS item 37042
BLADDER STRESS INCONTINENCE, sling procedure for, using autologous fascial sling, including harvesting of sling, with or without mesh, not being a service associated with a service to which item 30405 or 35599 applies
MBS Fee: $911.30 Benefit: 75% = $683.50

Table 2: Current MBS item descriptor for removal of urinary slings

Category 3 – Therapeutic procedures
MBS item 37341
URETHRAL SLING, division or removal of, for urethral obstruction or erosion, following previous surgery for urinary incontinence, suprapubic or combined suprapubic/vaginal approach, not being a service associated with a service to which item number 37340 applies
MBS Fee: $911.30 Benefit: 75% = $683.50

The application proposed three new MBS items for male stress urinary incontinence with new fees. The proposed items are:

- Synthetic sling insertion (MBS fee $1,235);
- Synthetic sling adjustment (MBS fee $408.75); and
- Synthetic sling removal (MBS fee $926.25).

No criteria for patient eligibility was proposed by the applicant, but only men who experience stress urinary incontinence would benefit from the insertion of a urinary sling.

The protocol approved by PASC in December 2014 suggested that pending evidence the use of synthetic slings may be best restricted to men with mild or moderate (not severe) stress urinary incontinence. However, a full assessment of the safety and effectiveness of the use of the sling in all levels of severity (mild, moderate and severe) would be required to ascertain whether restricting use to mild and moderate patients is reasonable and how these should be defined. These subgroups were examined in the review of clinical evidence.

There is also some evidence that the urinary synthetic sling may have reduced efficacy amongst men who have undergone radiotherapy treatment for prostate cancer, however this requires a full assessment before exclusion of this patient group from the MBS descriptor is warranted. This was also considered in the review of clinical evidence.

Clinical Evaluation

A literature review of the clinical evidence for synthetic slings for stress urinary incontinence was conducted in March 2015.

No studies were identified that directly compared any of the marketed synthetic slings with autologous slings. There were also no comparative studies located that compared different synthetic slings.

Based on the literature review it is difficult to draw any reliable conclusions regarding the comparative effectiveness and safety of the various slings. Conclusions based on cross-trial comparisons may be misleading for many reasons including the following:

- The studies enrolled different populations of subjects with respect to such factors as baseline level of incontinence and exposure to radiotherapy.
- The studies of the autologous sling enrolled a high proportion of subjects with intrinsic sphincter deficiency as a component of a neurogenic bladder, whereas studies of synthetic slings were generally conducted in subjects with post-prostatectomy stress urinary incontinence. Incontinence in subjects with neurogenic bladder is more complex and difficult to manage.
- The effectiveness outcomes studied varied widely, with no consistent definitions of endpoints such as cure, success and failure.

The following general conclusions can be drawn from the literature review:

- Most studies reported on the proportion of subjects who were 'dry' or 'cured' and the proportion of subjects who were 'improved'. In most studies, the majority of subjects fell into one of these two categories. In most studies, the procedure was deemed a 'failure' in < 30% of subjects.
- The sling procedures resulted in significant reductions in average daily pad use, and significant reductions in average pad weight.
- In most studies, the proportion of patients who were satisfied with the procedure was high (>70%).
- The procedures resulted in significant improvements in quality of life in those studies that measured this endpoint.
- Sling procedures have reduced effectiveness in subjects with severe stress urinary incontinence and those who have previously received radiotherapy. However, some studies report high success rates in these subjects and the procedure may therefore be of value for subjects in whom other treatment options have been unsuccessful or are not viable.
- Complications associated with sling implantation are generally not major. The Argus sling appears to be associated with a high incidence of urethral erosion and higher removal rate.

Options for funding synthetic sling procedures through MBS

There are three options for the implementation of funding for synthetic sling insertion, removal and adjustment:

- Create three new items for insertion, removal and adjustment of synthetic sling at the same cost as MBS item 37041 and 37042 and $408.75 for a new item for the adjustment of synthetic slings. This option is preferred by the policy area as there is no evidence that synthetic slings are more clinically effective than autologous slings and therefore the higher fee for autologous sling items proposed by the applicant is not justified;
- Create three new items at a higher cost than the current autologous items as requested by applicant; or

- Amend the two existing autologous sling items to allow for use with autologous and synthetic slings and create one new item at $408.75 for the adjustment of synthetic slings.

Financial impact

An economic analysis has not been conducted for this application because it was considered outside of the scope of the fit-for-purpose review deemed appropriate for this application.

The projected future use and cost to the MBS for the MBS items for autologous slings have been used to model the MBS impact based on two scenarios:

- Option 1: Create 3 new items (two at same fee as existing MBS items 37041 and 37042 for the insertion and removal of synthetic slings and) and one new item for the adjustment of synthetic slings at $408.75. This is projected to result in a $2,087 saving over the forward estimates. The saving is as a result of a shift of use from the more expensive item 37341 to a less expensive new item for the adjustment of synthetic slings.
- Option 2: Create two new items for the insertion and removal of synthetic slings at a higher cost than the current autologous items as requested by applicant and one new item for the adjustment of synthetic slings at $408.75. This is projected to result in a $317,237 cost over the forward estimates. The cost is a result of the higher fee for the new items for insertion and removal of synthetic slings compared to fees for the current items (37041 and 37042).

MSAC should note that the use of a synthetic rather than autologous sling will have an additional financial impact as the devices are listed on the prostheses list with a benefit of $5,718.

DETAILS OF THE PROPOSED MEDICAL SERVICE AND ITS INTENDED USE

Current arrangements for public reimbursement

Surgery to insert autologous or synthetic slings requires patient admission into a private or public hospital (depending on the level of health insurance cover) and is undertaken by a urologist on a patient under anaesthetic, with each operation taking between 90 to 120 minutes. Insertion and removal of autologous and synthetic slings are currently claimed for males and females under MBS item 37042 (insertion) and item 37341 (division or removal) (see Tables 1 and 2). There is currently no relevant MBS item for synthetic sling adjustment, but item 37341 covers division of a sling where there is urethral obstruction or erosion. Descriptor wording of item 37042 is inappropriate for synthetic slings (because it refers to 'autologous' sling, which is made from the patient's own cells or tissues). However, pending the assessment of evidence by MSAC, and the fact that a range of synthetic slings are approved on the Prostheses List, the Department has permitted continued claiming of item 37042 for synthetic slings. Lower-rebated MBS item 35599 (sling insertion, without being limited to autologous slings) is not being billed for male stress incontinence because it is located in the gynaecological section of the MBS (Subgroup 4 of Group T8).

Table 3: Current MBS item descriptor for <u>insertion</u> of urinary autologous slings

Category 3 – Therapeutic procedures
MBS item 37042
BLADDER STRESS INCONTINENCE, sling procedure for, using autologous fascial sling, including harvesting of sling, with or without mesh, not being a service associated with a service to which item 30405 or 35599 applies
MBS Fee: $911.30 Benefit: 75% = $683.50

Table 4: Current MBS item descriptor for <u>removal</u> of urinary slings

Category 3 – Therapeutic procedures
MBS item 37341
URETHRAL SLING, division or removal of, for urethral obstruction or erosion, following previous surgery for urinary incontinence, suprapubic or combined suprapubic/vaginal approach, not being a service associated with a service to which item number 37340 applies
MBS Fee: $911.30 Benefit: 75% = $683.50

At its first consideration of the Draft Protocol, the PASC considered that the current MBS items for autologous sling insertion (MBS item 37042) and removal (MBS item 37341) could be amended to specifically include synthetic slings and acknowledged that a new MBS item would be required for adjustment.

Funding to cover the cost of male urinary synthetic sling devices (inserted as part of a private, in-hospital admission) is primarily provided through private health insurance (PHI).

Four types of male stress urinary incontinence synthetic sling (bone anchored, retrourethral transobturator, quadratic and adjustable retropubic) are approved on the Prostheses List (six products; see Table 5 below). In private hospital/day surgery settings, PHI benefits contribute towards the cost of the sling device, medical service to insert the sling, and associated hospital accommodation, while MBS benefits contribute towards the cost of the medical service. Each synthetic sling is inserted by the same type of surgery and functions in the same way, but differs in the way the sling is anchored (Trost & Elliot 2012).

Bone anchored sling (BAS)

The synthetic or organic mesh is secured (and tightened to an appropriate tension) using six titanium screws on the inferior pubic ramus, as well as sutures. Synthetic slings are most commonly used as degradation of organic mesh was reported. The sling results in compression to the bulbar urethra.

Retrourethral transobturator sling (RTS)

The retrourethral transobturator sling is self-anchoring with bilateral polypropylene mesh arms placed in a transobturator fashion. The sling portion is secured at the proximal bulbar urethra with continence achieved through subsequent elevation of the urethra.

Quadratic sling (QS)

Similar to the bone-anchored sling, the quadratic sling is placed over the bulbar urethra. Like the retrourethral transobturator, it is self-secured with two arms placed in a transobturator and two other arms placed in a prepubic manner, and the arms can be further secured to create additional points of fixation.

Adjustable retropubic sling (ARS)

Similar to the retrourethral transobturator sling, the adjustable retropubic sling is secured at the proximal bulbar urethra, with traction sutures placed retropubicly. It acts by exerting urethral compression.

Figure 1 provides a graphical representation of the placement of each type of sling.

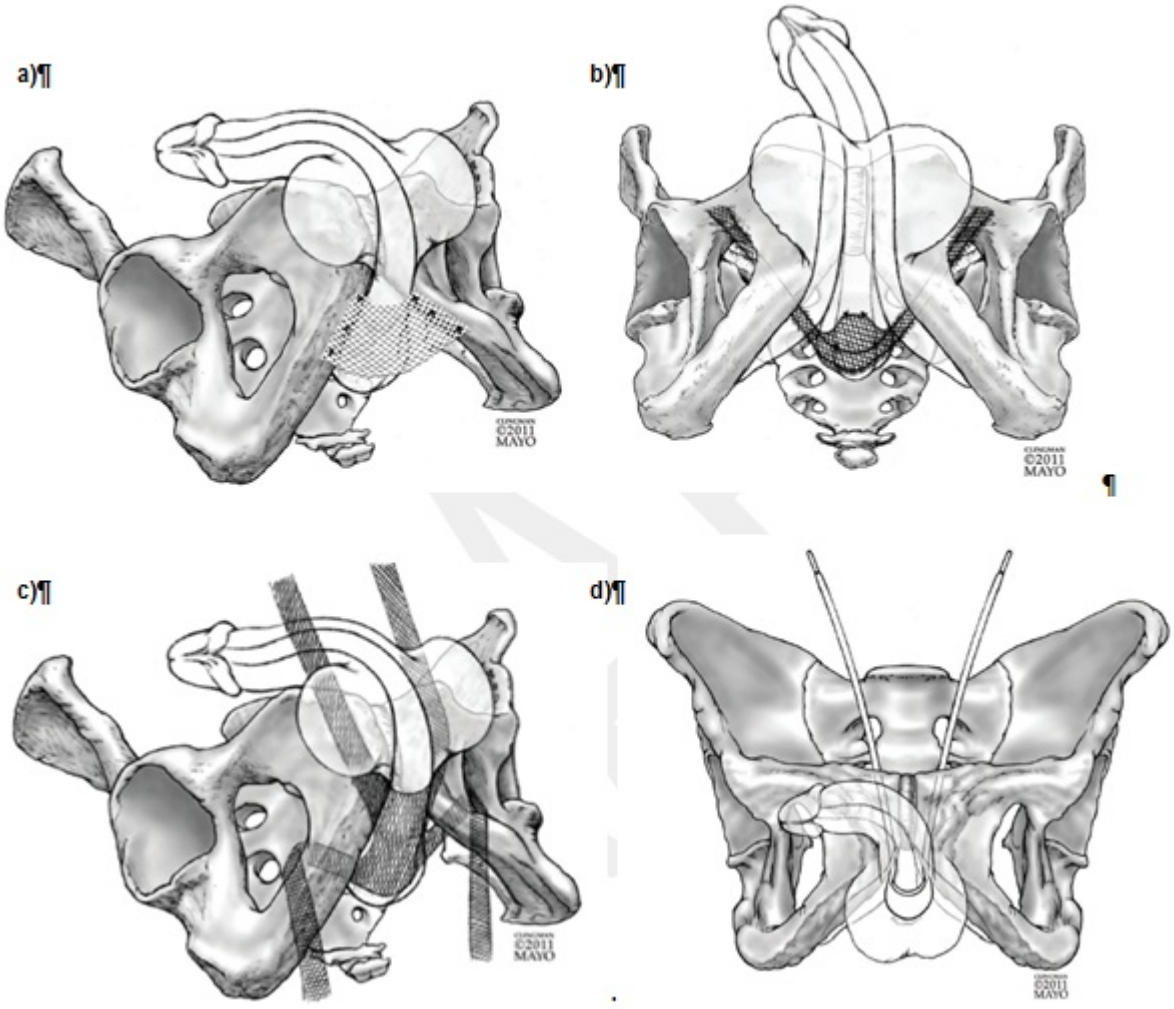

Figure 1:Diagrammatical representations of a) bone anchored sling (BAS), b) retrourethral transobturator sling (RTS), c) quadratic sling (QS) and d) adjustable retropubic sling (ARS) placement

Source: Figures 1-4, pp3-4 of Trost & Elliot 2012

Regulatory status

A summary of male urinary slings available on the prostheses list is provided in Table 5. The proposed MBS items for insertion, adjustment or removal of male urinary synthetic slings may be used in combination with any of the ARTG listed male urinary slings (and implicitly, any synthetic slings listed in the future).

Table 5: List of male urinary synthetic slings available on prostheses list

ARTG number	Name (Manufacturer)	Billing code	Description	Size	Type	Benefit
122095	InVance Male Sling System (American Medical Systems Pty Ltd)	AM017	Kit includes inserter with shaft, 6 bone screws with suture and silicone-coated sling surgical mesh	One Size	BAS	$5,718
126765	AdVance XP male Sling System (American Medical Systems Pty Ltd)	AM048	Sub-urethral sling implant for treatment of male stress urinary incontinence. Made from polypropylene monofilament mesh	Arm width: 1.2cm, Centre width: 3.55cm, Total Length: 35.5cm, 43.5cm	RTS	$5,718
187095	Virtue Male Sling System (Coloplast Pty Ltd)	CT015	Male sling system with quadratic fixation	One Size	QS	$5,718
118082	ARGUS (Endotherapeutics Pty Ltd)	ET050	Adjustable Male Sling made of silicone adjustable self-fixating columns and urethral cushion	One Size	ARS	$5,718
180393	Contrasure Remeex Male (Gytech Pty Ltd)	GP006	Adjustable male SUI sling	Varitnesor is 1 x 1 x 2.5cm, the sling is 22mm x 33mm.	ARS	$5,718
97288	TiLOOP male (Medical Specialties Australia Pty Ltd)	MS055	Tension-free mesh made out of titanized polypropylene for restoration of male urinary continence	65 g/m^2 (strong)	ARS	$5,718

BAS = Bone Anchored Sling, RTS = Retrourethral transobturator sling, QS = Quadratic Sling, ARS = Adjustable retropubic sling, SUI = stress urinary incontinence
Source: Prostheses List – Part A; http://www.health.gov.au/internet/main/publishing.nsf/Content/prostheses-list-pdf.htm [accessed 12 June 2014]

The PASC considered that an assessment of the comparative safety and effectiveness of the different types of synthetic slings would be informative.

Intervention

Description

Stress urinary incontinence is the involuntary loss of urine prompted by a physical movement. In stress incontinence, the sphincter muscle and/or the pelvic diaphragm, which support the bladder and urethra, are weakened or non-functioning. Suboptimal function may be caused by injury to the urethral area, surgery to the prostate or pelvic area etc. The sphincter is not able to prevent urine from flowing when intra-abdominal pressure is raised (such as when the patient coughs, laughs, or lifts heavy objects). Stress incontinence is more common in women than men and is unrelated to physiological stress. Leakage can lead to embarrassment for the patient and impact on quality of life as it may limit ability to work, exercise or restrict social contact.

Perineal slings are used to treat mild to moderate stress incontinence. Synthetic mesh (sling) is inserted surgically around the urethral bulb, slightly compressing the urethra and with the aim of improving urinary stress incontinence.

Delivery of the intervention

Urinary slings (autologous or synthetic) must be inserted surgically by a urologist, on a patient under anaesthetic, with each operation taking between 90 to 120 minutes. In males, incisions are made through the perineum and the synthetic sling is wrapped around the bulbar urethra, and anchored to surrounding structures such as bone for support, to change the position of the urethra. The applicant estimates around 400 synthetic slings are inserted each year, which is more than the 273 claims for MBS item 37042 in males between July 2012 and June 2013.

As the function of synthetic urinary slings relies on tension to alter the position of the urethra, it may be necessary to adjust the position of the synthetic sling at a later point in time. Removal of the synthetic sling may also be necessary if complications such as infection occur.

The six types of synthetic sling (i.e. specific products) listed on the prostheses list differ in how the sling is anchored, but the function of each sling is identical.

Prerequisites

Currently, only urologists are able to insert male urinary slings. Patients are referred by their general practitioner to a specialist, who will conduct a range of history/physical examinations including urinalysis, urodynamics assessment and cystoscopy, and also pad weight measurements to determine the severity of stress urinary incontinence before the appropriate therapy is chosen. Urinary slings are mainly indicated for mild to moderate stress urinary incontinence.

The insertion of male urinary slings must be conducted under anaesthetic and can be conducted in the hospital setting as either day surgery or more commonly as an overnight stay; therefore an anaesthetist must be involved as well as surgical assistants to the

urologist. Further, given that the synthetic urinary sling itself is not covered by the MBS, the synthetic sling must be purchased by the patient, hospital or private health insurer.

Co-administered and associated interventions

Whilst the aim of insertion of a sling would be to cure incontinence, the result may only be an improvement in incontinence, thus pad therapy or use of condom catheters may be a continuing co-administered intervention.

There are currently no listed restrictions on the types of patients covered by MBS item 37042, and no restrictions are included in the proposed MBS items requested by the applicant for changes/new listings to the MBS for insertion, removal and adjustment of male urinary synthetic slings. The applicant has not requested any changes to urinary synthetic slings already approved on the Prostheses List, but the proposed MBS fees for the amended/new MBS items for insertion and removal of synthetic slings are higher than existing MBS fees for insertion of autologous slings and removal of non-specified slings. It is unlikely that having new MBS items for insertion, removal and adjustment of male synthetic urinary slings will have any overall impact on the number of patients receiving male urinary slings.

Listing proposed and options for MSAC consideration

Proposed MBS listing

The application does not provide suggested wording for the proposed MBS items for male stress urinary incontinence synthetic sling insertion, adjustment or removal, but does propose an MBS fee for each item as summarised in Tables 4-6.

Table 6: Proposed MBS item descriptor and MBS fee for <u>insertion</u> of male synthetic sling

Category 3 – Therapeutic procedures
MBS item xxxxx
[Item descriptor - to be determined]
MBS Fee: $1,235 Benefit 75% = $926.25
[Relevant explanatory notes – to be determined, if necessary]

Table 7: Proposed MBS item descriptor and MBS fee for <u>adjustment</u> of male synthetic sling

Category 3 – Therapeutic procedures
MBS item xxxxx
[Item descriptor - to be determined] – including wording 'with or without replacement of sling'
MBS Fee: $545 Benefit 75% = $408.75
[Relevant explanatory notes – to be determined, if necessary]

Table 8: Proposed MBS item descriptor and MBS fee for <u>removal</u> of male synthetic sling

Category 3 – Therapeutic procedures
MBS item xxxxx
[Item descriptor - to be determined] – including wording 'with or without replacement of sling'
MBS Fee: $1,235 Benefit 75% = $926.25
[Relevant explanatory notes – to be determined, if necessary]

No proposed criteria for patient eligibility have been included by the applicant. However, only men who experience stress urinary incontinence would benefit from insertion of a urinary sling.

Insertion

<u>Surgical approach</u>

(i) Perineal incision for males versus vaginal approach for females.

(ii) Anatomical differences in surgical approaches between female and male sling insertion cannot be compared. The female urethra itself is not dissected and mobilised; indeed very little dissection is required. The body tissues divided to place a female sling are more superficial and easy to access than those dissected in placing a male sling, and the potential for complications is much less in the surgical approach to insert a female sling.

(iii) With insertion of a male sling, the potential exists for damage to the urethra itself, to posterior scrotal nerves leading to chronic pain issues, or to the erectile bodies leading to erectile dysfunction. The sling must be sutured to the urethra and adjusted under endoscopic control, or supporting washers must be positioned under the correctly measured urethral closing pressures.

<u>Stronger Muscular structures</u>

(i) Greater force and depth of passage is required for the male sling obturator needle pass.

<u>Post radical prostatectomy anatomy</u>

(i) Prolapsed urethra in the male versus healthy urethra in females.

(ii) Often compromised tissue in men (i.e. from radiation).

<u>Relocation and supportive requirements of sling</u>

(i) Female incontinence slings neither relocate nor continuously support (under tension) the female urethra. The male sling is required to do both and is constructed to provide a mechanism of action that relocates the bulbar urethra, in an action parallel to the urethral lumen. Some sling designs may require adjustment post primary surgery, requiring a second but simpler procedure.

<u>Removal of the male sling</u>

(i) Removal of the sling requires a procedure similar in technical difficulty to the primary placement of the device, with similar dissection differences as described above in "Surgical approach" and also described below.

Adjustment

Adjustment requires perineal and, potentially, transabdominal/retropubic surgery to locate, mobilise and adjust the sling.

Removal of sling

Removal of the male sling is a technically challenging procedure with, potentially, a combined perineal / abdominal / retropubic surgical procedure. Mesh material often erodes or becomes adherent, due to scarring, to surrounding structures. This dramatically increases the extent and need for dissection and mesh resection / removal. Patients will require a period of bladder drainage and post-operative inpatient care to ensure the urinary tract is stably managed and infective risk averted.

Clinical place for proposed intervention

The clinical algorithm with and without male urinary sling in the management of stress urinary incontinence is similar. The main difference between the two algorithms is that, after stress incontinence has been diagnosed and the severity defined (based on pad weight measurement), urinary synthetic slings may be used as an alternative to autologous slings and Macroplastique injections in mild incontinence, as well as an alternative to autologous slings, condom catheters and artificial urinary sphincters in moderate to severe incontinence. However, it is unclear whether urinary synthetic slings are an appropriate therapy for severe urinary incontinence, as there is evidence that the success rate of urinary slings in severe urinary incontinence (>6 pads per day) is poor (Castle et al 2005).

Currently, funding for Macroplastique injections is available under MBS item 37339 and the agent itself is covered by private health insurance and listed on the prostheses list. For the artificial urinary sphincter (AUS), funding is similar to the urinary sling where the procedure to implant the AUS is covered under the MBS (MBS items 37381, 37384, 37387 and 37390), but the actual sphincter is covered by private health insurance and listed on the Prostheses List. Limited funding by the Australian Government under the Continence Aids Payment Scheme (CAPS) is provided for purchases of pads for pad therapy or condom catheter accessories, and there are also state government initiatives which may provide further funding or support for incontinence services.

However, it should be noted that the proposed changes to the MBS items will not alter the clinical algorithm in any way, as urinary synthetic slings are currently funded through private or public means.

The proportion of men assumed to undertake treatment for stress urinary incontinence via use of the male sling, Macroplastique and artificial urinary sphincters can be elucidated from current MBS item claims. However, with respect to male slings, it will be difficult to identify the use of autologous versus synthetic slings. The proportion opting to cope with symptoms of urinary incontinence via the use of pads or condom catheters may be difficult to estimate.

CLINICAL EVALUATION FOR THE MAIN INDICATION

INTRODUCTION

A request for MBS listing of insertion of a synthetic sling for the treatment of male stress urinary incontinence (SUI) was made by American Medical Systems Pty Ltd in September 2013. The Protocol Advisory Sub-Committee (PASC) issued a final protocol to guide the assessment of the proposed procedure in December 2014.

The final protocol identified the autologous sling as the appropriate comparator for the assessment. Effectiveness outcomes of interest were:

- Cure rate for incontinence;
- Rate of improvement for continence;
- Reduction in pad or condom catheter use;
- The rate of adjustment (for synthetic slings) or division (for autologous slings);
- Life-time of the slings (i.e. when a replacement of the sling would be required;
- Quality of life measures.

Safety outcomes of interest were:

- Complications from surgery (including but not limited to wound infection and perineal pain);
- Complications from the sling (including, but not limited to urinary retention, urinary tract infections).

PASC also identified the following issues for consideration:

- The comparative safety and effectiveness of the different types of synthetic slings;
- The safety and effectiveness of slings in all levels of severity of SUI (mild, moderate and severe), to ascertain whether restricting use to patients with mild or moderate SUI is reasonable;
- The efficacy of slings in patients who have undergone radiotherapy treatment for prostate cancer, to ascertain whether this group should be excluded from MBS listing.

As summarized in the final protocol, there are currently six synthetic sling systems registered in Australia. These are:

Name	Sponsor	Features
InVance	American Medical Systems	Bone-anchored sling Non-adjustable
AdVance	American Medical Systems	Transobturator sling Non-adjustable
Argus	Endotherapeutics Pty Ltd	Retropubic sling Adjustable
Remeex	Gytech Pty Ltd	Retropubic sling Adjustable
Virtue	Coloplast Pty Ltd	Quadratic sling (Transobturator and pre-pubic). Non-Adjustable.
TiLOOP	Medical Specialties Australia Pty Ltd	Transobturator sling Non-adjustable.

Search strategy

A search for clinical studies was conducted on the following databases: Ovid Medline, Embase, Science Direct, Pubmed, Regulatory Agencies and WHO, Health Policy Reference Centre on the Ebsco platform. The search was restricted to English language articles

The search of the Medline and Embase databases was conducted in January 2015. The complete search strategy used is presented in the following table.

Database	Search strategy
EMBASE And MEDLINE	*1.* stress incontinence/ *2.* SUI.mp. *3.* urinary incontinence.mp. or urine incontinence/ *4.* 1 or 2 or 3 *5.* limit 4 to (human and male and english language) *6.* male sling.mp. *7.* suburethral sling.mp. or suburethral sling/ *8.* perineal sling.mp. *9.* bulbo-urethral sling.mp. *10.* bone-anchored sling.mp. *11.* transobturator sling.mp. *12.* retrourethral sling.mp. *13.* adjustable sling.mp. *14.* re-adjustable sling.mp. *15.* quadratic sling.mp. *16.* 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 *17.* 5 and 16 *18.* clinical study/ or clinical stud*.mp. *19.* 17 and 18

The references cited in retrieved articles were hand-searched for further studies. A series of review articles, identified by a Pubmed Search, were obtained (Adamakis 2013, Cerruto 2013, Osman 2013, Trost 2012, Welk 2011, Bauer 2011c, Bogermann 2010) and the references cited were also hand-searched.

Only studies that used the specific synthetic slings that are marketed in Australia were reviewed. There are other commercially available synthetic sling systems described in the literature, which are not marketed in Australia. In addition, several studies described 'in-house' methods for sling placement using various forms of surgical mesh.

Studies that provided data on less than 10 subjects and conference abstracts were excluded. Studies that reported only combined results for a variety of slings were also excluded.

Search results

Studies included for review were as follows:

- InVance sling: 11 studies
- AdVance sling: 15 studies;
- Autologous sling: 3 studies;
- Argus sling: 6 studies;

- Remeex sling 1 study;
- Virtue sling 1 study.

No studies were identified that used the TiLOOP male sling as a stand-alone procedure.

The studies were generally single-arm prospective studies or retrospective analyses. None of the studies compared autologous vs. synthetic slings and none compared one synthetic sling against another. A small number of studies retrospectively compared a synthetic sling against the artificial urinary sphincter (AUS). However, in the final protocol the AUS was not considered to be an appropriate comparator for synthetic slings and therefore these comparisons are not considered relevant.

Details of the studies are summarized in the following tables.

InVance sling

The InVance sling involves attachment of a surgical mesh to the descending pubic rami bilaterally with bone screws. The currently marketed product uses silicone-coated polypropylene mesh, however in early studies a variety of mesh materials were used. The sling supports the bulbar urethra and is believed to act through urethral compression

Onur 2004 (and Rajpurkar 2005)

Location	Wayne State University, Detroit, Michigan, USA
Study date	May 2001 – April 2004
Study design	Single centre, retrospective analysis.
Inclusion criteria	Stress urinary incontinence
Exclusion criteria	None stated
Number of patients	46
Age of patients	Mean 67 years; range 30 – 80.
Cause of SUI	RP - 35, EBRT - 2; RP+EBRT – 6; TURP – 1; Pelvic trauma – 1; intrinsic sphincter deficiency/neurogenic bladder – 1.
SUI severity	Mild (1-2 PPD) - 3; Moderate (3-5 PPD) – 33; Severe (>5 PPD) - 10
Sling materials	Absorbable (e.g. dermis, fascia lata) n = 8; Non-absorbable: 38
Follow-up	Mean 18 months; range 6-30 (Onur 2004) Mean 24 months; range 14-36 (Rajpurkar 2005)

Subsets of patients from this cohort were also the subject of other publications (Samli 2005 and Crivellaro 2008).

Comiter 2005

Location	University of Arizona, Tucson, Arizona, USA
Study date	March 2000 – April 2003
Study design	Single centre, prospective study.
Inclusion criteria	Stress urinary incontinence
Exclusion criteria	Bladder outlet obstruction, detrusor hypocontractility.
Number of patients	48
Age of patients	Mean 67.6 (± 9.7) years.
Cause of SUI	RP - 42, EBRT - 2; TURP – 2; Pelvic trauma – 1; myelomeningocoele – 1.
SUI severity	Subgroups according to pre-op SUI severity were not defined.
Sling materials	Polypropylene mesh (21), silicone-coated polyester mesh (27).
Follow-up	Median 48 months; range 24-60

Earlier reports of this study were also published (Comiter 2002, Ullrich 2004).

Castle 2005

Location	Mayo Clinic, Scottsdale, Arizona, USA
Study date	March 2002 – October 2003
Study design	Single centre, retrospective analysis.
Inclusion criteria	Post-prostatectomy urinary incontinence
Exclusion criteria	None stated.
Number of patients	38
Age of patients	Mean 71.6 (range 55-90) years.
Cause of SUI	RP - 35; TURP – 2; Simple prostatectomy – 1. (8 subjects had a history of RTX)
SUI severity	Mild (1-3 PPD) - 18; Moderate (4-6 PPD) – 8; Severe (>6 PPD) - 12
Sling materials	Silicone-coated polyester mesh, and a sheet of porcine dermis.
Follow-up	Mean 18 months; range 6-26

Fessi-Fehri 2007

Location	Edouard Herriot Hospital, Lyon, France.
Study date	June 2003 – April 2005
Study design	Single centre, prospective study.
Inclusion criteria	Stress urinary incontinence
Exclusion criteria	None stated.
Number of patients	50
Age of patients	Mean 70 (range 48-81) years.
Cause of SUI	RP - 33; TURP – 4; Endoscopic prostatectomy – 13. (8 subjects had a history of RTX)
SUI severity	Mild (1-2 PPD) - 10; Moderate (3-4 PPD) – 30; Severe (3-5+ PPD or penile sheath) - 10
Sling materials	Silicone-coated polyester mesh.
Follow-up	Mean 6 months; range 1-22

Fischer 2007

Location	New York University, New York, New York, USA.
Study date	April 2002 – December 2005
Study design	Single centre, prospective study.
Inclusion criteria	Stress urinary incontinence
Exclusion criteria	None stated.
Number of patients	62
Age of patients	Mean 67.2 (range 45-84) years.
Cause of SUI	RP - 47; RP + RTx – 11; RTx alone – 3; TURP – 1.
SUI severity	Subgroups according to pre-op SUI severity were not defined.
Sling materials	Silicone-coated polyester mesh.
Follow-up	Mean 15 months; range 3-37

Gallagher 2007

Location	University of Iowa, Iowa City, Iowa, USA.
Study date	October 2002 - May 2005
Study design	Single centre, prospective study.
Inclusion criteria	Stress urinary incontinence
Exclusion criteria	None stated.
Number of patients	31
Age of patients	Mean 66 (range 54-83) years.
Cause of SUI	RP - 29; Suprapubic prostatectomy - 1; Neurogenic bladder – 1. (6 subjects had a history of RTX)
SUI severity	Mild (1-2 PPD) - 8; Moderate (2-4 PPD) – 9; Severe (4+ PPD) - 14
Sling materials	Silicone-coated polyester mesh.
Follow-up	Mean 15 months; range 9-21

Giberti 2008

Location	San Paolo Hospital, Savona, Italy.
Study date	July 1999 - September 2005
Study design	Single centre, retrospective analysis.
Inclusion criteria	Iatrogenic urinary incontinence
Exclusion criteria	None stated.
Number of patients	42
Age of patients	Mean 68 (± 6.5) years (range 56-81).
Cause of SUI	RP - 36; Simple open prostatectomy - 1; TURP 5. (3 subjects had a history of RTX)
SUI severity	All subjects had severe SUI at baseline
Sling materials	Silicone-coated mesh (20); polypropylene mesh (6); porcine dermal collagen (2); cadaveric fascia lata (2); polypropylene mesh and porcine dermal collagen (12).
Follow-up	Mean 41 months; range 5-74.

Giberti 2009

Location	San Paolo Hospital, Savona, Italy.
Study date	December 2002 – December 2007
Study design	Single centre, retrospective analysis.
Inclusion criteria	Iatrogenic urinary incontinence
Exclusion criteria	None stated.
Number of patients	40
Age of patients	Mean 66 (± 6.3) years (range 56-78).
Cause of SUI	RP - 32; robot-assisted prostatectomy - 3; TURP 5. (11 subjects had a history of RTX)
SUI severity	All subjects had severe SUI at baseline (> 4 PPD).
Sling materials	Silicone-coated surgical mesh.
Follow-up	Mean 35.2 months; range 2-62.

The above two studies were conducted at the same centre and reported by the same authors. In Giberti 2008 a variety of sling materials were used whereas in Giberti 2009 all patients were treated with silicone-coated surgical mesh. It is likely that there was some overlap in patients between the two studies.

Guimaraes 2009

Location	3 hospitals in Porto, Portugal
Study date	July 2003 – July 2007
Study design	3 centres. Not stated whether prospective or retrospective.
Inclusion criteria	Stress urinary incontinence after prostate surgery.
Exclusion criteria	None stated.
Number of patients	62
Age of patients	Mean 69 years (range 57-78).
Cause of SUI	RP - 58; Prostatectomy for BPH - 4 (18 subjects had a history of RTX)
SUI severity	Mild (1-2 PPD) - 8; Moderate (3-5 PPD) – 41; Severe (6+ PPD) – 13.
Sling materials	Silicone-coated polypropylene mesh.
Follow-up	Mean 28 months;

Athanasopoulos 2010a

Location	University of Michigan, Ann Arbor, Michigan, USA.
Study date	February 2004 – November 2006
Study design	Single centre, retrospective analysis.
Inclusion criteria	Stress urinary incontinence
Exclusion criteria	None stated.
Number of patients	43
Age of patients	Mean 68.1 years (range 21-90).
Cause of SUI	RP - 31; RP + RTX - 2; Neuropathy – 5; RTX alone – 2; TURP – 2; TURP + neuropathy 1. (4 subjects had a history of RTX)
SUI severity	Mild (1-2 PPD) - 6; Moderate (3-5 PPD) – 23; Severe (6+ PPD or penile sheath) - 14
Sling materials	Silicone-coated polyester mesh.
Follow-up	Mean 24.2 months; range 4-38.

Carmel 2010

Location	University of Sherbrooke, Quebec, Canada.
Study date	September 2003 – December 2008
Study design	Single centre, prospective study.
Inclusion criteria	Stress urinary incontinence after prostate surgery. Stable PSA for 12 months
Exclusion criteria	Bladder outlet obstruction, overactive bladder, detrusor hypocontractility, abnormal bladder compliance.
Number of patients	45
Age of patients	Mean 68.0 (± 6.3) years.
Cause of SUI	RP - 42; TURP – 2; Holmium laser enucleation of prostate - 1. (12 subjects had a history of RTX)
SUI severity	Moderate (2-3 PPD) – 18; Severe (4+ PPD) - 27
Sling materials	Polypropylene mesh.
Follow-up	Median 36 months; range 2-64.

AdVance sling

With the AdVance sling, surgical mesh is placed beneath the urethral bulb and attached arms are placed through retropubic space and then through the obturator foramina. The sling is believed to act through relocation of the posterior urethra into a more proximal position, and not via urethral compression. The sling system uses polypropylene mesh and this was the material used in all the retrieved studies.

Rehder 2010

Location	Medical University Innsbruck, Innsbruck, Austria.
Study date	April 2006 – October 2008
Study design	Single centre, retrospective analysis.
Inclusion criteria	Mild or moderate stress urinary incontinence after prostate surgery.
Exclusion criteria	Severe SUI, detrusor overactivity or urethral stricture.
Number of patients	118
Age of patients	Mean 65.2 years (range 51 – 79).
Cause of SUI	RP or TURP (numbers not stated). 4 subjects had a history of RTX.
SUI severity	Mild (1-2 PPD) or Moderate (3-4 PPD). Numbers not stated
Follow-up	12 months (all subjects).

An earlier report of this study was also published (Rehder 2007).

Bauer 2010, Soljanik 2012

This group has produced several publications on their results with the AdVance sling. The most recent efficacy data were published in Soljanik 2012 with results from 178 subjects. The Bauer 2010 paper provided safety results on 230 subjects.

Location	Ludwig-Maximilian University, Munich, Germany.
Study date	Feb 2006 – December 2009
Study design	Single centre, prospective study.
Inclusion criteria	Stress urinary incontinence after prostate surgery.
Exclusion criteria	PSA recurrence, detrusor sphincter dyssynergia, detrusor overactivity, absence of external sphincter contraction.
Number of patients	Soljanik 2012: 178 (efficacy data). Bauer 2010: 230 (safety data).
Age of patients	Bauer 2010: Median 70 years (range 49 - 87).
Cause of SUI	Soljanik 2012: RP – 165; TURP – 10; TURP + HIFU – 2; Adenomectomy – 1. Bauer 2010: RP - 213; TURP – 15; Radical cystectomy with neobladder -2.
SUI severity	Soljanik 2012: Mild (1-2 PPD) – 24; Moderate (3-5 PPD) - 82. Severe (>5 PPD) – 72.
Follow-up	Soljanik 2012: Mean 20.8 months (range 12-43 months) Bauer 2010: Mean 17 months (range 4-42 months)

Earlier reports of this study were also published (Gozzi 2008, Bauer 2009, Bauer 2011 b). Several other reports describing results in subgroups of subjects were also published (Soljanik 2010, 2011, 2013 and Bauer 2011a, 2013).

Cornu 2011

Location	University of Paris VI, Paris, France.
Study date	April 2007 – June 2009
Study design	Single centre, prospective study.
Inclusion criteria	Mild or moderate stress urinary incontinence after prostate surgery.
Exclusion criteria	Severe SUI.
Number of patients	136
Age of patients	Mean 67.4 (± 6.8) years (range 54-84).
Cause of SUI	RP – 125; TURP – 8; adenomectomy - 3. (23 subjects had a history of RTX).
SUI severity	Mild (1-2 PPD) – 91; or Moderate (3-4 PPD) - 45.
Follow-up	Mean 21.6 (± 6) months, range 12-36

An earlier report of this study was also published (Cornu 2009).

Rehder 2012
This publication was an analysis of data from the above three centres (Innsbruck, Munich and Paris). It focused on subjects with longer-term follow-up. Although not stated in the publication, it is likely that there was some overlap in patients between this study and the above three studies.

Location	Innsbruck, Austria; Munich, Germany; Paris, France.
Study date	February 2006 – March 2008.
Study design	Three centres, prospective study.
Inclusion criteria	Stress urinary incontinence after prostatectomy.
Exclusion criteria	Anastomotic or urethral stricture, incomplete sphincter function.
Number of patients	156
Age of patients	Mean 68.0 years (range 63-72).
Cause of SUI	RP – 145; TURP – 9; open adenomectomy for BPH - 2. (22 subjects had a history of RTX).
SUI severity	Mild (1-2 PPD) – 38; or Moderate (3-4 PPD) - 62. Severe (5+ PPD) – 55; Not measured – 1.
Follow-up	Mean 40.1 (± 6.0) months

Zuckerman 2014

Location	Eastern Virginia Medical School, Norfolk, Virginia, USA.
Study date	August 2006 – June 2011
Study design	Single centre, retrospective analysis.
Inclusion criteria	Stress urinary incontinence. Adequate bladder capacity and compliance. Adequate sphincter contraction.
Exclusion criteria	None stated.
Number of patients	102
Age of patients	Mean 66.1 (± 9.3) years.
Cause of SUI	RP – 88; Other – 14 (surgery for BPH, RTX or cryotherapy for prostate Ca). (23 subjects had a history of RTX).
SUI severity	Mean pad use = 4.2 PPD. 36 subjects had severe SUI (> 5 PPD). Numbers with mild/moderate SUI not reported.
Follow-up	Mean 36.2 (± 16.5) months, range 12.1 – 71.7

An earlier report of this study was also published (Davies 2009). A report describing results in a subgroup of subjects who had received radiotherapy has also been published (Zuckerman 2011).

Cornel 2010

Location	ZGT Hospital, Hengelo and Leiden University Medical Centre, Leiden, The Netherlands.
Study date	September 2007 – June 2008
Study design	Two centres, prospective study.
Inclusion criteria	Stress urinary incontinence. Residual sphincter function demonstrated.
Exclusion criteria	Urethral stricture, bladder neck stenosis, intravesical pathology.
Number of patients	35
Age of patients	Mean 68.5 (range 55-82.6) years.
Cause of SUI	RP – 28; RP + RTX – 5; TURP – 2.
SUI severity	Mild (1-2 PPD) – 8; or Moderate (3-4 PPD) - 16. Severe (5+ PPD) – 11.
Follow-up	12 months (all subjects)

Li 2012

Location	Case Western Reserve University and Cleveland Clinic, Cleveland, Ohio, USA.
Study date	May 2007 – December 2009
Study design	Two centres, retrospective chart review and prospective telephone survey.
Inclusion criteria	Stress urinary incontinence.
Exclusion criteria	None stated.
Number of patients	66
Age of patients	Mean 67 years.
Cause of SUI	RP – 65; Not stated -1.
SUI severity	Subgroups based on pre-operative severity were not defined. Median preoperative PPD = 2 (range 1-3)
Follow-up	Median 23.8 months (range 16.9 – 28.4)

An earlier report of this study was also published (Gill 2010).

Berger 2011

Location	Academic Teaching Hospital, Feldkirch, Austria.
Study date	Not stated.
Study design	Single centre, retrospective analysis.
Inclusion criteria	Stress urinary incontinence after prostate surgery.
Exclusion criteria	Evidence of scarring, bladder-neck contracture, previous bulking agents, urethral stricture, neurogenic incontinence.
Number of patients	26
Age of patients	Median 67 years (range 52-79).
Cause of SUI	RP – 24; TURP -2. (5 subjects had received RTX)
SUI severity	Subgroups based on pre-operative severity were not defined. Mean preoperative PPD = 5.58 (range 2-12)
Follow-up	Median 22 months (range 10-27)

Suskind 2011

Location	University of Connecticut, Farmington, Connecticut, USA.
Study date	2006 - 2010
Study design	Single centre, retrospective analysis.
Inclusion criteria	Urinary incontinence after prostatectomy or RTX. Competent sphincter. Normal bladder compliance.
Exclusion criteria	Bladder-neck contracture, urethral stricture, previous bulking agents, neurogenic incontinence. Detrusor instability.
Number of patients	42
Age of patients	Mean 63.6 years (range 51-82).
Cause of SUI	RP – 39; RTX – 2; Brachytherapy – 1.
SUI severity	Subgroups based on pre-operative severity were not defined. Mean preoperative PPD = 2.1 (range 1 - 5.5)
Follow-up	Mean 18.8 months (range 1-40)

Mueller 2012

Location	University Hospital, Ulm, Germany.
Study date	September 2010 – September 2011
Study design	Single centre, prospective study.
Inclusion criteria	Stress urinary incontinence after prior prostate surgery. Sphincter contraction present.
Exclusion criteria	None stated.
Number of patients	32
Age of patients	Median 70.5 years (range 61-88).
Cause of SUI	RP – 28; TURP – 4. (10 subjects had received prior RTX).
SUI severity	Mild (1-2 PPD) – 6; or Moderate (3-5 PPD) - 18. Severe (6+ PPD) – 8.
Follow-up	Median 9 months (range 3-14)

Grimsby 2012

Location	Mayo Clinic, Phoenix, Arizona, USA.
Study date	September 2008 – June 2010.
Study design	Single centre, retrospective analysis.
Inclusion criteria	Stress urinary incontinence after prior prostate surgery. Sphincter contraction present.
Exclusion criteria	None stated.
Number of patients	31
Age of patients	Mean 71 years (range 49-85).
Cause of SUI	RP – 28; Holmium laser enucleation of prostate – 2; Transurethral drainage of prostate abscess – 1. (1 subject had a history of RTX)
SUI severity	Subgroups based on pre-operative severity were not defined. Mean preoperative PPD = 4 (range 1 - 20)
Follow-up	Median 12.8 months (range 6.2 – 26.5)

Cornu 2014

In 2010, a revised version of the AdVance sling was introduced with the trade name 'AdVance XP'. The revised version included a redesigned sling, longer arms, and distinct tissue anchors. This study compared outcomes of the 'AdVance' and 'AdVance XP' versions.

Location	University of Paris VI, Paris, France.	
Study date	April 2007 – May 2012	
Study design	Single centre, prospective, non-randomised study.	
Inclusion criteria	Mild or moderate stress urinary incontinence after radical prostatectomy.	
Exclusion criteria	Prior periurethral injection or balloon implantation, "redo" sling, SUI after BPH surgery.	
	Advance	**Advance XP**
Number of patients	121	110
Age of patients	Mean 66.7 (± 6.5) years (range 54-80).	Mean 66.6 (± 6.9) years (range 51-81).
Cause of SUI	RP (all subjects)	
SUI severity	Median PPD = 2 (range 1-3)	Median PPD = 2 (range 1-3)
Follow-up	Median 21 months (range 16-26)	Median 16 months (range 12-25)

Collado 2013

Location	1 centre in Valencia and 1 centre in Madrid, Spain.
Study date	February 2008 – June 2011
Study design	Two centres. Not stated whether prospective or retrospective.
Inclusion criteria	Stress urinary incontinence.
Exclusion criteria	Absent sphincter contraction.
Number of patients	61
Age of patients	Median 65 years (range 56-83).
Cause of SUI	RP – 58; TURP – 3. (3 subjects had a history of RTX)
SUI severity	Subgroups based on pre-operative severity were not defined. At baseline: 1 PPD – 20; 2 PPD – 17; 3+ PPD – 24.
Follow-up	Median 26 months (range 12-53). The only efficacy data presented were from follow-up at 3 months.

Torrey 2013

Location	City of Hope Cancer Centre, Duarte, California, USA.
Study date	April 2008 – June 2010
Study design	Single centre, retrospective analysis.
Inclusion criteria	Stress urinary incontinence post-prostatectomy. Stable bladder.
Exclusion criteria	Bladder outlet obstruction.
Number of patients	37
Age of patients	Median 68 years (interquartile range 62-71).
Cause of SUI	RP – 37. (7 subjects had a history of RTX)
SUI severity	Subgroups based on pre-operative severity were not defined. At baseline median PPD = 1.5 (IQR 1.0 – 2.5).
Follow-up	Median 17.3 months (IQR: 7.1 – 25.0).

Hoy 2014

This study compared results obtained with the AdVance sling to those obtained with the artificial urinary sphincter (AUS). Only the data relating to the AdVance sling are presented in this report.

Location	University of Alberta, Edmonton, Alberta, Canada.
Study date	August 2004 – March 2013.
Study design	Single centre, retrospective analysis.
Inclusion criteria	Mild to moderate urinary incontinence post-prostatectomy.
Exclusion criteria	Untreated overactive bladder
Number of patients	76
Age of patients	Mean 66.2 years.
Cause of SUI	RP – 70; Other - 6. (3 subjects had a history of RTX)
SUI severity	All subjects had mild to moderate UI (≤ 5 PPD).
Follow-up	Median 24 months (range: 1 - 61).

Autologous sling

Daneshmand 2003

Location	University of Southern California, Los Angeles, California, and Sheperd Medical Center, Atlanta, Georgia, USA.
Study date	February 1998 – February 2001
Study design	Two centres. Not stated whether prospective or retrospective.
Inclusion criteria	Sphincteric incompetence associated with neurogenic bladder.
Exclusion criteria	None stated.
Number of patients	12
Age of patients	Mean 37.1 years (range 24-56).
Cause of SUI	Spinal cord injury – 9; myelomeningocele -3. No subject had prior RTX.
SUI severity	Not stated.
Sling materials	Autologous rectus fascia
Other surgery	10/12 subjects underwent simultaneous augmentation cystoplasty
Follow-up	Median 14.3 months (range: 1 - 39).

Athanasopoulos 2010b

Location	University of Michigan, Ann Arbor, Michigan, USA.
Study date	March 2001 – March 2004
Study design	Single centre. Retrospective analysis.
Inclusion criteria	Stress urinary incontinence.
Exclusion criteria	None stated.
Number of patients	32
Age of patients	Mean 46.4 years (range 14-76).
Cause of SUI	Neurogenic bladder – 17; RP - 15. No subject had prior RTX.
SUI severity	Moderate (3-5 PPD) – 6; Severe (6+ PPD or use of penile sheath) - 26.
Sling materials	Autologous rectus fascia
Other surgery	"Vast majority" of neurogenic bladder subjects underwent simultaneous augmentation cystoplasty
Follow-up	Mean 29.5 months (range: 24-52).

Heidari 2012

Location	Lorestan University of Medical Sciences, Lorestan, Iran.
Study date	December 2003 – February 2008
Study design	Single centre. Not stated whether prospective or retrospective.
Inclusion criteria	Stress urinary incontinence.
Exclusion criteria	None stated.
Number of patients	28
Age of patients	Range 64 – 85 years.
Cause of SUI	RP – 8, open prostatectomy 8, TURP – 12. No subject had prior RTX.
SUI severity	Subgroups according to baseline severity were not defined. Median PPD at baseline = 5 (range 3-8)
Sling materials	Autologous rectus fascia
Other surgery	None stated.
Follow-up	12 months (all subjects)

Argus sling
The Argus sling involves placement of a silicon foam cushion beneath the bulbar urethra. The cushion is attached to two silicon arms that are placed through the retropubic space and are fixed to the abdominal rectus fascia. The silicon arms can be loosened or tightened post-operatively. The sling is believed to act through urethral compression.

Romano 2006

Location	6 centres in Argentina and Brazil
Study date	April 2003 – September 2004
Study design	Six centres. Prospective trial.
Inclusion criteria	Stress urinary incontinence after prostatectomy.
Exclusion criteria	None stated.
Number of patients	48
Age of patients	Mean 67.7 years (range 52 – 77).
Cause of SUI	RP – 39; Adenectomy for BPH – 9. (No subjects had prior RTX)
SUI severity	Subgroups according to baseline severity were not defined. Severity was described as 'moderate to severe'. 19 subjects wore pads (mean 5 PPD, range 3-8). 29 subjects used a clamp or condom catheter.
Follow-up	Mean 7.5 months (range 1 – 17.5)

Bochove-Overgaauw 2011

Location	1 centre in 's-Hertogenbosch, the Netherlands
Study date	April 2005 – October 2008.
Study design	Single centre, retrospective analysis
Inclusion criteria	Stress urinary incontinence after prostatectomy or radiotherapy.
Exclusion criteria	Detrusor overactivity
Number of patients	100
Age of patients	Mean 66 years (range 50 - 89).
Cause of SUI	RP – 96; TURP – 3; RTX alone – 1. (A total of 14 subjects had prior RTX)
SUI severity	Mild (1-2 PPD) – 13; or Moderate (3-5 PPD) - 46. Severe (6+ PPD) – 41.
Follow-up	Median 27 months (range 14 - 57)

Dalpiaz 2011

Location	1 centre in Graz, Austria and 1 in Dortmund, Germany.
Study date	October 2006 – July 2007.
Study design	Two centres, retrospective analysis
Inclusion criteria	Stress urinary incontinence.
Exclusion criteria	None stated.
Number of patients	29
Age of patients	Mean 71 years (IQR: 61-79).
Cause of SUI	RP – 27; TURP – 2. RTX alone – 1. (4 subjects had prior RTX)
SUI severity	Mild (1-2 PPD) – 2; Moderate (3-5 PPD) – 16; Severe (6+ PPD) – 11.
Follow-up	Median 35 months (range 29 - 45)

Hubner 2011

Location	1 centre in Koreuburg, Austria.
Study date	April 2005 – April 2009
Study design	Single centre, retrospective analysis.
Inclusion criteria	Stress urinary incontinence after prostatic surgery.
Exclusion criteria	None stated.
Number of patients	101
Age of patients	Mean 69.6 years (range: 51-84).
Cause of SUI	RP – 87; TURP – 10; Open prostatectomy for BPH – 3; RTX alone – 1. (22 subjects had prior RTX)
SUI severity	Moderate (2 PPD) or severe (> 2 PPD). Numbers not stated.
Follow-up	Mean 25.2 months (range 1.2 - 54)

Basiri 2013

Location	Shahid Behesti University, Tehran, Iran.
Study date	January 2010 – January 2012
Study design	Single centre, retrospective analysis.
Inclusion criteria	Stress urinary incontinence.
Exclusion criteria	None stated.
Number of patients	17
Age of patients	Mean 64 years (range: 17 - 80).
Cause of SUI	RP – 6; TURP – 4; Prostatectomy for BPH – 5; Neurogenic bladder – 1; exstropy - epispadiasis – 1. (0 subjects had prior RTX).
SUI severity	Moderate (2-5 PPD) – 5; or severe (> 5 PPD) - 12.
Follow-up	Mean 11.8 months (range 3-22).

Lim 2014

This study compared results obtained with the Argus sling to those obtained with the artificial urinary sphincter (AUS). Only the data relating to the Argus sling are presented in this report.

Location	University of Ulsan, Seoul, Korea.
Study date	January 2009 – June 2013
Study design	Single centre, retrospective analysis.
Inclusion criteria	Moderate stress urinary incontinence post-prostatectomy.
Exclusion criteria	None stated.
Number of patients	20
Age of patients	Mean 70.9 ± 5.1 years
Cause of SUI	RP – 20. (2 subjects had prior RTX).
SUI severity	Moderate (2-4 PPD) – 20.
Follow-up	Mean 24.7 ± 11.8 months.

Remeex sling

The Remeex system involves placement of a polypropylene sling beneath the bulbar urethra. The sling is connected to two threads which are placed through the retropubic space and connected to a mechanical regulator (varitensor) which is implanted subcutaneously on the abdominal rectus fascia. The varitensor can be manipulated from outside the body to loosen or tighten the sling post-operatively.

Sousa-Escandon 2007

Location	7 centres in Europe – Monforte and Madrid, Spain; Milan and Genoa, Italy; Salonica, Greece; Berlin, Germany and Lisbon, Portugal.
Study date	October 2002 – August 2005
Study design	7 centres, prospective study.
Inclusion criteria	Stress urinary incontinence.
Exclusion criteria	Urinary obstruction, severe vesical instability, very reduced bladder capacity.
Number of patients	51
Age of patients	Median 69 years (range: 58 - 81).
Cause of SUI	RP – 43; TURP – 4; Open prostatectomy – 4; (10 subjects had prior RTX).
SUI severity	Mild (1-2 PPD) – 9; Moderate (3-4 PPD) – 10; or severe (> 4 PPD) - 32.
Follow-up	Median 32 months (range 16-50).

Virtue sling

The Virtue sling is described as a quadratic sling. It consists of a polypropylene mesh sling that is placed under the bulbar urethra. It is attached to four arms. Two of these are coursed underneath the skin anterior to the pubic bone, with the other two placed through the retropubic space and obturator foramina. It is claimed to work through both urethral elevation and urethral compression.

Comiter 2014
This study compared results of an early version of the sling (implanted without fixation; n= 98) and the version that was approved for marketing (implanted with fixation; n=31). The earlier version was found to be inferior. Only the results of the later version are presented in this report.

Location	5 centres in North America – Stanford and San Diego, California and New York, New York, USA; Quebec and Toronto, Canada.
Study date	Not stated.
Study design	5 centres, prospective study.
Inclusion criteria	Stress urinary incontinence after prostatectomy.
Exclusion criteria	RTX or cryosurgery within the previous 6 months, active stricture, detrusor areflexia, post-void residual > 150 mLs.
Number of patients	31
Age of patients	Mean 66.2 years (range: 56-79).
Cause of SUI	TURP – 3; Other prostatectomy – 28; (0 subjects had prior RTX).
SUI severity	Mild (< 100g/day on 24 hour pad test) – 13; Moderate (100 – 400 g/day) – 7; or severe (>400 g/day) - 10. 1 subject not measured.
Follow-up	12 months (all subjects).

Effectiveness outcomes

1. Rates for cured/improved and success/failure

Most studies provided data on the proportion of patients who were 'dry' or 'cured' postoperatively, although the definition of these terms varied between studies. Most studies also reported on the proportion of subjects who did not meet the criteria for dry/cured but were nevertheless 'improved' to some degree. The definition of 'improvement' also varied widely between studies.

Several studies reported on the proportion of subjects who only used 0 or 1 pad(s) per day (PPD) postoperatively.

In most instances, studies reported 'success' rate as the sum of dry/cured rate and the 'improved' rate. 'Failure' rate was generally reported as the proportion of subjects who did not meet criteria for dry/cured or improved.

The following table summarises the results for these endpoints. The definitions used for dry/cured/improved/success are listed below the table. Where a study presented data for several time points, only the latest results are included in the table.

Results for dry/cured/improvement and success/failure.

	N	FU (m)	'Dry / cured'	0-1 PPD	'Improved'	Success	Failure
InVance sling							
Rajpurkar 2005	46	24	37% [a]	-	37% [i]	74% [w]	26%
Comiter 2005	48	48	65% [a]	79%	21% [j]	85% [w]	15%
Castle 2005	38	18	15.8% [b]	39.5%	-	-	-
Fassi-Fehri 2007	50	6	50% [a]	76%	26% [k]	76% [w]	24%
Fischer 2007	62	15	34% [a]	-	-	58% [x]	42%
Gallagher 2007	31	15	-	58%	-	58% [y]	42%
Giberti 2008	42	41	62% [c]	-	8% [l]	70% [w]	30%
Giberti 2009	40	32.5	55% [c]	-	12.5% [l]	67.5% [w]	32.5%
Guimares 2009	62	28	65% [a]	-	23% [m]	88% [w]	12%
Ath'poulos 2010a	43	24.2	30.2% [b]	51.2%	39.5% [n]	69.8% [w]	30.2%
Carmel 2010	45	36	36% [a]	-	40% [i]	76% [w]	24%
AdVance sling							
Rehder 2010	118	12	73.7% [d]	90.7%	16.9% [o]	90.7% [w]	9.3%
Bauer 2011b	137	27	51.6% [e]	-	23.8% [p]	75.4% [w]	24.6%
Cornu 2011	136	21	61.8% [a]	-	16.2% [q]	78.0% [w]	22.0%
Rehder 2012	156	36	53.0% [e]	-	23.8% [r]	76.8% [w]	23.2%
Zuckerman 2014	102	36.2	40.0% [e]	-	22.0% [s]	62.0% [w]	38.0%
Cornel 2010	33	12	9% [f]	-	45.5% [t]	54.5% [w]	45.5%
Li 2012	66	23.8	39.3% [a]	-	23.2% [u]	62.5% [w]	37.5%
Berger 2011	26	22	61.5% [a]	-	26.9% [i]	88.4% [w]	11.6%
Mueller 2012	32	9	56.3% [a]	-	21.9% [p]	78.2% [w]	21.9%
Cornu 2014							
- Advance	121	21	62.8% [e]	-	15.7% [q]	78.5% [w]	21.5%
- Advance XP	110	16	59.1% [e]	-	17.3% [q]	76.4% [w]	23.6%
Collado 2013	61	3	80% [a]	-	8% [t]	88% [w]	12%
Torrey 2013	37	17.3	51.4% [a]		27.0% [v]	78.4% [w]	21.6%
Hoy 2014	76	24	-	88.2%	-	94.7% [z]	5.3%
Autologous sling							
D'shmand 2003	12	14.3	66.6% [b]	83.3%	16.7% [k]	83.3% [w]	16.7%
Ath'poulos 2010b	32	29.5	15.6% [b]	31.2%	31.2% [n]	46.9% [w]	53.1%
Heidari 1191	28	12	-	100%	-	100% [y]	0%
Argus sling							
Romano 2006	48	7.5	72.9% [a]	83.3%	10.4% [k]	83.3% [w]	16.7%
Bochove-O' 2011	100	27	54.0% [e]	-	18.0% [r]	72.0% [w]	28.0%
Dalpiaz 2011	29	35	17.2% [e]	-	-	-	-
Hubner 2011	101	25.2	79.2% [g]	-	-	-	-
Basiri 2013	17	11.8	52.9% [a]	94.1%	-	-	-
Lim 2014	20	24.7	85.0% [e]	-	0.0% [p]	85.0% [w]	15.0%
Remeex sling							
Sousa-Esc' 2007	51	32	64.7% [e]	-	19.6% [q]	84.3% [w]	15.7%
Virtue sling							
Comiter 2014	31	12	46% [h]		33.2% [t]	79.2% [w]	20.8%

FU = average duration of follow up; **m** = months; **N** = number of subjects; **PPD** = pads per day;

'Dry / cured'
a 0 PPD
b "completely dry"
c perfectly dry on stress test and 1-hour pad weight = 0-1g;

d 0 PPD or an occasional pad for security reasons;
e 0 PPD or 1 prophylactic/safety/security PPD
f 0 PPD and 24-hour pad weight < 2 g;
g 20-minute pad weight = 0-2 g;
h 24-hour pad weight < 1.3 g;

'Improved'
i 1-2 PPD
j Patient rating of incontinence as mild or moderate problem.
k 1 PPD
l positive stress test and 1-hour pad weight 2-50 g;
m a ≥ 50% decrease in PPD and level of SUI considered a small or small/medium problem by the patient;
n 1PPD or: ≥ 50% decrease in PPD and only 2PPD;
o 1 PPD and ≥ 50% decrease in PPD;
p 1-2 PPD or ≥ 50% decrease in PPD;
q a ≥ 50% decrease in PPD;
r 1-2 PPD and ≥ 50% decrease in PPD;
s a ≥ 50% decrease in PPD and patient satisfied with surgical outcome;
t a ≥ 50% decrease in 24-hour pad weight;
u 1-2 PPD and a decrease from baseline in PPD;
v any decrease from baseline in PPD;

Success
w 'Dry' + 'Improved'
x Very much improved or much improved on PGI-I score.
y 0-1 PPD
z any decrease from baseline in PPD.

2. Reduction in pad use

Several studies on change in pad use (average number of pads per day). Results are summarized in the following table. No studies reported on reduction in condom catheter use.

	N	FU (m)	Statistic	Pre-op PPD	Post-op PPD	p-value
InVance sling						
Comiter 2005	48	48	Mean ± SD	4.6 ± 2.1	1.0 ± 1.7	<0.01
Gallagher 2007	31	15	Mean (IQR)	3.0 (2 – 5.5)	1.0 (0 – 3.5)	<0.01
Carmel 2010	45	36	Median ± SD	7.0 ± 1.0	1.0 ± 2.5	nr
AdVance sling						
Rehder 2010	118	12	Mean ± SD	2.3 ± 1.2	0.7 ± 0.8	<0.001
Soljanik 2012	178	20.8	Mean ± SD	5.4 ± 3.3	1.7 ± 2.4	<0.001
Cornu 2011	136	21	Mean ± SD	2.1 ± 1.2	0.6 ± 1.0	<0.001
Rehder 2012	156	36	Mean (IQR)	4.0 (2 – 6)	1.0 (0 – 2)	<0.0001
Li 2012	50	23.8	Mean ± SD	2.8 ± 2.4	1.8 ± 2.6	= 0.0004
Berger 2011	26	22	Mean (range)	5.6 (2 – 12)	1.1 (0 – 7)	<0.001
Suskind 2011	36	18.8	Mean (range)	2.1 (1 – 5.5)	1.2 (0 – 6)	nr
Mueller 2012	32	9	Mean (range)	5.1 (2-10)	1.8 (0 – 10)	<0.001
Torrey 2013	37	17.3	Median (IQR)	1.5 (1-2.5)	0.0 (0 – 1)	nr
Autologous sling						
Heidari 1191	28	12	Mean ± SD	5.6 ± 1.9	0.3 ± 0.5	<0.001
Argus sling						
Lim 2014	20	24.7	Mean ± SD	-	2.2 [a] ± 0.8 (change)	nr
Remeex sling						
Sousa-Esc' 2007	51	32	Mean ± SD	4.5 nr	1.4 nr	nr

FU = average duration of follow up; **IQR** = interquartile range; **m** = months; **N** = number of subjects; **nr** = not reported; **PPD** = pads per day; **SD** = standard deviation;

a Lim 2014 reported the average change in PPD from baseline, without giving pre-op and post-op values.

Pad weight measurement

Reduction in measured pad weight was reported in some studies, as summarized in the following table.

	N	FU (m)	Time of pad collection	Statistic	Pre-op (gm)	Post-op (gm)	p-value
InVance sling							
Giberti 2008	42	41	1 hour	Mean ± SD	104.6 ± 65.3	47.3 ± 22.1	<0.05
Giberti 2009	40	32.5	1 hour	Mean ± SD	110.6 ± 59.2	51.3 ± 25.6	<0.05
Carmel 2010	45	36	1 hour	Median ± SD	39.0 ± 69.5	0.0 ± 10.9	<0.001
AdVance sling							
Rehder 2010	118	12	24 hours	Mean ± SD	132 ± 90	21 ± 12.3	<0.001
Soljanik 2012	178	20.8	1 hour	Mean ± SD	169.3 ± 162.4	21.3 ± 59.2	<0.001
Argus sling							
Hubner 2011	101	25.2	20 minutes	Mean (range)	30.9 (1-117)	2.2 (0-90)	<0.001
Virtue sling							
Comiter 2014	51	32	24 hours	Median (IQR)	147.0 43-431	18.0 4-109	<0.01

FU = average duration of follow up; **IQR** = interquartile range; **gm** = grams; **m** = months; **N** = number of subjects; **nr** = not reported; **SD** = standard deviation;

3. Quality of Life

A variety of QoL measures were used in the reviewed studies.

Patient satisfaction/Patient Global Impression of Improvement (PGI-I)

A number of studies reported on the proportion of patients who were 'satisfied' with the results of their surgery. Several studies also presented results of the PGI-I, which asks patients to rate their level of improvement on a 7-point scale (from 1 – very much better to 7 – very much worse). In the reviewed studies the proportion of subjects who rated themselves as 'very much improved' or 'much improved' was presented.

Results for these two endpoints are summarized in the following table.

				PGI-I		
	N	**FU (m)**	**Patient Satisfaction**	**Very Much Improved**	**Much Improved**	**Total**
InVance sling						
Rajpurkar 2005	46	24	70%	-	-	-
Fassi-Fehri 2007	50	6	76%	-	-	-
Fischer 2007	62	15	-	37.1%	21.0%	58.1%
Gallagher 2007	24	6	75%	-	-	-
Guimares 2009	62	28	81%	-	-	-
Ath'poulos 2010a	43	24.2	69.6%	-	-	-
Carmel 2010	45	36	72%	-	-	-
AdVance sling						
Cornu 2009	102	13	-	49.0%	25.5%	74.5%
Cornel 2010	33	12	54.5%	-	-	-
Li 2012	56	23.8	-	nr	nr	53.6%
Berger 2011	24	22	87.5%	-	-	-
Suskind	36	18.8	-	25.0%	50.0%	75.0%
Grimsby 2012			-	nr	nr	53.6%
Cornu 2014						
- Advance	121	21	-	51.2%	22.3%	73.5%
- Advance XP	110	16	-	68.2%	11.8%	80.0%
Argus sling						
Bochove-O' 2011	95	27	-	nr	nr	84.2%
Dalpiaz 2011	29	35	27.6%	-	-	-
Remeex sling						
Sousa-Esc' 2007	51	32	84.3%	-	-	-
Virtue sling						
Comiter 2014	31	12	-	nr	nr	70.9%

FU = average duration of follow up; **m** = months; **N** = number of subjects; **PGI-I** = Patient Global Impression of Improvement.

Incontinence Quality of Life Questionnaire (I—QoL)

The I-QoL consists of 22 items covering 3 domains - avoidance and limiting behavior, psychosocial impact and social embarrassment. Subjects use a 5-point response scale with values ranging from 1 (extremely) to 5 (not at all). Scores are transformed to a 0-100 scale, with higher scores indicating a better quality of life. Results from reviewed studies that used this instrument are summarized in the following table.

	N	**FU (m)**	**Statistic**	**Pre-op**	**Post-op**	**p-value**
InVance sling						
Giberti 2008	42	41	Mean ± SD	25 ± 9.6	75.7 ± 28.5	<0.05
Giberti 2009	40	35.2	Mean ± SD	25.7 ± 8.5	72.9 ± 25.7	<0.05
AdVance sling						
Soljanik 2012	178	20.8	Mean ± SD	54.6 ± 18.1	81.1 ± 23.6	<0.001
Rehder 2012	101	36	Median (IQR)	61.0 (45 – 71)	93.0 (72 - 105)	nr
Argus sling						
Hubner 2011	20	24.7	Mean (range)	28.8 (14.5-61.8)	63.2 (16.4-115)	<0.001

FU = average duration of follow up; **m** = months; **N** = number of subjects; **nr** = not reported; **SD** = standard deviation.

In two studies, the range of post-op values included readings > 100 points. The reasons for this were not explained.

International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF)
The ICIQ-SF consists of three items. Possible range of scores is 0-21, with higher scores indicating reduced quality of life. Results from reviewed studies that used this instrument are summarized in the following table.

	N	FU (m)	Statistic	Pre-op	Post-op	p-value
AdVance sling						
Rehder 2010	118	12	Mean ± SD	18.2 ± 4.2	4.1 ± 2.8	<0.001
Soljanik 2012	178	20.8	Mean ± SD	16.6 ± 3.8	9.5 ± 8.9	<0.001
Rehder 2012	101	36	Median (IQR)	17.0 (14 - 19)	7.0 (3-14)	nr
Mueller 2012	32	9	Mean ± SD	15.4 ± 3.5	5.7 ± 6.3	<0.001
Collado 2013	61	3	Median (range)	16 (5-21)	3 (0-21)	nr
Argus sling						
Romano 2006	48	7.5	Mean (range)	19.2 (12-21)	4 (0 - 21)	nr

FU = average duration of follow up; **m** = months; **N** = number of subjects; **nr** = not reported; **SD** = standard deviation

Various other QoL life measures were used in single studies. These generally demonstrated an improvement in QoL post-op compared to baseline.

4. Rates of Removal/revision/adjustment

Reviewed studies that reported rates of removal and revision or adjustment are summarized in the following table. No studies reported on the rate of replacement of slings in the long term.

	N	FU (m)	Removal	Revision	Adjustment
InVance sling					
Rajpurkar 2005	46	24	2.2%	-	-
Comiter 2005	48	48	-	4.2%	-
Fassi-Fehri 2007	50	6	8%	-	-
Fischer 2007	62	15	4.8%	11.3%	-
Gallagher 2007	31	15	12.9%	-	-
Giberti 2009	40	32.5	10%	-	-
Guimares 2009	62	28	3.2%	1.6%	-
Ath'poulos 2010a	43	24.2	9.3%	23.3%	-
Carmel 2010	45	36	2.2%	-	-
AdVance sling					
Bauer 2011b	137	27	1.6%	-	-
Cornu 2011	136	21	0%	0%	-
Rehder 2012	156	36	0.6%	1.9%	-
Zuckerman 2014	102	36.2	1.0%	13.6%	-
Cornel 2010	33	12	2.8%	-	-
Berger 2011	26	22	0%	0%	-
Mueller 2012	32	9	3.1%	-	-
Grimsby 2012	31	12.8	0%	3.2%	-
Cornu 2014					
- Advance	121	21	0%	-	-
- Advance XP	110	16	0%	-	-
Collado 2013	61	3	0%	0%	-
Hoy 2014	76	24	0%	0%	-
Autologous sling					
Ath'poulos 2010b	32	29.5	3.1%	3.1%	-
Heidari 2012	28	12	-	7.1%	-
Argus sling					
Romano 2006	48	7.5	10.4%	-	10.4%
Bochove-O' 2011	100	27	11.0%	-	32.0%
Dalpiaz 2011	29	35	34.4%	-	37.9%
Hubner 2011	101	25.2	15.8%	-	38.6%
Basiri 2013	17	11.8	5.9%	-	58.8%
Lim 2014	20	24.7	15.0%	-	45.0%
Remeex sling					
Sousa-Esc' 2007	51	32	2.0%	-	86.3%

nr = not reported; **NS** = not significant (p-value not stated); **PPD** = Pads per day; **PW** = pad weight

The most common reason for removal was infection. Other reasons were urethral erosion, persistent pain, irritation symptoms, persistent retention, misplaced sling and inflammation of the pubic symphysis. Based on the above table it appears that the Argus sling may be associated with higher rates of removal.

Revision rates for non-adjustable slings were variable. The most common reason for attempted revision was persistent incontinence. However the practice of attempting revision appears to have varied between studies. With failure of an implanted sling, many authors

appeared to have used alternative treatments (e.g. the AUS) rather than attempting a sling revision. Other reasons given for sling revision were persistent retention/obstruction and bone screw dislodgement. Rates of adjustment for the adjustable slings were high.

5. Effect of baseline severity of incontinence

Many of the reviewed studies examined the effect of severity of incontinence at baseline on effectiveness outcomes. Results are summarized in the following table. The studies consistently found a decreasing level of effectiveness with increasing severity of baseline incontinence. However, the differences did not always reach statistical significance. High success rates were observed in patients with severe incontinence in some studies (e.g. Soljanik 2012, Bochove-Overgaauw 2011, Sousa-Escandon 2007).

	Endpoint	**Pre-op Categories**	**Results**	**p-value**
InVance sling				
Onur 2004	Success rate	Mild/moderate	83%	0.19
		Severe	50%	
Castle 2005	Success rate	Mild	67%	
		Moderate	50%	**<0.001**
		Severe	0%	
Fassi-Fehri 2007	Success rate	Mild	90%	
		Moderate	76.6%	0.22
		Severe	50%	
Guimaraes 2009	Success rate	≤ 5PPD	92%	nr
		> 5 PPD	69%	
Ath'poulos 2010a	0-1 PPD	Mild	100%	**<0.05**
		Moderate/Severe	43.2%	
AdVance sling				
Soljanik 2012	Success rate	Mild	91.7%	
		Moderate	69.5%	0.089
		Severe	75.0%	
Rehder 2012	Cure rate	Mild/moderate	58.6%	**0.042**
		Severe	42.3%	
Mueller 2012	Cure rate	Mild	83.3%	
		Moderate	61.1%	NS
		Severe	25.0%	
Collado 2013	Success rate	24-hour PW < 100g	86%	
		24-hour PW 100 – 400 g	83%	**0.018**
		24-hour PW > 400g	40%	
Argus sling				
Bochove-O' 2011	Success rate	Mild	92%	
		Moderate	67%	nr
		Severe	67%	
Remeex sling				
Sousa-Esc' 2007	Success rate	Mild	100%	
		Moderate	90%	nr
		Severe	78.1%	

nr = not reported; **NS** = not significant (p-value not stated); **PPD** = Pads per day; **PW** = pad weight

6. Effect of prior radiotherapy

Studies that examined the effect of prior radiotherapy on effectiveness outcomes are summarized in the following table. The studies generally found that subjects who had received prior radiotherapy had worse outcomes than those who had not received prior radiotherapy. The differences in outcome were not always statistically significant. Despite the worse outcomes generally, high cure/success rates were observed in irradiated subjects in some studies (Onur 2004, Hubner 2011).

	Endpoint	**Pre-op Categories**	**Results**	**p-value**
InVance sling				
Onur 2004	Success rate	Prior RTX No Prior RTX	75% 76%	NS
Castle 2005	Success rate	Prior RTX No Prior RTX	13% 47%	0.15
Fassi-Fehri 2007	Success rate	Prior RTX No Prior RTX	25% 83.7%	**< 0.001**
Gallagher 2007	Change in mean PPD	Prior RTX No Prior RTX	from 4.5 to 2.8 from 3.4 to 0.8	0.49 **0.002**
Giberti 2009	Cure rate	Prior RTX No Prior RTX	0% 75.8%	**< 0.05**
Guimaraes 2009	Cure rate	Prior RTX No Prior RTX	28% 79.5%	nr
Ath'poulos 2010a	Success rate	Prior RTX No Prior RTX	25% 74.3%	**<0.05**
AdVance sling				
Soljanik 2012	Success rate	Prior RTX No Prior RTX	59.3% 77.5%	0.315
Cornu 2009	Success rate	Prior RTX No Prior RTX	59% 85%	**= 0.039**
Rehder 2012	Cure rate	Prior RTX No Prior RTX	18.2% 43.5%	= 0.0723
Zuckerman 2014	Cure rate	Prior RTX No Prior RTX	26% 44%	= 0.10
Berger 2011	Success rate	Prior RTX No Prior RTX	60% 95.2%	**=0.004**
Mueller 2012	Success rate	Prior RTX No Prior RTX	60% 81.8%	= 0.218
Torrey 2013	Success rate	Prior RTX No Prior RTX	28.6% 90%	**= 0.01**
Argus sling				
Bochove-O' 2011	Success rate	Prior RTX No Prior RTX	15% 79%	nr
Hubner 2011	Cure rate	Prior RTX No Prior RTX	90.1% 75.9%	nr
Remeex sling				
Sousa-Esc' 2007	Success rate	Prior RTX No Prior RTX	60% 90.2%	nr

nr = not reported; **NS** = not significant (p-value not stated); **PPD** = Pads per day; **PW** = pad weight

Safety outcomes

1. Mortality

There were no deaths reported in any of the reviewed studies.

2. Complications

The incidences of complications reported in the reviewed studies are summarized in the following tables. Common complications included the following:

- Infection. The incidence of infection was variable across studies but was generally < 10%. There was no clear difference in incidence between the various slings.
- Urinary retention. Incidence figures for urinary retention were highly variable. In the majority of cases the retention was transient and settled with intermittent catheterization over a period of days or weeks. There was no clear difference in incidence between slings.
- Perineal pain, numbness, parasthesiae etc were reported commonly. These symptoms were generally transient although prolonged symptoms occurred in a small proportion of subjects.
- A variety of urinary symptoms such as urgency, urge incontinence, dysuria etc. were reported. Again, there was no clear difference in incidence between slings.
- Urethral erosion. The incidence of this complication appeared low with most of the slings (< 3%). However, the Argus sling appeared to be associated with a higher incidence (up to 13%).
- Bladder perforation was reported only with the adjustable slings (Argus and Remeex).

	InVance sling										
	Rajpurkar 2005	Comiter 2005	Castle 2005	Fassi-Fehri 2007	Fischer 2007	Gallagher 2007	Giberti 2008	Giberti 2009	Guimaraes 2009	Athanasop' 2010	Carmel 2010
Overall complications											
Infection	2.2		7.9	6.0	6.5	6.5	4.8	15.0	3.2	11.6	2.2
Urinary tract disorders											
Urinary retention				12.0	3.2	3.2				2.3	6.7
Urethral erosion		2.1	2.6		1.6						
Urinary tract infection											
Intraoperative urethral injury											
Injury to corpus spongiosum											
Bladder perforation											
Stricture											
Exacerbation urinary symptoms				2.0							
Urge incontinence					1.6					7.0	
Urgency										14.0	
Detrusor overactivity							12.0	5.0			
Hyperactive bladder											4.4
Dysuria – early post-op period											
Dysuria (mild) during follow-up											
Dysuria											
Altered sensation on voiding											
Feeling of incomplete voiding											
Mild voiding difficulties											

	AdVance sling															
	Rehder 2010	Bauer 2010	Cornu 2011	Rehder 2012	Zuck'mn 2014	Cornel 2010	Li 2012	Berger 2011	Suskind 2011	Mueller 2012	Grimsby 2012	Cornu 2014 Advance	Cornu 2014 Advance XP	Collado 2013	Torrey 2013	Hoy 2014
Overall complications	26.3	23.9					13.6									19.7
Infection		0.4		0.6	1.0	2.8			2.4	9.3						1.3
Urinary tract disorders																
Urinary retention	5.1	21.3		9.0	11.8	2.8	9.1	34.6	7.1	15.6	29.0	1.7	1.8	14.8	43.2	18.4
Urethral erosion									2.4							
Urinary tract infection		0.4		0.6	1.0											
Intraoperative urethral injury					2.0										2.7	
Injury to corpus spongiosum					2.0											
Bladder perforation																
Stricture																
Exacerbation urinary symptoms																
Urge incontinence																
Urgency				0.6										8.2		
Detrusor overactivity																
Hyperactive bladder																
Dysuria – early post-op period			1.5	4.5												
Dysuria (mild) during follow-up			14.0													
Dysuria																
Altered sensation on voiding							6.0									
Feeling of incomplete voiding							1.5									
Mild voiding difficulties												13.0	12.0			

	Autologous			Argus						Remeex	Virtue
	Daneshm'd 2003	Athanasop' 2010	Heidari 2012	Romano 2006	Bochove 2011	Dalpiaz 2011	Hubner 2011	Basiri 2013	Lim 2014	Sousa-Esc' 2007	Comiter 2014
Overall complications	0.0	21.9			55.0	82.8					
Infection				4.2	8.0	6.9	6.0	11.8	10.0	3.9	
Urinary tract disorders											
Urinary retention			14.3	14.6	16.0	34.5					
Urethral erosion				6.3	3.0	10.3	13.0			2.0	
Urinary tract infection					2.0						
Intraoperative urethral injury				6.3							
Injury to corpus spongiosum											
Bladder perforation					6.0	10.3	5.0			9.8	
Stricture		6.2			12.0	3.4					
Exacerbation urinary symptoms											
Urge incontinence		9.4									
Urgency		3.1			1.0	13.8					
Detrusor overactivity											
Hyperactive bladder											
Dysuria – early post-op period											
Dysuria (mild) during follow-up											
Dysuria				20.8							
Altered sensation on voiding											
Feeling of incomplete voiding											
Mild voiding difficulties											

	InVance sling										
	Rajpurkar 2005	Comiter 2005	Castle 2005	Fassi-Fehri 2007	Fischer 2007	Gallagher 2007	Giberti 2008	Giberti 2009	Guimaraes 2009	Athanasop' 2010	Carmel 2010
Pain											
Perineal pain – early/transient Perineal pain < 4 weeks			100.0				76.0	73.0	19.3		
Perineal pain < 6 months Perineal pain – prolonged	4.4										
Perineal pain > 6 weeks Perineal pain > 3 months				12.0	8.1						
Scrotal pain/perineal discomfort Mild perineal pain – 4-6 weeks											
Scrotal/groin pain Suprapubic pain											
Post-operative pain > 1 month Severe adductor pain											
Lower extremity discomfort **Numbness/parasthesiae**											
Scrotal numbness/hypersen. Perineal numbness 1-3 mths		14.6									22.0
Perineal parasthesiae Perineal parasthesiae > 6 mths											
Penile numbness/hypersens. Decreased urethral sensitivity											

AdVance sling

	AdVance sling															
	Rehder 2010	Bauer 2010	Cornu 2011	Rehder 2012	Zuck'mn 2014	Cornel 2010	Li 2012	Berger 2011	Suskind 2011	Mueller 2012	Grimsby 2012	Cornu 2014 Advance	Cornu 2014 Advance XP	Collado 2013	Torrey 2013	Hoy 2014
Pain																
Perineal pain – early/transient						100.0										
Perineal pain < 4 weeks								19.2								
Perineal pain < 6 months				50.0												
Perineal pain – prolonged		0.4					4.5					5.0	2.0			
Perineal pain > 6 weeks											3.2					
Perineal pain > 3 months																
Scrotal pain/perineal discomfort	19.5													8.2		
Mild perineal pain – 4-6 weeks		2.2														
Scrotal/groin pain					5.9										2.7	
Suprapubic pain																
Post-operative pain > 1 month																
Severe adductor pain	1.7															
Lower extremity discomfort															10.8	
Numbness/parasthesiae																
Scrotal numbness/hypersen.															18.9	
Perineal numbness 1-3 mths																
Perineal parasthesiae			1.5													
Perineal parasthesiae > 6 mths												1.7				
Penile numbness/hypersens.															8.1	
Decreased urethral sensitivity															2.7	

	Autologous			Argus						Remeex	Virtue
	Daneshm'd 2003	Athanasop' 2010	Heidari 2012	Romano 2006	Bochove 2011	Dalpiaz 2011	Hubner 2011	Basiri 2013	Lim 2014	Sousa-Esc' 2007	Comiter 2014
Pain											
Perineal pain – early/transient					9.0	27.6	14.9				
Perineal pain < 4 weeks											
Perineal pain < 6 months											6.5
Perineal pain – prolonged					5.0						6.5
Perineal pain > 6 weeks											
Perineal pain > 3 months											
Scrotal pain/perineal discomfort											
Mild perineal pain – 4-6 weeks											
Scrotal/groin pain											
Suprapubic pain					2.0						
Post-operative pain > 1 month									30.0		
Severe adductor pain											
Lower extremity discomfort											
Numbness/parasthesiae											
Scrotal numbness/hypersen.											
Perineal numbness 1-3 mths											
Perineal parasthesiae											19.4
Perineal parasthesiae > 6 mths											
Penile numbness/hypersens.											
Decreased urethral sensitivity											

	InVance sling										
	Rajpurkar 2005	Comiter 2005	Castle 2005	Fassi-Fehri 2007	Fischer 2007	Gallagher 2007	Giberti 2008	Giberti 2009	Guimaraes 2009	Athanasop' 2010	Carmel 2010
Other complications											
Perineal haematoma				4.0							
Haematoma											
Wound dehiscence											
Rupture of sling											
Dislocation of sling											
Bone screw dislodgement		4.2							1.6		
Clostridium difficile colitis											2.2
Emesis											
Myocardial infarction											
Fungal rash											

	AdVance sling															
Other complications	Rehder 2010	Bauer 2010	Cornu 2011	Rehder 2012	Zuck'mn 2014	Cornel 2010	Li 2012	Berger 2011	Suskind 2011	Mueller 2012	Grimsby 2012	Cornu 2014 Advance	Cornu 2014 Advance XP	Collado 2013	Torrey 2013	Hoy 2014
Perineal haematoma			0.7	3.2								0.8	0.9	3.3		
Haematoma																
Wound dehiscence																
Rupture of sling																
Dislocation of sling																
Bone screw dislodgement																
Clostridium difficile colitis																
Emesis															2.7	
Myocardial infarction																
Fungal rash							3.0									

	Autologous			Argus						Remeex	Virtue
	Daneshm'd 2003	Athanasop' 2010	Heidari 2012	Romano 2006	Bochove 2011	Dalpiaz 2011	Hubner 2011	Basiri 2013	Lim 2014	Sousa-Esc' 2007	Comiter 2014
Other complications											
Perineal haematoma										5.9	
Haematoma		3.1			1.0						
Wound dehiscence					6.0						
Rupture of sling					1.0						
Dislocation of sling						6.9					
Bone screw dislodgement											
Clostridium difficile colitis											
Emesis											
Myocardial infarction					1.0						
Fungal rash											

Interpretation

No studies were identified that directly compared any of the marketed synthetic slings with autologous slings. Also, there were no comparative studies located that compared synthetic slings.

It is difficult to draw any reliable conclusions regarding the comparative effectiveness and safety of the various slings. Conclusions based on cross-trial comparisons may be misleading for many reasons including the following:

- The studies enrolled different populations of subjects with respect to such factors as baseline level of incontinence and exposure to radiotherapy.
- The studies of the autologous sling enrolled a high proportion of subjects with intrinsic sphincter deficiency as a component of a neurogenic bladder, whereas studies of synthetic slings were generally conducted in subjects with post-prostatectomy SUI. Incontinence in subjects with neurogenic bladder is more complex and difficult to manage.
- The effectiveness outcomes studied varied widely, with no consistent definitions of endpoints such as cure, success and failure.

The following general conclusions can be drawn:

- Most studies reported on the proportion of subjects who were 'dry' or 'cured' and the proportion of subjects who were 'improved'. In most studies, the majority of subjects fell into one of these two categories. In most studies, the procedure was deemed a 'failure' in < 30% of subjects.
- The sling procedures resulted in significant reductions in average daily pad use, and significant reductions in average pad weight.
- In most studies, the proportion of patients who were satisfied with the procedure was high (>70%).
- The procedures resulted in significant improvements in quality of life in those studies that measured this endpoint.
- Sling procedures have reduced effectiveness in subjects with severe SUI and those who have previously received radiotherapy. However, some studies report high success rates in these subjects and the procedure may therefore be of value for subjects in whom other treatment options have been unsuccessful or are not viable.
- Complications associated with sling implantation are generally not major. The Argus sling appears to be associated with a high incidence of urethral erosion and higher removal rate.

ESTIMATION OF UTILISATION AND FINANCIAL IMPACTS

Current and projected usage of sling insertion MBS item

MBS Item 30742, for the insertion of an autologous fascial sling for bladder stress incontinence, is currently used for the insertion of the synthetic male slings listed on the Prostheses List. Six synthetic slings are currently listed on the prostheses list each with a benefit of $5,718. Prostheses List data indicates that in 2013-14 there were 244 claims for the insertion of synthetic slings associated with item 37042.

Table 10: total usage of MBS item 37042 in males from 2009-2014

Descriptor	MBS Item Number	2009-10	2010-11	2011-12	2012-13	2013-14
Insertion of sling for bladder stress incontinence	37042	162	204	220	273	264

It is unknown if the introduction of a dedicated MBS item would lead to an increased number of synthetic sling insertion procedures, however given that funding has been available through the Prostheses List and MBS item 37042 a rapid increase of service volumes with the introduction of new items is unlikely.

Table 11 shows the projected volume of services for the insertion of male synthetic slings for stress urinary incontinence based on current usage trends of item 37042 in association with a synthetic sling listed on the Prostheses List.

Table 11: Projected usage of item 37042 for synthetic sling insertion for male bladder stress incontinence for 2014 to 2020

2014-15	2015-16	2016-17	2017-18	2018-19	2019-20
291	314	337	360	384	407

Current and projected usage of sling revision, adjustment and removal item

Table 12 taken from the review of clinical evidence shows that the removal, revision and adjustment of synthetic slings is relatively low.

Table 12: Rate of removal, revision and adjustment for different brands of synthetic slings

	N	FU (m)	Removal	Revision	Adjustment
InVance sling					
Rajpurkar 2005	46	24	2.2%	-	-
Comiter 2005	48	48	-	4.2%	-
Fassi-Fehri 2007	50	6	8%	-	-
Fischer 2007	62	15	4.8%	11.3%	-
Gallagher 2007	31	15	12.9%	-	-
Giberti 2009	40	32.5	10%	-	-
Guimares 2009	62	28	3.2%	1.6%	-
Ath'poulos 2010a	43	24.2	9.3%	23.3%	-
Carmel 2010	45	36	2.2%	-	-
AdVance sling					
Bauer 2011b	137	27	1.6%	-	-
Cornu 2011	136	21	0%	0%	-
Rehder 2012	156	36	0.6%	1.9%	-
Zuckerman 2014	102	36.2	1.0%	13.6%	-
Cornel 2010	33	12	2.8%	-	-
Berger 2011	26	22	0%	0%	-
Mueller 2012	32	9	3.1%	-	-
Grimsby 2012	31	12.8	0%	3.2%	-
Cornu 2014					
- Advance	121	21	0%	-	-
- Advance XP	110	16	0%	-	-
Collado 2013	61	3	0%	0%	-
Hoy 2014	76	24	0%	0%	-
AVERAGE OF AdVance sling			**0.76%**	**2.6%**	
Autologous sling					
Ath'poulos 2010b	32	29.5	3.1%	3.1%	-
Heidari 2012	28	12	-	7.1%	-
Argus sling					
Romano 2006	48	7.5	10.4%	-	10.4%
Bochove-O' 2011	100	27	11.0%	-	32.0%
Dalpiaz 2011	29	35	34.4%	-	37.9%
Hubner 2011	101	25.2	15.8%	-	38.6%
Basiri 2013	17	11.8	5.9%	-	58.8%
Lim 2014	20	24.7	15.0%	-	45.0%
Remeex sling					
Sousa-Esc' 2007	51	32	2.0%	-	86.3%
Average			5.49%	5.33%	44.14%

The MBS data on the usage of item 37341, see table 13, is supportive of the evidence of clinical trials indicating that the proportion of use of item 37341 is low compared to the usage of item 37042.

Table 13: 2009-2014 MBS Item 37341 for revision/adjustment and removal usage and usage as a proportion of 37342 in males

Descriptor	MBS Item Number	2009-10	2010-11	2011-12	2012-13	2013-14
Adjustment or removal of the synthetic sling	37341	9	13	9	8	4
% of total services which were adjustment or removal compared with insertion (Item 37342) for that financial year		5.56%	6.37%	4.09%	2.93%	1.52%

Based on the current usage of the division and removal item and rates of division and removal of synthetic slings in the clinical literature table 14 shows the projected usage of a division and removal item for synthetic slings. The numbers are low and therefore there may be a large margin of error for percentage change in usage, however the overall financial impact of this change would be negligible.

Table 14 projected usage of new MBS Items for synthetic slings, by financial year, for revision/adjustment and removal predicted usage for 2014 to 2020

	2014-15	2015-16	2016-17	2017-18	2018-19	2019-20
Revision/ Adjustment	2	2	2	2	2	2
Removal	2	2	2	2	2	2

Cost impact of the introduction of the proposed new items

The applicant has requested a higher fee for items for the insertion and removal of autologous slings because in their opinion the insertion and removal of synthetic slings are more complex and time consuming than autologous slings.

If introducing the three new MBS items specifically for the synthetic sling it seems appropriate to use the proposed lower fee for sling adjustment or revision as the applicant has indicated this is an appropriate for the time and complexity of the intervention. However limited clinical evidence has been provided to justify the proposed higher rate for removal or insertion.

The financial impact of the two different options for funding the insertion, removal and adjustment of synthetic slings has been modeled:

- Attachment A: shows the financial impact of creating 3 new items (two at same fee as existing MBS items 37041 and 37042 for the insertion and removal of synthetic slings and) and one new item for the adjustment of synthetic slings at $408.75. This is projected to result in a $2,087 saving to the MBS over the forward estimates. The saving is as a result of a shift of use from the more expensive item 37341 to a less expensive new item for the adjustment of synthetic slings.
- Attachment B: Shows the financial impact of creating two new items for the insertion and removal of synthetic slings at a higher cost than the current autologous items as requested by applicant and one new item for the adjustment of synthetic slings at

$408.75. This is projected to result in a $317,237 cost to the MBS over the forward estimates. The cost is a result of the higher fee for the new items for insertion and removal of synthetic slings compared to fees for the current items (37041 and 37042).

MSAC should note that the use of a synthetic rather than autologous sling will have an additional financial impact as the devices are listed on the Prostheses List with a benefit of $5,718.

ABBREVIATIONS

AUS	Artificial Urinary Sphincter
BPH	Benign Prostatic Hypertrophy
EBRT	External Beam Radiotherapy
IQR	Interquartile Range
MBS	Medicare Benefits Schedule
PASC	Protocol Advisory Sub-Committee
PPD	Pads per day
PW	Pad Weight
RP	Radical Prostatectomy
RTX	Radiotherapy
SUI	Stress Urinary Incontinence
TURP	Transurethral Resection of the Prostate

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