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

Evidence for Medical Services Advisory Committee (MSAC)

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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 37042BLADDER 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 37341URETHRAL 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 insertion of urinary autologous slings**

| Category 3 – Therapeutic procedures |
| --- |
| MBS item 37042BLADDER 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 removal of urinary slings**

| Category 3 – Therapeutic procedures |
| --- |
| MBS item 37341URETHRAL 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, Centrewidth: 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/m2 (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 insertion 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 adjustment 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 removal 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**

Surgical approach

1. Perineal incision for males versus vaginal approach for females.
2. 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.
3. 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.

Stronger Muscular structures

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

Post radical prostatectomy anatomy

1. Prolapsed urethra in the male versus healthy urethra in females.
2. Often compromised tissue in men (i.e. from radiation).

Relocation and supportive requirements of sling

1. 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.

Removal of the male sling

1. 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 slingNon-adjustable |
| AdVance | American Medical Systems | Transobturator slingNon-adjustable |
| Argus | Endotherapeutics Pty Ltd | Retropubic slingAdjustable |
| Remeex | Gytech Pty Ltd | Retropubic slingAdjustable |
| Virtue | Coloplast Pty Ltd | Quadratic sling (Transobturator and pre-pubic). Non-Adjustable. |
| TiLOOP | Medical Specialties Australia Pty Ltd  | Transobturator slingNon-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 inthe 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- Advance XP | 121110 | 2116 | 62.8% e59.1% e | -- | 15.7% q17.3% q | 78.5% w76.4% w | 21.5%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.

1. 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-opPPD | Post-opPPD | 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 | 4.5nr | 1.4nr | 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) | 147.043-431 | 18.04-109 | <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;

1. 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- Advance XP | 121110 | 2116 | -- | 51.2%68.2% | 22.3%11.8% | 73.5%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.

1. 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- Advance XP | 121110 | 2116 | 0%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.

1. 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/moderateSevere | 83%50% | 0.19 |
| Castle 2005 | Success rate | MildModerateSevere | 67%50%0% | **<0.001** |
| Fassi-Fehri 2007 | Success rate | MildModerateSevere | 90%76.6%50% | 0.22 |
| Guimaraes 2009 | Success rate | ≤ 5PPD> 5 PPD | 92%69% | nr |
| Ath’poulos 2010a | 0-1 PPD | MildModerate/Severe | 100%43.2% | **<0.05** |
| **AdVance sling** |  |  |  |  |
| Soljanik 2012 | Success rate | MildModerateSevere | 91.7%69.5%75.0% | 0.089 |
| Rehder 2012 | Cure rate | Mild/moderateSevere | 58.6%42.3% | **0.042** |
| Mueller 2012 | Cure rate | MildModerateSevere | 83.3%61.1%25.0% | NS |
| Collado 2013 | Success rate | 24-hour PW < 100g24-hour PW 100 – 400 g24-hour PW > 400g | 86%83%40% | **0.018** |
| **Argus sling** |  |  |  |  |
| Bochove-O’ 2011 | Success rate | MildModerateSevere | 92%67%67% | nr |
| **Remeex sling** |  |  |  |  |
| Sousa-Esc’ 2007 | Success rate | MildModerateSevere | 100%90%78.1% | nr |

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

1. 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 RTXNo Prior RTX | 75%76% | NS |
| Castle 2005 | Success rate | Prior RTXNo Prior RTX | 13%47% | 0.15 |
| Fassi-Fehri 2007 | Success rate | Prior RTXNo Prior RTX | 25%83.7% | **< 0.001** |
| Gallagher 2007 | Change in mean PPD | Prior RTXNo Prior RTX | from 4.5 to 2.8from 3.4 to 0.8 | 0.49**0.002** |
| Giberti 2009 | Cure rate | Prior RTXNo Prior RTX | 0%75.8% | **< 0.05** |
| Guimaraes 2009 | Cure rate | Prior RTXNo Prior RTX | 28%79.5% | nr |
| Ath’poulos 2010a | Success rate | Prior RTXNo Prior RTX | 25%74.3% | **<0.05** |
| **AdVance sling** |  |  |  |  |
| Soljanik 2012 | Success rate | Prior RTXNo Prior RTX | 59.3%77.5% | 0.315 |
| Cornu 2009 | Success rate | Prior RTXNo Prior RTX | 59%85% | **= 0.039** |
| Rehder 2012 | Cure rate | Prior RTXNo Prior RTX | 18.2%43.5% | = 0.0723 |
| Zuckerman 2014 | Cure rate | Prior RTXNo Prior RTX | 26%44% | = 0.10 |
| Berger 2011 | Success rate | Prior RTXNo Prior RTX | 60%95.2% | **=0.004** |
| Mueller 2012 | Success rate | Prior RTXNo Prior RTX | 60%81.8% | = 0.218 |
| Torrey 2013 | Success rate | Prior RTXNo Prior RTX | 28.6%90% | **= 0.01** |
| **Argus sling** |  |  |  |  |
| Bochove-O’ 2011 | Success rate | Prior RTXNo Prior RTX | 15%79% | nr |
| Hubner 2011 | Cure rate | Prior RTXNo Prior RTX | 90.1%75.9% | nr |
| **Remeex sling** |  |  |  |  |
| Sousa-Esc’ 2007 | Success rate | Prior RTXNo 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.

1. 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 | Li2012 | Berger 2011 | Suskind 2011 | Mueller 2012 | Grimsby 2012 | Cornu 2014 Advance | Cornu 2014 Advance XP | Collado 2013 | Torrey 2013 | Hoy2014 |
| **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 | Lim2014 |  | 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 |  |  | 100.0 |  |  |  | 76.0 | 73.0 | 19.3 |  |  |
| Perineal pain < 4 weeks |  |  |  |  |  |  |  |  |  |  |  |
| 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. |  | 14.6 |  |  |  |  |  |  |  |  |  |
| Perineal numbness 1-3 mths |  |  |  |  |  |  |  |  |  |  | 22.0 |
| Perineal parasthesiae |  |  |  |  |  |  |  |  |  |  |  |
| Perineal parasthesiae > 6 mths |  |  |  |  |  |  |  |  |  |  |  |
| Penile numbness/hypersens. |  |  |  |  |  |  |  |  |  |  |  |
| Decreased urethral sensitivity |  |  |  |  |  |  |  |  |  |  |  |

|  | AdVance sling |
| --- | --- |
|  | Rehder 2010 | Bauer 2010 | Cornu 2011 | Rehder 2012 | Zuck’mn 2014 | Cornel 2010 | Li2012 | Berger 2011 | Suskind 2011 | Mueller 2012 | Grimsby 2012 | Cornu 2014 Advance | Cornu 2014 Advance XP | Collado 2013 | Torrey 2013 | Hoy2014 |
| **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 | Lim2014 |  | 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 |
| --- | --- |
|  | Rehder 2010 | Bauer 2010 | Cornu 2011 | Rehder 2012 | Zuck’mn 2014 | Cornel 2010 | Li2012 | Berger 2011 | Suskind 2011 | Mueller 2012 | Grimsby 2012 | Cornu 2014 Advance | Cornu 2014 Advance XP | Collado 2013 | Torrey 2013 | Hoy2014 |
| **Other complications** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 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 | Lim2014 |  | 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- Advance XP | 121110 | 2116 | 0%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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