

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedures overview of biological slings for stress urinary incontinence

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in December 2004 and updated in September 2005.

Procedure name

- Biological slings for stress urinary incontinence.

Specialty societies

- British Association of Urological Surgeons (BAUS).
- Royal College of Obstetricians and Gynaecologists (RCOG).

Description

Indications

Stress urinary incontinence.

Stress urinary incontinence is the involuntary leakage of urine during exercise or certain movements such as coughing, sneezing and laughing. It is usually due to weak or damaged muscles in the pelvic floor or sphincter. Estimates of the overall prevalence of any incontinence have varied between 10 and 52% of adult women.¹

Current treatment and alternatives

Conservative treatments include pelvic floor muscle training, electrical stimulation, biofeedback, and mechanical devices (urethral plugs and inserts). Surgery is usually used if conservative treatments fail. There are four main types of surgical intervention: colposuspension, insertion of a tension-free vaginal tape, traditional suburethral slings and injectable agents. Of these four operation types, colposuspension and the insertion of a tension-free vaginal tape are currently the most common.

Colposuspension (open or laparoscopic) involves lifting the tissues near the bladder neck and proximal urethra, and suturing them in place. Insertion of a tension-free vaginal tape is a minimal-access procedure that involves passing a polypropylene

tape beneath the urethra to restore it to its correct position. No tension is used and the ends of the tape are left unfixed. The tape is introduced via a small vaginal incision over the mid-urethra and positioned by the use of two needle carriers passed blindly through the retropubic space. Cystoscopy is recommended to detect any bladder perforation.

What the procedure involves

Biological slings may be made from the patient's own fascia lata or rectus fascia (autograft), from human donor tissue (allograft) or from animal tissue (xenograft). Allografts are solvent-dehydrated or freeze-dried and may be gamma-irradiated. Autologous fascia slings are the most established of these options.

Suburethral sling procedures use a combined vaginal and abdominal approach and are usually performed under general anaesthesia. An instrument is tunnelled from the abdominal to the vaginal site and the sling or suture arms are then pulled through from the vaginal site to the abdominal site. There are three main methods of positioning the sling, depending on its length. A full-length sling is placed in the retropubic space, passing from underneath the urethra on either side and is fixed by sutures to the rectus fascia at each end. A half-length sling extends into the retropubic space above the perineal membrane and is suspended by sutures applied to the tails. The third method involves a patch of sling, the tails of which are attached by sutures that extend through the retropubic space to the attachment site. Alternatively, bone screws may be used to hold the sutures in place and anchor the sling to the pubis. Once the sling is in position, a cystoscopy is usually performed to check that there has been no bladder perforation.

Efficacy

One randomised controlled trial reported that 82% (56/68) of women were cured of stress urinary incontinence after the biological sling procedure, compared with 88% (53/60) of women having a vaginal tape procedure (not statistically significant). The patient satisfaction rates were also similar for the two groups. Two non-randomised controlled trials compared cadaveric fascia lata slings with autograft slings. These reported similar cure rates of 71% (45/63) and 74% (77/104) for the allograft groups and 77% (55/71) and 73% (22/30) for the autograft groups. One of these studies reported that 89% (93/104) of women having allograft slings were satisfied and would undergo the procedure again, compared with 90% (27/30) of women having autograft slings. A case series of 198 women with autologous fascia slings reported an overall success rate of 72% (142/197) after a median follow-up of 6 years. Another case series reported that 85% (75/88) of patients followed up for longer than 5 years were continent.

In a recent study published only in abstract form, three techniques were compared for the treatment of stress urinary incontinence. At 12 months there were six failures requiring re-operation - all in the xenograft group. As a result the study investigators decided to discontinue the recruitment of patients into the xenograft arm of the study.

The Specialist Advisors stated that there are concerns about long term efficacy of the newer biological slings used for this procedure.

Safety

The two most commonly reported complications were urge incontinence, which affected between 3% (5/152) and 50% (5/10) of women, and voiding difficulties or urinary retention, affecting between 3% (4/134) and 94% (232/247) of women. Two studies reported severe or persistent pain in 1% (1/74) and 4% (5/134) of women.

Other complications included infection, release of sling, pelvic haematoma, haemorrhage and urethral dilatation.

The Specialist Advisors noted that potential adverse effects include urethral obstruction and retention, bladder perforation, haemorrhage, infection and urgency. There is also a potential risk of infection associated with the use of cadaveric tissue.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to biological slings for stress urinary incontinence. Searches were conducted via the following databases, covering the period from their commencement to September 2005: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and Science Citation Index. Trial registries and the Internet were also searched. No language restriction was applied to the searches.

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

Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology unless it was thought to add to the published evidence base.
Patient	Women with stress urinary incontinence.
Intervention/test	Insertion of biological slings.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on a randomised controlled trial², two non-randomised controlled trials^{3,4}, and four case series^{5,6,7,8}. These seven studies are summarised in Table 1. A systematic review on suburethral sling procedures has also been summarised, but this is not restricted to biological slings.⁹ Additional studies that were considered to be relevant to the procedure are listed in Appendix 1.

Two studies were added to Table 1 following consultation and an updated literature search.^{22, 23}

Existing reviews on this procedure

A Cochrane Review on suburethral sling operations for urinary incontinence in women was published in 2001 and updated in 2003.⁹ Twelve trials were included in the review and the conclusion was that evidence is lacking on the comparison between suburethral slings and other surgical or conservative management. Six types of sling were included (Teflon, polytetrafluoroethylene, prolene used for tension

free vaginal tape, porcine dermis, lyophilized dura mater and rectus fascia). This review is summarised in Table 1.

Table 1 Summary of key efficacy and safety findings on biological slings for stress urinary incontinence

Abbreviations used: IIQ = Incontinence Impact Questionnaire, UDI = Urogenital Distress Inventory, SUI = stress urinary incontinence																																																			
Study details	Key efficacy findings	Key safety findings	Comments																																																
<p>Abdel-Fattah M (2004)²</p> <p>Randomised controlled trial</p> <p>UK</p> <p>142 women</p> <ul style="list-style-type: none"> • 52% (74/142) Biological sling • 48% (68/142) Tension-free vaginal tape <p>Mean age:</p> <ul style="list-style-type: none"> • Biological sling = 53 years (range 34 to 75) • Tension-free vaginal tape = 54 years (range 32 to 83) <p>Inclusion criteria: pure urinary stress incontinence persisting after unsuccessful conservative therapy.</p> <p>Biological sling: Acellular porcine dermal collagen - Pelvicol® (Bard)</p> <p>Vaginal tape: TVT® (Gynecare)</p> <p>Median follow-up:</p> <ul style="list-style-type: none"> • Biological sling = 34 months • Tension-free vaginal tape = 36 months 	<p>Outcome measures: subjective cure rates of stress urinary incontinence and quality of life improvement (measured by a postal questionnaire)</p> <p>Overall cure rates:</p> <table border="1"> <thead> <tr> <th></th> <th>Biological sling</th> <th>Vaginal tape</th> </tr> </thead> <tbody> <tr> <td>Dry</td> <td>82% (56/68)</td> <td>88% (53/60)</td> </tr> <tr> <td>Improved</td> <td>10% (7/68)</td> <td>5% (3/60)</td> </tr> <tr> <td>Failed</td> <td>7% (5/68)</td> <td>7% (4/60)</td> </tr> </tbody> </table> <p>p > 0.5</p> <p>Adjusted cure rates (assuming non-responders still incontinent):</p> <table border="1"> <thead> <tr> <th></th> <th>Biological sling</th> <th>Vaginal tape</th> </tr> </thead> <tbody> <tr> <td>Dry</td> <td>78% (56/72)</td> <td>79% (53/67)</td> </tr> <tr> <td>Improved</td> <td>10% (7/72)</td> <td>4% (3/67)</td> </tr> <tr> <td>Failed</td> <td>12% (9/72)</td> <td>16% (11/67)</td> </tr> </tbody> </table> <p>p > 0.5</p> <p>Satisfaction rates:</p> <table border="1"> <thead> <tr> <th></th> <th>Biological sling</th> <th>Vaginal tape</th> </tr> </thead> <tbody> <tr> <td>> 90%</td> <td>71% (48/68)</td> <td>78% (47/60)</td> </tr> <tr> <td>75–90%</td> <td>12% (8/68)</td> <td>10% (6/60)</td> </tr> <tr> <td>< 75%</td> <td>18% (12/68)</td> <td>12% (7/60)</td> </tr> </tbody> </table> <p>p > 0.5</p> <p>Adjusted satisfaction rates (assuming non-responders were failures):</p> <table border="1"> <thead> <tr> <th></th> <th>Biological sling</th> <th>Vaginal tape</th> </tr> </thead> <tbody> <tr> <td>> 90%</td> <td>67% (48/72)</td> <td>70% (47/67)</td> </tr> <tr> <td>75–90%</td> <td>11% (8/72)</td> <td>9% (6/67)</td> </tr> <tr> <td>< 75%</td> <td>22% (16/72)</td> <td>21% (14/67)</td> </tr> </tbody> </table> <p>p > 0.5</p>		Biological sling	Vaginal tape	Dry	82% (56/68)	88% (53/60)	Improved	10% (7/68)	5% (3/60)	Failed	7% (5/68)	7% (4/60)		Biological sling	Vaginal tape	Dry	78% (56/72)	79% (53/67)	Improved	10% (7/72)	4% (3/67)	Failed	12% (9/72)	16% (11/67)		Biological sling	Vaginal tape	> 90%	71% (48/68)	78% (47/60)	75–90%	12% (8/68)	10% (6/60)	< 75%	18% (12/68)	12% (7/60)		Biological sling	Vaginal tape	> 90%	67% (48/72)	70% (47/67)	75–90%	11% (8/72)	9% (6/67)	< 75%	22% (16/72)	21% (14/67)	<p>Complications</p> <p>Haemorrhage:</p> <ul style="list-style-type: none"> • Biological sling = 4.1% (3/74) • Vaginal tape = 2.9% (2/68) <p>Infection:</p> <ul style="list-style-type: none"> • Biological sling = 0% (0/74) • Vaginal tape = 1.5% (1/68) <p>Severe pain:</p> <ul style="list-style-type: none"> • Biological sling = 1.4% (1/74) • Vaginal tape = 0% (0/68) <p>Release of sling:</p> <ul style="list-style-type: none"> • Biological sling = 6.8% (5/74) • Vaginal tape = 2.9% (2/68) <p>Urethral dilatation:</p> <ul style="list-style-type: none"> • Biological sling = 2.7% (2/74) • Vaginal tape = 1.5% (1/68) <p>Postoperative urinary urgency:</p> <ul style="list-style-type: none"> • Biological sling = 17.6% (12/68) • Vaginal tape = 15.0% (9/60) <p>Postoperative voiding difficulties:</p> <ul style="list-style-type: none"> • Biological sling = 5.9% (4/68) • Vaginal tape = 8.3% (5/60) <p>Postoperative dyspareunia:</p> <ul style="list-style-type: none"> • Biological sling = 0.0% (0/68) • Vaginal tape = 3.3% (2/60) 	<p>Randomisation was described.</p> <p>There were no statistically significant differences in mean parity, duration of problems, and proportion of patients having previous incontinence surgery or hysterectomy, between the two groups.</p> <p>Response rate to questionnaire:</p> <ul style="list-style-type: none"> • Biological sling = 92% (68/74) • Vaginal tape = 88% (60/68) <p>At 3 years, 5% (4/74) of patients in the biological sling group and 10% (7/68) of patients in the tension-free vaginal tape group were lost to follow-up.</p> <p>Three patients died during the course of the study: 2 in the biological sling group and 1 in the tension-free vaginal tape group.</p> <p>No objective testing.</p>
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Abbreviations used: IIQ = Incontinence Impact Questionnaire, UDI = Urogenital Distress Inventory, SUI = stress urinary incontinence			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Brown S (2000)³</p> <p>Non-randomised controlled study</p> <p>Washington, USA</p> <p>1994–1999</p> <p>167 women</p> <ul style="list-style-type: none"> 72% (121/167) cadaveric fascia lata sling 28% (46/167) autologous fascia lata sling <p>Mean age:</p> <ul style="list-style-type: none"> cadaveric sling = 62 years autologous sling = 62 years <p>Mean follow-up:</p> <ul style="list-style-type: none"> cadaveric sling = 12 months autologous sling = 44 months 	<p>Outcome measure: cure and patient satisfaction assessed by postal questionnaire.</p> <p>Cured (no or minimal leakage not requiring pads):</p> <ul style="list-style-type: none"> cadaveric sling = 74% (77/104) autologous sling = 73% (22/30) <p>Improved (1 to 3 pads used daily):</p> <ul style="list-style-type: none"> cadaveric sling = 19% (20/104) autologous sling = 27% (8/30) <p>Failed (more than 3 pads used daily):</p> <ul style="list-style-type: none"> cadaveric sling = 7% (7/104) autologous sling = 0% (0/30) <p>Patient satisfied and would undergo procedure again:</p> <ul style="list-style-type: none"> cadaveric sling = 89% (93/104) autologous sling = 90% (27/30) 	<p>Complications</p> <p>Prolonged urinary retention:</p> <ul style="list-style-type: none"> cadaveric sling = 2% (2/104) autologous sling = 10% (3/30) <p>Suprapubic abscess:</p> <ul style="list-style-type: none"> cadaveric sling = 2% (2/104) autologous sling = 0% (0/30) <p>Lower extremity neuropathy:</p> <ul style="list-style-type: none"> cadaveric sling = 1% (1/104) autologous sling = 0% (0/30) <p>Suprapubic haematoma:</p> <ul style="list-style-type: none"> cadaveric sling = 1% (1/104) autologous sling = 0% (0/30) <p>Cerebrovascular accident:</p> <ul style="list-style-type: none"> cadaveric sling = 0% (0/104) autologous sling = 3% (1/30) <p>Persistent thigh pain at 6 weeks:</p> <ul style="list-style-type: none"> cadaveric sling = 0% (0/104) autologous sling = 11% (5/30) 	<p>Retrospective study.</p> <p>Consecutive patients.</p> <p>Autologous fascia lata was used from 1994 to 1997 and cadaveric fascia lata from 1997 to 1999.</p> <p>Mean follow-up was shorter for cadaveric slings.</p> <p>Included patients with mixed incontinence as well as those with pure stress incontinence.</p> <p>Response rate to questionnaire:</p> <ul style="list-style-type: none"> cadaveric sling = 86% (104/121) autologous sling = 65% (30/46) <p>The cadaveric fascia group contained more women with genuine stress incontinence and higher leak point pressure and than the autologous fascia group.</p>

Abbreviations used: IIQ = Incontinence Impact Questionnaire, UDI = Urogenital Distress Inventory, SUI = stress urinary incontinence			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Flynn B (2002)⁴</p> <p>Non-randomised controlled study</p> <p>Pennsylvania, USA</p> <p>1995–1998</p> <p>134 women</p> <ul style="list-style-type: none"> 47% (63/134) allograft sling 53% (71/134) autograft sling (rectus abdominis or fascia lata) <p>Mean age:</p> <ul style="list-style-type: none"> allograft sling = 54 years (range 21 to 77) autograft sling = 53 years (range 33 to 76) <p>p = 0.65</p> <p>Mean follow-up:</p> <ul style="list-style-type: none"> allograft sling = 29 months (range 24 to 36) autograft sling = 44 months (range 30 to 56) <p>p < 0.05</p>	<p>Outcome measures: chart review, third party telephone interview and selective videourodynamics</p> <p>Cured (no pads required in 24-hour period):</p> <ul style="list-style-type: none"> allograft sling = 71% (45/63) autograft sling = 77% (55/71) <p>Improved (1 pad required in 24-hour period):</p> <ul style="list-style-type: none"> allograft sling = 13% (8/63) autograft sling = 13% (9/71) <p>Failed (more than 1 pad required in 24-hour period):</p> <ul style="list-style-type: none"> allograft sling = 16% (10/63) autograft sling = 10% (7/71) <p>Mean hospital stay (days):</p> <ul style="list-style-type: none"> allograft sling = 1.2 autograft sling = 1.9 <p>p < 0.05</p> <p>Mean weeks lost from work:</p> <ul style="list-style-type: none"> allograft sling = 3.4 autograft sling = 6.4 <p>p < 0.05</p>	<p>Complications</p> <p>Urinary tract infection:</p> <ul style="list-style-type: none"> allograft sling = 6%(4/63) autograft sling = 27% (19/71) <p>Abdominal wound infection:</p> <ul style="list-style-type: none"> allograft sling = 0%(0/63) autograft sling = 6% (4/71) <p>Prolonged urinary retention:</p> <ul style="list-style-type: none"> allograft sling = 2%(1/63) autograft sling = 4% (3/71) <p>New onset urge incontinence:</p> <ul style="list-style-type: none"> allograft sling = 28%(7/25) autograft sling = 5% (2/39) <p>p < 0.05</p> <p>Mean postoperative pain (verbal numerical scale):</p> <ul style="list-style-type: none"> allograft sling = 2.0 autograft sling = 5.8 <p>p < 0.05</p>	<p>Retrospective study.</p> <p>Consecutive patients.</p> <p>In original study, 140 women were treated. For this follow-up study, 96% (134/140) of patients were still available.</p> <p>From 1995 to 1997, only autografts were available. Allografts became available in 1997. Patients selected the sling material.</p> <p>Preoperative parameters were similar in each group.</p> <p>The mean follow-up was significantly shorter for the allograft group (may have created a lead-time bias for detecting recurrent stress urinary incontinence).</p> <p>The majority of failures presented 2 to 3 years after the sling procedure.</p> <p>Suprapubic cystotomy tubes were routinely used in the autograft group before 1997.</p>

Abbreviations used: IIQ = Incontinence Impact Questionnaire, UDI = Urogenital Distress Inventory, SUI = stress urinary incontinence			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Morgan T (2000)^b</p> <p>Case series</p> <p>Texas, USA</p> <p>1993–1996</p> <p>247 women</p> <p>Autologous rectus fascia sling</p> <p>Mean age: 54.5 years (range 10 to 84)</p> <p>Mean follow-up: 52 months (range 24 to 70)</p> <p>Inclusion criteria: Type II or type III SUI (Type II = abdominal leak point pressure > 90 cm water and urethral mobility > 2 cm, Type III = abdominal leak point pressure < 60 cm water).</p>	<p>Outcome measures: duration of self-catheterisation, pad usage and urgency assessed at 3 months routine examination, long-term outcome and patient satisfaction assessed by chart review and patient-completed UDI short form.</p> <p>Complete resolution of SUI with no urge incontinence at follow-up = 88% (207/235)</p> <p>Cure rate in patients followed for more than 5 years = 85% (75/88)</p> <p>Resolution of preoperative concurrent urge related incontinence = 74% (81/109)</p> <p>92% (216/235) of patients were highly satisfied with outcome.</p>	<p>Complications</p> <ul style="list-style-type: none"> De novo urgency in women with pure SUI preoperatively = 23% (32/138) Transient postoperative urinary retention > 1 day postoperatively = 94% (232/247) <p>(mean duration of catheterisation = 8.4 days, normal voiding began 3 months postoperatively in 98% of patients)</p> <ul style="list-style-type: none"> Sling failure = 3.2% (8/247) Hypersuspended urethra = 2.4% (5/247) Pelvic haematoma = 0.8% (2/247) Incisional hernia = 0.8% (2/247) Deep venous thrombosis = 0.4% (1/247) Pulmonary embolus = 0.4% (1/247) Sling erosion = 0% (0/247) 	<p>Retrospective study.</p> <p>Postal questionnaire and chart review.</p> <p>95% (235/247) response rate.</p> <p>Validated questionnaire (UDI).</p> <p>44% (109/247) of patients had concomitant urge incontinence prior to study.</p> <p>160 concomitant procedures were performed, including cystocele repair, rectocele repair, sacrospinous ligament fixation, and hysterectomy. It is not clear how many patients were involved.</p> <p>6% (14/247) of patients had secondary procedures.</p>

Abbreviations used: IIQ = Incontinence Impact Questionnaire, UDI = Urogenital Distress Inventory, SUI = stress urinary incontinence			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Hawkins E (2002)^b</p> <p>Case series</p> <p>UK</p> <p>1979–1996</p> <p>198 women</p> <p>Autologous fascial sling</p> <p>Mean age: 51 years (range 36 to 75)</p> <p>Median follow-up: 6 years (range 2 to 18)</p>	<p>Outcome measures: patient's perception of current symptoms compared with preoperative</p> <p>Response to "how do you think your bladder symptoms are compared with before the operation?"</p> <ul style="list-style-type: none"> • Cure = 41% (80/197) • Much better = 38% (75/197) • Little better = 15% (29/197) • No change = 4% (8/197) • Worse = 2% (5/197) <p>Overall success rate according to symptom severity score as well as patient perception = 72% (142/197)</p> <p>28% (29/103) of women who were followed up for six years or more reported that the operation had failed. 55% (16/29) of these thought the operation had worked for between 5 and 10 years.</p> <p>1.5% (3/198) of women need to perform intermittent self-catheterisation.</p> <p>4% (8/198) of women had subsequent prolapse or incontinence surgery.</p>	<p>Complications (from notes)</p> <ul style="list-style-type: none"> • Haemorrhage requiring blood transfusion = 4% (7/178) • Wound infection = 3% (6/178) • Bladder perforation = 2% (3/178) • Postoperative sling release = 1% (2/178) <p>Complications reported at follow-up:</p> <ul style="list-style-type: none"> • Urgency = 29% (57/198) (Of these women, 35% were improved as compared with 87% (122/141) of women without symptoms of urgency). • Difficulty with bladder emptying = 9% (18/198) • Abdominal pain = 11% (22/198) • Recurrent urinary tract infections = 4% (8/198) • Loss of abdominal tone = 3% (6/198) • Incisional hernia = 4.5% (9/198) 	<p>Retrospective study.</p> <p>A pre-validated questionnaire was sent to all women who had a cruciate fascial sling.</p> <p>80% (198/246) response rate.</p> <p>15% (30/198) of women had concomitant surgery (27 hysterectomies, 2 posterior repair and 1 incisional hernia repair).</p> <p>Old notes could not be traced for 20 women, so there was no information on previous surgery or intraoperative complications for these cases.</p> <p>67% (132/198) of women had the sling performed as primary surgery, 23% (46/198) as secondary surgery.</p>
<p>Rutner A (2003)^f</p> <p>Case series</p> <p>California, USA</p> <p>152 women</p> <p>Processed porcine small intestine submucosal sling</p> <p>Mean age: 62 years (range 30 to 91)</p> <p>Median follow-up: 28 months (range 4 to 48)</p> <p>Inclusion criteria: SUI by history and physical examination</p>	<p>Outcome measures: state of dryness determined at office visits and by patient-completed questionnaires</p> <ul style="list-style-type: none"> • Dry = 93% (142/152) • Improved = 2% (3/152) • Failed = 5% (7/152) <p>(The failures of two were related to the bone anchors becoming dislodged)</p>	<p>Complications</p> <ul style="list-style-type: none"> • De novo urgency = 3% (5/152) <p>No instances of graft infection, erosion or extrusion occurred</p>	<p>Prospective study.</p> <p>Consecutive patients.</p> <p>'Many' patients had cystoceles repaired at the same time.</p> <p>Bone anchors were used.</p>

Abbreviations used: IIQ = Incontinence Impact Questionnaire, UDI = Urogenital Distress Inventory, SUI = stress urinary incontinence			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Richter H (2003)^b</p> <p>Case series</p> <p>Alabama, USA</p> <p>1997–2001</p> <p>102 women</p> <p>Cadaveric fascia lata sling</p> <p>Mean age: 63 years (range 29 to 87)</p> <p>Inclusion criteria: stress incontinence associated with intrinsic sphincter deficiency.</p> <p>Sling: Repliform cadaveric human dermal allograft (LifeCell Corp., The Woodlands, Texas)</p> <p>Mean follow-up: 35 months</p>	<p>Outcome measures: Incontinence Impact Questionnaire (IIQ-7) and Urogenital Distress Inventory (UDI-6)</p> <p>Mean preoperative IIQ score = 55.1</p> <p>Mean postoperative IIQ scores (a lower score indicates less impact of urinary incontinence) :</p> <ul style="list-style-type: none"> • 12 months = 11.0, p < 0.001 • 24 months = 9.6, p ≤ 0.001 • 36 months = 11.0, p ≤ 0.001 • 48 months = 12.5, p ≤ 0.001 <p>Mean preoperative UDI score = 67.1</p> <p>Mean postoperative UDI scores (a lower score indicates fewer symptoms):</p> <ul style="list-style-type: none"> • 12 months = 28.0, p < 0.001 • 24 months = 25.8, p < 0.01 • 36 months = 29.1, p < 0.01 • 48 months = 28.0, p < 0.01 <p>Leakage better or much better (as reported by patient):</p> <ul style="list-style-type: none"> • 12 months = 80% (59/74) • 24 months = 77% (41/53) • 36 months = 75% (27/36) • 48 months = 75% (9/12) <p>Patients somewhat or completely satisfied with their progress:</p> <ul style="list-style-type: none"> • 12 months = 90% (74/82) • 24 months = 90% (53/59) • 36 months = 85% (34/40) • 48 months = 86% (12/14) 	<p>Complications (responses to patient satisfaction questionnaire at 12 months)</p> <ul style="list-style-type: none"> • Vaginal pain, pressure or protrusion = 28% (21/74) • Bladder or kidney infection = 33% (25/75) • Less able to have sexual relations = 5% (4/78) 	<p>Prospective study.</p> <p>59% (61/102) of women underwent one or more concomitant procedures, including anterior repair, posterior repair and sacrospinous vaginal vault suspension.</p> <p>A full-length sling was used.</p> <p>Response rates were 88% at 12 months, 78% at 24 months, 84% at 36 months and 93% at 48 months = 93%.</p> <p>At the time outcome data were abstracted, 96% (98/102) of women were at least 12 months from the procedure, 78% (80/102) at least 24 months, 49% (50/102) at least 36 months and 15% (15/102) of women were at least 48 months from the procedure.</p> <p>Questionnaires used were validated instruments to assess life impact and symptom distress.</p>

Abbreviations used: IIQ = Incontinence Impact Questionnaire, UDI = Urogenital Distress Inventory, SUI = stress urinary incontinence			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Bezerra C (2001)⁹</p> <p>Systematic Review (Cochrane) Date of search: July 2002</p> <p>890 women (543 treated with suburethral slings)</p> <p>12 randomised or quasi-randomised trials included:</p> <ul style="list-style-type: none"> • Barbalias (1997)⁸, Goretex versus rectus fascia, n = 48 • Demirci (2001)⁹, Burch colposuspension versus rectus fascia sling, n = 46 • Enzelsberger (1996)¹⁰, modified Burch colposuspension versus lyophilized dura mater sling, n = 72 • Fischer (2001)¹¹, Burch retropubic urethropexy versus suburethral sling, n = 22 [abstract only] • Halaska (2001)¹², Burch colposuspension versus TVT, n = 26 [abstract only] • Han (2001)¹³, Burch colposuspension versus TVT, n = 50 [abstract only] • Henriksson (1978)¹⁴, Teflon sling versus colposuspension, n = 30 • Hilton (1989)¹⁵, Stamey bladder-neck needle suspension versus porcine dermis sling, n = 20 • Liapsis (2002)¹⁶, Burch colposuspension versus TVT, n = 71 • Lucas (2000)¹⁷, long rectus fascia versus short rectus fascia sling, n = 165 • Sand (2000)¹⁸, PTFE sling versus modified Burch colposuspension, n = 36 • Ward (2002)¹⁹, Colposuspension versus TVT, n = 344 	<p>Suburethral sling versus open abdominal retropubic suspension Overall cure rates similar (Relative risk = 0.82, 95% confidence intervals 0.37 to 1.80)</p> <p>Suburethral sling versus open abdominal retropubic suspension Failure rates at 24 months:</p> <ul style="list-style-type: none"> • Needle suspension = 30% (3/10) • Porcine dermis sling = 10% (1/10) <p>Rectus fascia versus Goretex sling Failure rates at 30 months:</p> <ul style="list-style-type: none"> • Rectus fascia = 34% (11/32) • Goretex = 12.5% (2/16) <p>Long rectus fascia sling versus short rectus fascia sling Patient satisfaction at 12 months:</p> <ul style="list-style-type: none"> • Long rectus fascia = 74% (62/84) • Short rectus fascia = 70% (57/81) 	<p>Suburethral sling versus open abdominal retropubic suspension No detectable differences in peri-operative complications overall</p> <p>Suburethral sling versus open abdominal retropubic suspension Postoperative complications:</p> <ul style="list-style-type: none"> • Needle suspension = 20% (2/10) • Porcine dermis sling = 90% (9/10) <p>Voiding problems at 3 months:</p> <ul style="list-style-type: none"> • Needle suspension = 20% (2/10) • Porcine dermis sling = 40% (4/10) <p>Urge incontinence:</p> <ul style="list-style-type: none"> • Needle suspension = 30% (3/10) • Porcine dermis sling = 50% (5/10) <p>Rectus fascia versus Goretex sling Erosion of urethra:</p> <ul style="list-style-type: none"> • Rectus fascia = 0% (0/32) • Goretex = 12.5% (2/16) <p>Recurrent urinary tract infections:</p> <ul style="list-style-type: none"> • Rectus fascia = 0% (0/32) • Goretex = 19% (3/16) 	<p>Includes studies on the less invasive TVT sling procedure, which is not covered by this overview.</p> <p>Includes studies using slings made from synthetic materials, which are not covered by this overview.</p> <p>Includes women with stress or mixed urinary incontinence.</p> <p>Two trials were reported only as abstracts.</p>

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<p>Mc Bride (2005)²²</p> <p>Non randomised controlled study – unclear whether historical control</p> <p>1998 - 2001</p> <p>71 patients undergoing suburethral sling for urodynamic stress incontinence – 47 were evaluable for evaluation.</p> <p>- 26 autologous fascia lata (originally 39 patients) Mean age: 60 years Mean follow-up: 42.4 months</p> <p>- 21 Tutoplast allograft fascia lata (originally 32 patients) Mean age: 74 years Mean follow-up: 35.2 months</p>	<p>Outcome measures: Objective Subjective</p> <table border="1"> <thead> <tr> <th>Urodynamic parameters</th> <th>Autograft n=17</th> <th>Allograft n=12</th> </tr> </thead> <tbody> <tr> <td>Recurrent urodynamic stress incontinence</td> <td>0.0%</td> <td>41.7%</td> </tr> <tr> <td>Cystometric bladder capacity mL</td> <td></td> <td></td> </tr> <tr> <td>- Preoperative mean</td> <td>456.3</td> <td>456.4</td> </tr> <tr> <td>-postoperative mean</td> <td>414.3</td> <td>341.1</td> </tr> <tr> <td>MUCP cm H2O</td> <td></td> <td></td> </tr> <tr> <td>Preoperative mean</td> <td>28.0</td> <td>33.1</td> </tr> <tr> <td>-postoperative mean</td> <td>37.1</td> <td>40.4</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th>Self-reported and subjective outcomes</th> <th>Autograft n=26</th> <th>Allograft n=21</th> </tr> </thead> <tbody> <tr> <td>Mean IIQ-7 score</td> <td>10.3</td> <td>4.1</td> </tr> <tr> <td>Mean UDI-6 score</td> <td>20.9</td> <td>20.6</td> </tr> <tr> <td>Mean pad use/day</td> <td>0.29</td> <td>0.90</td> </tr> <tr> <td>Mean incontinence episodes/day</td> <td>0.56</td> <td>0.71</td> </tr> <tr> <td>Pad use/day</td> <td></td> <td></td> </tr> <tr> <td>None</td> <td>73.1%</td> <td>42.9%</td> </tr> <tr> <td>1</td> <td>26.9%</td> <td>38.1%</td> </tr> <tr> <td>2 or more</td> <td>0.0%</td> <td>19.0%</td> </tr> <tr> <td>Incontinence episodes/day</td> <td></td> <td></td> </tr> <tr> <td>None</td> <td>57.7%</td> <td>52.4%</td> </tr> <tr> <td>1</td> <td>26.9%</td> <td>38.1%</td> </tr> <tr> <td>2 or more</td> <td>15.4%</td> <td>9.5%</td> </tr> </tbody> </table>		Urodynamic parameters	Autograft n=17	Allograft n=12	Recurrent urodynamic stress incontinence	0.0%	41.7%	Cystometric bladder capacity mL			- Preoperative mean	456.3	456.4	-postoperative mean	414.3	341.1	MUCP cm H2O			Preoperative mean	28.0	33.1	-postoperative mean	37.1	40.4	Self-reported and subjective outcomes	Autograft n=26	Allograft n=21	Mean IIQ-7 score	10.3	4.1	Mean UDI-6 score	20.9	20.6	Mean pad use/day	0.29	0.90	Mean incontinence episodes/day	0.56	0.71	Pad use/day			None	73.1%	42.9%	1	26.9%	38.1%	2 or more	0.0%	19.0%	Incontinence episodes/day			None	57.7%	52.4%	1	26.9%	38.1%	2 or more	15.4%	9.5%	<p>Complications Not reported</p>	<p>Identified during consultation Retrospective - unclear</p> <p>Of the original 71 patients deemed eligible, 47 returned for evaluation with either objective an or subjective instruments.</p> <p>Remaining 24 were lost to follow-up or declined entry into the study.</p> <p>Objective measures were only reported in 17 patients in the autograft group and 12 patients in the allograft group. An additional 9 patients in each group completed subjective evaluation.</p> <p>The mean age and parity was significantly greater in the allograft group. Also significantly more patients in the allograft group underwent other surgical repairs at the time of sling placement compared with the autograft group.</p> <p>Please note not all outcomes reported in the study have been reported here.</p>
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<p>Lucas (2004)²³</p> <p>Randomised controlled trial</p> <p>139 patients with stress incontinence</p> <p>42 patients with Tension Free Vaginal Tape (TVT)</p> <p>6 months follow-up: 31 patients</p> <p>12 months follow-up: 26 patients</p> <p>48 patients Porcine Xenograft (Pelvicol)</p> <p>6 months follow-up: 40 patients</p> <p>12 months follow-up: 28 patients</p> <p>47 patients short autologous fascial sling technique</p> <p>6 months follow-up: 33 patients</p> <p>12 months follow-up: 20 patients</p>	<p>Outcome measures: primary outcome measures were to be change in Bristol femal lower urinary tract symptom score and Euro QOL at 6 months and 12 months. Lengths of stay, hospital re-admissions and re-operations were also recorded.</p> <table border="1"> <thead> <tr> <th></th> <th>TVT</th> <th>Pelvicol</th> <th>Fascia</th> </tr> </thead> <tbody> <tr> <td>SUI some to all of the time</td> <td></td> <td></td> <td></td> </tr> <tr> <td>6 months</td> <td>5</td> <td>8</td> <td>4</td> </tr> <tr> <td>12 months</td> <td>3</td> <td>11</td> <td>3</td> </tr> <tr> <td>SUI bothersome or worse</td> <td></td> <td></td> <td></td> </tr> <tr> <td>6 months</td> <td>5</td> <td>18</td> <td>4</td> </tr> <tr> <td>12 months</td> <td>3</td> <td>18</td> <td>4</td> </tr> <tr> <td>Mean change in total symptom score</td> <td></td> <td></td> <td></td> </tr> <tr> <td>6 months</td> <td>-21</td> <td>-15</td> <td>-13</td> </tr> <tr> <td>12 months</td> <td>-18.5</td> <td>-8</td> <td>-13</td> </tr> <tr> <td>Mean change in total problem score</td> <td></td> <td></td> <td></td> </tr> <tr> <td>6 months</td> <td>-22</td> <td>-13.5</td> <td>-14.5</td> </tr> <tr> <td>12 months</td> <td>-22</td> <td>-8</td> <td>-14</td> </tr> <tr> <td>Dissatisfaction or worse</td> <td></td> <td></td> <td></td> </tr> <tr> <td>6 months</td> <td>7</td> <td>13</td> <td>10</td> </tr> <tr> <td>12months</td> <td>5</td> <td>13</td> <td>5</td> </tr> <tr> <td>Reoperations for incontinence</td> <td>0</td> <td>6</td> <td>0</td> </tr> </tbody> </table>		TVT	Pelvicol	Fascia	SUI some to all of the time				6 months	5	8	4	12 months	3	11	3	SUI bothersome or worse				6 months	5	18	4	12 months	3	18	4	Mean change in total symptom score				6 months	-21	-15	-13	12 months	-18.5	-8	-13	Mean change in total problem score				6 months	-22	-13.5	-14.5	12 months	-22	-8	-14	Dissatisfaction or worse				6 months	7	13	10	12months	5	13	5	Reoperations for incontinence	0	6	0	<p>Complications:</p> <p>6 patients in the pelvicol group. Authors note that a review of these six patients shows that all were initially relieved of their incontinence but suffered a delayed (more than 6 months) and sudden failure of support.</p>	<p>Identified during consultation</p> <p>Conference abstract – limited information available on outcomes and how outcomes have been measured.</p> <p>Study required 260 patients to have a 95% chance of detecting a 10% differences in quality of life scores with 80% power.</p> <p>Authors concluding comments 'The investigators feel that it is no longer ethical, nor possible, to remain equipoised when offering the three trial alternatives to potential patients. Recruitment to the Pelvicol arm has therefore been closed but the trial will continue to completion for TVT and autologous fascia.'</p>
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Validity and generalisability of the studies

- The studies included heterogeneous populations of women. There were variations in the extent of stress incontinence and a proportion of women had mixed incontinence. There were also variations in the extent of previous treatments that the women had undergone.
- Some women were treated with concomitant procedures, such as prolapse repairs, at the same time as the biological sling procedure.
- The randomised controlled trial, comparing biological sling with tension-free vaginal tape, did not report that the patients were blinded to their treatment option. This study only reported subjective outcome measures.²
- The systematic review included synthetic slings as well as biological slings. It also included tension-free vaginal tape as a sling procedure.⁹
- There were variations in the procedure; some studies used bone anchors to hold the sutures in place.

Specialist Advisors' opinions

- There are different types of biological slings and they may behave differently from each other.
- This procedure is a minor variation of an existing procedure.
- There is a lack of long-term data for some types of sling.
- The procedure is likely to have a moderate impact on the NHS, in terms of numbers of patients eligible for treatment and use of resources.

Issues for consideration by IPAC

A multicentre randomised controlled trial is in progress, comparing the efficacy and morbidity of three materials for performing sling surgery for stress incontinence in women. These are autologous rectus fascia, TVT (already reported by NICE) and Pelvicol. The study aimed to recruit 260 patients over a 2-year period but has been slow to recruit. The Pelvicol arm has now been closed because of high incidence of sudden delayed failure, a problem that has not occurred with the other techniques.

A NICE consultation scope for a guideline titled 'Urinary incontinence: the management of urinary incontinence in women', was issued at the end of August 2004. The expected date of issue of the guideline is October 2006.

The BAUS Section of Female and Reconstructive Urology established an incontinence surgery database in August 2004. The database will be accessible to all members of the BAUS Section of Female and Reconstructive Urology. Initially, it will not be collecting outcome data and only those people who wish to submit their data will do so. The British Society of Urogynaecology (BSUG) has also established an audit system for incontinence surgery and this will include outcome data. At present, the database may only be accessed by BSUG members via the Secretariat.

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Appendix A: Additional papers on biological slings for stress urinary incontinence not included in the summary tables

Article title	Number of patients/ follow-up	Comments	Direction of conclusions
Almeida S, Gregorio E, Grando J, et al. Pubovaginal sling using cadaveric allograft fascia for the treatment of female urinary incontinence. <i>Transplantation Proceedings</i> 2004; 36: 995–6.	60 women. Mean follow-up = 36 months (allograft), 33 months (autograft).	Non-randomised controlled trial. Cadaveric fascia versus autologous fascia.	Cure or improvement: <ul style="list-style-type: none"> Allograft = 68% Autograft = 90% $p < 0.05$ No sling erosions or infections.
Amundsen C, Visco A, Ruiz H, et al. Outcome in 104 pubovaginal slings using freeze-dried allograft fascia lata from a single tissue bank. <i>Urology</i> 2000; 56: 2–8.	104 women. Mean follow-up = 19 months.	Freeze-dried allograft fascia lata. Questionnaire (88% response rate)	Mean preoperative daily pad usage = 4.6 Mean postoperative daily pad usage = 1.1 $p < 0.0001$
Blaivas JG, Jacobs BZ. Pubovaginal fascial sling for the treatment of complicated stress urinary incontinence. <i>Journal of Urology</i> 1991; 145: 1214–8.	67 women. Mean follow-up = 3.5 years.	Case series.	82% continent. 9% incontinent on daily basis. 3% (2/67) required intermittent self-catheterisation.
Borup K, Nielsen JB. Results in 32 women operated for genuine stress incontinence with the pubovaginal sling procedure ad modum Ed McGuire. <i>Scandinavian Journal of Urology & Nephrology</i> 2002; 36: 128–33.	32 women. 5 year follow-up.	Case series.	94% cured from SUI. 6% (2/32) require intermittent self-catheterisation.
Carbone J, Kavalier E, Hu K, et al. Pubovaginal sling using cadaveric fascia and bone anchors: disappointing early results. <i>Journal of Urology</i> 2001; 165: 1605–11.	154 women. Mean follow-up = 11 months.	Case series. Cadaveric fascial sling and bone anchors.	38% recurrent moderate to severe SUI. 17% reoperations – all due to failure of sling material.
Chaikin D, Rosenthal J, Blaivas J. Pubovaginal fascial sling for all types of stress urinary incontinence: long-term analysis. <i>Journal of Urology</i> 1998; 160: 1312–6.	251 women. Median follow-up = 3 years.	Case series. Autologous fascial sling.	92% cure or improvement with at least 1 year follow-up. Permanent urinary retention = 2%
Crivellaro S, Smith J, Kocjancic E, et al. Transvaginal sling using acellular human dermal allograft: safety and efficacy in 253 patients. <i>Journal of Urology</i> 2004; 172: 1374–8.	253 women. Mean follow-up = 18 months.	Questionnaires (IIQ and UDI). Cadaveric human dermal allograft (Repliform).	78% cure or improvement. De novo urgency = 5% Recurrent SUI = 15% Retention = 2% Slow vaginal wall healing = 2%
Elliott, DS, Boone TB. Is fascia lata allograft material trustworthy for pubovaginal sling repair? <i>Urology</i> 56: 772–6.	26 women. Mean follow-up = 15 months.	Solvent-dehydrated cadaveric fascia lata.	77% of patients completely dry. 92% used 1 or fewer pads a day.
Fitzgerald MP, Edwards SR, Fenner D. Medium-term follow-up on use of freeze-dried, irradiated donor fascia for sacrocolpopexy and sling procedures. <i>Int Urogynecol J</i> 2004; 15: 238–42.	27 women with sling procedure. Median follow-up = 12 months.	Freeze-dried, irradiated fascia lata allografts.	52% (14/27) failures with recurrent SUI after 2 weeks to 24 months.

Article title	Number of patients/ follow-up	Comments	Direction of conclusions
Fulford S, Flynn R, Barrington J, et al. An assessment of the surgical outcome and urodynamic effects of the pubovaginal sling for stress incontinence and the associated urge syndrome. <i>Journal of Urology</i> 1999; 162: 135–7.	85 women. Follow-up = 3 months.	Case series. Rectus fascial sling.	97% symptomatically cured. 78% of patients were satisfied.
Giri SK, Drumm J, Saunders JA, et al. Day-case sling surgery for stress urinary incontinence: feasibility and safety. <i>BJU International</i> 2005; 95: 827–32.	40 women. 6 month follow-up.	Porcine dermal sling.	90% cure of SUI or improvement.
Huang YH, Lin AT, Chen KK, et al. High failure rate using allograft fascia lata in pubovaginal sling surgery for female stress urinary incontinence. <i>Urology</i> 2001; 58: 943–6.	18 women. Mean follow-up = 9.2 months.	Solvent dehydrated gamma-irradiated human fascia lata.	Success = 72%. 28% (5/18) failure with full recurrence of SUI within 3 to 6 months.
Kaplan S, Santarosa R, Te A. Comparison of fascial and vaginal wall slings in the management of intrinsic sphincter deficiency. <i>Urology</i> 1996; 47: 885–9.	79 women (43 fascial slings, 36 vaginal wall slings).	Non-randomised controlled trial.	Persistent SUI: <ul style="list-style-type: none"> • Fascial = 5% • Vaginal = 3% Urge or urge incontinence: <ul style="list-style-type: none"> • Fascial = 16% • Vaginal = 11% Patients satisfied: <ul style="list-style-type: none"> • Fascial = 89% • Vaginal = 94%
Kuo HC. Comparison of video urodynamic results after the pubovaginal sling procedure using rectus fascia and polypropylene mesh for stress urinary incontinence. <i>Journal of Urology</i> 2001; 165: 163–8.	50 women. Mean follow-up = 2 years.	Quasi – randomised controlled trial. Patients assigned to rectus fascia or polypropylene mesh according to consecutive study entry.	Continence: <ul style="list-style-type: none"> • Fascial = 96% (23/24) • Mesh = 100% (26/26) Patient satisfaction: <ul style="list-style-type: none"> • Fascial = 92% (22/24) • Mesh = 92% (24/26) Mesh group had shorter hospital stay and fewer complications than rectus fascia.
Muller S, Steinbach F, Maurer F, et al. Long-term results of fascial sling procedures. <i>International Urogynecology Journal</i> 1993; 4: 203.	108 women. Mean follow-up = 5 years.	Case series.	75% success rate for patients with pure genuine SUI, 37% for patients with preoperative urge component.
O'Reilly K, Govier F. Intermediate term failure of pubovaginal slings using cadaveric fascia lata: a case series. <i>Journal of Urology</i> 2002; 167: 1356–8.	121 women. 12 month mean follow-up.	Case series. Cadaveric fascial sling.	7% (8/121) of patients had failure at 4 to 13 months.
Owens D, Winters JC. Pubovaginal sling using Duraderm graft: intermediate follow-up and patient satisfaction. <i>Neurourology & Urodynamics</i> 2004; 23: 115–8.	25 women. Mean follow-up = 15 months.	Case series. Duraderm allograft sling.	Cure or improvement at 6 months = 92%. Cure or improvement at 15 months = 68%. 76% satisfied.
Palma PCR, Dambros M, Riccetto CLZ, et al. Pubovaginal sling using the porcine small intestine submucosa for stress urinary incontinence. <i>Brazilian Journal of Urology</i> 2001; 27: 483–8.	30 women. Mean follow-up = 8 months.	Case series. Porcine small intestine submucosa.	93% (28/30) cure. Urinary retention = 10%.

Article title	Number of patients/ follow-up	Comments	Direction of conclusions
Reichelt O, Weirich T, Wunderlich H, et al. Pubovaginal cutaneous fascial sling procedure for stress urinary incontinence: 10 years' experience. <i>Urologia Internationalis</i> 2004; 72: 318–24.	129 women. Mean follow-up = 39 months.	Case series. Questionnaire (67% response rate). Autologous fascial sling.	62% cure or significant improvement. Worsening = 2% 26% completely dry. 63% satisfied.
Rodrigues P, Hering F, Meler A, et al. Pubo-fascial versus vaginal sling operation for the treatment of stress urinary incontinence: a prospective study. <i>Neurourology and Urodynamics</i> 2004; 23: 627–31.	232 women. Mean follow-up = 70 months (fascial sling), 45 months (vaginal sling).	Non-randomised controlled trial.	Total urinary control and no voiding dysfunction: • Fascial = 74% • Vaginal = 62% Obstruction and persistent voiding difficulty: • Fascial = 11% • Vaginal = 9%
Soergel T, Shott S, Heit M. Poor surgical outcomes after fascia lata allograft slings. <i>International Urogynecology Journal</i> 2001; 12: 247 – 53.	45 women. (33 autologous rectus fascia and 12 cadaveric fascia lata)	Non-randomised controlled trial.	Success: • Rectus fascia autograft = 79% • Fascia lata allograft = 33% p = 0.006
Viseshsindh W, Kochakarn W, Waikakul W, et al. A randomized controlled trial of pubovaginal sling versus vaginal wall sling for stress urinary incontinence. <i>Journal of the Medical Association of Thailand</i> 2003; 86: 308–15.	26 women. Median follow-up = 7 months.	Randomised controlled trial. Vaginal wall sling versus autologous fascial sling.	Persistence of SUI: • Fascial = 7% • Vaginal = 0% De novo urge incontinence: • Fascial = 13% • Vaginal = 9% Patients satisfied: • Fascial = 80% • Vaginal = 100%
Walsh IK, Nambirajan T, Donellan SM , et al. Cadaveric fascia lata pubovaginal slings: early results on safety, efficacy and patient satisfaction. <i>BJU International</i> 2002; 90: 415–9.	31 women. Mean follow-up = 13.5 months.	Case series. Cadaveric fascia lata.	93% complete resolution of SUI. 80% of patients would undergo procedure again.
Wang D, Bresette J, Smith J. Initial experience with acellular human dermal allograft (Repliform) pubovaginal sling for stress urinary incontinence. <i>Journal of Pelvic Medicine and Surgery</i> 2004; 10: 23–6.	115 women. Follow-up = 36 months.	Case series. Cadaveric human dermal allograft (Repliform).	95% cure or improvement. 85% of patients highly satisfied. 1% de novo urgency 5% recurrent SUI 3% retention
Wiedermann A, Otto M. Small intestinal submucosa for pubourethral sling suspension for the treatment of stress incontinence: first histopathological results in humans. <i>Journal of Urology</i> 2004; 172: 215–8.	15 women. Mean follow-up = 13 months.	Case series. Porcine small intestinal submucosa sling.	Recurrent SUI = 20% (3/15). At reoperation, no evidence of a specific tissue reaction. Only focal residues of the implant were found.
Wright E, Iselin C, Carr L, et al. Pubovaginal sling using cadaveric allograft fascia for the treatment of intrinsic sphincter deficiency. <i>Journal of Urology</i> 1998; 160: 759–62.	92 women (59 allograft, 33 autograft). Mean follow-up = 11.5 months.	Non-randomised controlled trial. Autologous versus cadaveric fascia slings.	No significant difference in efficacy. No infection or erosion. Allograft shortened operative time and hospital stay.

Appendix B: Literature search for biological slings for stress urinary incontinence

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in EMBASE, Current Contents, PreMedline and all EMB databases.

For all other databases a simple search strategy using the key words in the title was employed.

1	pelvicol.tw. (5)
2	(bio\$ adj10 sling\$.tw. (28)
3	stratasis.tw. (2)
4	tutoplast.tw. (27)
5	(collagen adj10 sling\$.tw. (25)
6	(fascia\$ adj10 sling\$.tw. (256)
7	(porcine adj10 sling\$.tw. (14)
8	or/1-7 (334)
9	allograft\$.tw. (31461)
10	xenograft\$.tw. (13297)
11	fascia/ (4787)
12	or/9-11 (48908)
13	sling\$.tw. (2215)
14	12 and 13 (139)
15	8 or 14 (374)
16	*urinary incontinence, stress/ (4047)
17	(stress adj5 incontinence).tw. (4597)
18	16 or 17 (5471)
19	15 and 18 (181)
20	female/ (4194301)
21	female\$.tw. (298885)
22	women.tw. (313906)
23	woman.tw. (80358)
24	or/20-23 (4223496)
25	19 and 24 (171)