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Summaries of the Safety/Adverse Effects of Vaginal Tapes/Slings/Meshes for Stress Urinary Incontinence and Prolapse

Final Report

Providing Consultancy & Research in Health Economics

JAMES MAHON, Associate
MARIA CIKALO, Associate
DANIELLE VARLEY, Research Assistant
JULIE GLANVILLE, Project Director

THE UNIVERSITY of York
INVESTORS IN PEOPLE

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GLOSSARY

AE	Adverse effects/events
BMI	Body mass index
HRQoL	Health related quality of life
ICS	International Continence Society
MHRA	Medicines and Healthcare Products Regulatory Agency
MUI	Mixed urinary incontinence
NICE	National Institute for Health and Clinical Excellence
PFMT	Pelvic floor muscle training
POP	
QoL	Quality of life
RCT	Randomised controlled trial
SPARC	Supra pubic arch sling
SR	Systematic review
SUI	Stress urinary incontinence
TMAS	The Medical Advisory Secretariat
TOT	Transobturator sling
TVT	Tension-free vaginal tape
TVT-O	Tension-free vaginal tape (obturator)
UDI	Urogenital Distress Inventory
UI	Urinary incontinence
USI	Urodynamic stress incontinence
UTI	Urinary tract infection
VAS	Visual analogue scale
YHEC	York Health Economics Consortium

Summary table of the Safety/Adverse Effects of Vaginal Tapes/Slings/Meshes for Stress Urinary Incontinence and Prolapse

	Postoperative pain/discomfort after 6 months	Erosion	Deterioration in sexual function six months postoperatively	Need for reoperation on sling/tape/mesh	Organ perforation (POP only)
Incontinence surgery					
TVT / SPARC	0.0% (0.0% - 1.5%) Included Studies = 3	1.1% (0.0% - 5.8% Included Studies = 24	9.3% (3.8% - 13.5%) Included Studies = 3	0.9% (0.5% - 6.0%) Included Studies = 6	N/A
TOT	0.9% (0.6% - 5.1%) Included Studies = 4	2.4% (0.0% - 5.6%) Included Studies = 25	2.5% (1.9% - 3.2%) Included Studies = 2	0.0% (-) Included Studies = 1	N/A
Single incision system	1.1% (0.0% - 1.9%) Included Studies = 3	0.0% (-) Included Studies = 1	No studies	No studies	N/A
Sling (fascial / pubovaginal)	No studies	0.0% (-) Included Studies = 1	No studies	No studies	N/A
Prolapse surgery: anterior/ posterior					
Synthetic non-absorbable	5.5% (-) n=1	6.5% (0.9%-19.6%) Included Studies = 13	15.3% (12.8%-17.7%) Included Studies = 2	4.8% (0.9%-10.9%) Included Studies = 9	2.1% (0.9%-2.8%) Included Studies = 4
Biological absorbable	2.7% (0.8%-7.5%) Included Studies = 3	1.2% (0.0%-21.4%) Included Studies = 7	No studies	3.2% (1.0%-5.4%) Included Studies = 2	0.0% (-) Included Studies = 1
Prolapse surgery: Uterine / vault					
Synthetic non-absorbable	2.0% (1.2%-2.3%) Included Studies = 3	5.5% (0.0%-25.6%) Included Studies = 31	14.5% (-) Included Studies = 1	4.0% (0.8%-7.1%) n =12	1.8% (0.4% - 7.9%) Included Studies = 16
Biological absorbable	No studies	No studies		No studies	No studies

Section 1: Introduction

This document presents summaries of the safety/adverse events of vaginal tapes/slings/meshes for stress urinary incontinence (SUI) and pelvic organ prolapse (POP).

These summaries have been developed using the data reported in systematic reviews of the effects and safety of vaginal tapes/slings/meshes, published in the last 10 years.

The methods for identifying the systematic reviews and more detailed information on the reviews' findings are presented in an earlier report (April 2012) commissioned from York Health Economics Consortium (YHEC), University of York, by the Medicines and Healthcare Products Regulatory Agency (MHRA).

In order to synthesise the data from these diverse reviews, we extracted data from 'relevant treatment arms/groups' (i.e. treatments that clearly evaluated a synthetic mesh or biological graft) from the individual studies within the reviews. The studies (or treatment arms/groups) had to report on one or more of the following outcomes: pain persisting after six months, mesh exposure, sexual problems or pain following the procedure, procedures to remove the device or organ perforation (for POP only).

In presenting findings for stress urinary incontinence (SUI), the data have been presented using the following groupings:

- Tension free trans-vaginal tape ("TVT") or supra pubic arch sling ("SPARC");
- Tape implanted through the obturator foramen using an inside out approach ("in-out TOT, including TVT-Obturator (TVT-O)" and tape implanted through the obturator foramen using an outside-in approach ("out-in TOT, including MONARC");
- Tape inserted with a single incision ("Single incision procedures, including TVT-Secur");
- Fascial or pubovaginal slings.

We note that SUI and USI appear in the studies and we have reported these as reported by the authors of the reviews. Stress urinary incontinence (SUI) is involuntary leakage of urine from the urethra on exertion or effort, straining or coughing. Urodynamic stress incontinence (USI) (formerly termed 'genuine stress incontinence') is the involuntary leakage of urine during increased abdominal pressure in the absence of a detrusor contraction, noted during filling cystometry.

In presenting findings for POP, we have grouped findings by whether the surgery was anterior/posterior or uterine/vault prolapse surgery and then by whether the mesh used was synthetic non-absorbable or biological absorbable.

Data have been selected only from trials with 50 or more patients tables of all included studies (or the ten largest studies where more than ten studies were found in the reviews) are provided underneath each text summary.

Not all the outcomes were consistently described in the systematic reviews: this can make comparison difficult. Some outcomes of interest were not reported in the recent systematic reviews identified: we note that it is possible that those outcomes may have been reported in individual study reports but were not reported in the systematic reviews.

Section 2: Stress Urinary Incontinence: Midurethral Slings

2.1 TENSION-FREE VAGINAL TAPE (TVT)

2.1.1 Outcome/Adverse Events (AE): Postoperative Pain/Discomfort after Six Months

Number of systematic reviews reviewed for this outcome: Two (Ogah, Latthe).

Number of unique studies identified within the reviews: Three (All RCTs).

Reported median and range in the percentage of patients experiencing this outcome from identified studies: 0.0% (0.0% to 1.5%).

Discussion: Three studies were identified that provided evidence for at least 50 patients for postoperative pain lasting at least six months for patients undergoing a single incision procedure. The studies ranged in size from 66 to 136 patients.

The highest reported rate of 1.5% (groin pain) was in the largest of the three studies. This was an RCT, conducted by a team based in Finland, of patients followed up for 12 months with SUI, BMI ≤ 35 and no previous incontinence surgery.

The remaining two studies found no incidences of groin or thigh pain at six and 12 months, respectively, in women who had urinary stress incontinence (USI) with urethral hypermobility and no previous incontinence surgery or vaginal prolapse.

Findings from the included studies show that cases of persistent postoperative pain with single incision appears to be rare, with the available evidence suggesting no more than one in 67 women will experience persistent pain 12 months after the procedure. The available evidence suggests that the rate may be far lower and affect less than one in 114 women. The evidence therefore suggests that as there is evidence that some women have persistent pain at 12 months, there will also be women who experience persistent pain at six months. However, the risk of pain a year after the operation to an individual woman with the same characteristics as women in the identified studies and treated in a similar clinical setting is low.

Study details are presented in Table 2.1. The * indicates that the country is the country of the lead author and it is uncertain whether this is also the country in which the study was conducted. NR indicates that the information was not reported in the review. However, this information may be reported in the original study report.

Table 2.1: TVT Outcome/adverse events (AE): Groin or thigh pain from all identified studies

Systematic Review	Study	Year	Type of study	Number of patients	Country	Type of pain	Mean age	Type of incontinence	Additional patient inclusion criteria	Exclusion criteria	Follow up (mean months)	Patients with AE	
												No.	%
Ogah 2010	Rinne	2008	RCT	136	Finland*	Groin pain	NR	SUI	History of SUI, indication for surgical treatment of stress incontinence, positive cough-stress test, Detrusor Instability Score (DIS) 7 or less	Previous incontinence surgery, PRV>100ml, more than 3 UTIs in past year, BMI>35, prolapse>second degree, past or present pelvic malignancy	12	2	1.5%
Ogah 2010	Meschia	2007	RCT	114	Italy*	Groin pain	NR	USI	USI and urethral hypermobility	Previous incontinence surgery, vaginal prolapse, coexisting pelvic pathology, detrusor overactivity	6	0	0.0%
Latthe 2007	Riva	2006	Prospective RCT	66	NR	Thigh pain	NR	USI	USI with urethral hypermobility, age 40–85 years, urethra cystocele of grade 0–2	Previous prolapse or continence surgery, vaginal wall repair	12	0	0.0%

2.1.2 Outcome/Adverse Events (AE): Deterioration of Sexual Function At Least 6 Months Postoperatively

Number of systematic reviews reviewed for this outcome: One (Jha).

Number of unique studies identified within the reviews: Three (All prospective cohort studies).

Reported median and range in the percentage of patients experiencing this outcome from identified studies: 9.3% (3.8% to 13.5%).

Discussion: Three studies were identified that provided evidence for at least 50 patients on deterioration of sexual function lasting at least six months following the insertion of TVT.

The studies ranged in size from 52 to 54 patients and so were relatively small compared to studies providing evidence for other outcomes and/or procedures.

One UK-based study was identified. This was the largest of the three studies and reported on 54 women with USI or mixed incontinence and no prolapsed. These women had a mean age of 49 and underwent a TVT procedure. At six months' follow up, 9.3% of women reported deterioration of sexual function.

The highest reported rate of 13.5% was from a prospective cohort study, conducted by a research team based in Austria. This study was of 52 women with SUI and a mean age of 60, who were followed up for 18 months. The lowest rate of 3.8% (at six months) was reported in a study by an Italian research team. This study included 53 women with USI and a mean age of 51 who explicitly did not have prolapse or detrusor overactivity.

Findings from the included studies show the majority of women undergoing a TVT procedure do not experience a deterioration of sexual function at six months, but that some do. The limited evidence suggests that in the UK the rate could be as high as one in 11 women, but similarly limited evidence from other countries suggest it could be as high as just over one in seven or as low as one in 26 women. The range of different rates could be a reflection of the different populations on whom the procedure was undertaken or an artefact of relatively small trials. The highest rate was in the study with the oldest women where it is not clear whether the women also suffered from prolapse. The studies are relatively small and so the evidence base is not substantial.

It must also be noted that each of the included studies specifically included *de novo* or worsening coital incontinence as a cause of deterioration of sexual functioning. The studies therefore did not solely look at painful sex that occurred or worsened after the operation, which was the focus for some studies for other procedures. The exception was the TOT procedure where studies looked at the identical outcome. This should be kept in mind when comparing the rates of sexual deterioration for TVT or TOT with other procedures.

Study details are presented in Table 2.2. The * indicates that the country is the country of the lead author and it is uncertain whether this is also the country in which the study was conducted. NR indicates that the information was not reported in the review. However, this information may be reported in the original study report.

Table 2.2: TVT Outcome/adverse events (AE): *De novo* sexual difficulties

Systematic Review	Study	Year	Type of study	Description of sexual difficulties	No. of patients	Country	Mean age	Type of incontinence	Additional patient inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
												No.	%
Jha 2012	Jha	2009	Prospective cohort	Deterioration of sexual function, including coital incontinence	54	UK	49.1	USI/MUI	NR	Prolapse	6	5	9.3%
Jha 2012	Ghezzi	2005	Prospective cohort	Deterioration of sexual function, including coital incontinence	53	Italy*	51	USI	USI	Prolapse or detrusor overactivity	6	2	3.8%
Jha 2012	Marszalek	2007	Prospective cohort	Deterioration of sexual function, including coital incontinence	52	Austria*	59.9	SUI	SUI	NR	18	7	13.5%

2.1.3 Outcome/Adverse Events (AE): Erosion

Number of systematic reviews reviewed for this outcome: Four (Ogah, Cody, Novara, Latthe).

Number of unique studies identified within the reviews: Twenty-four (22 RCTs, two case series).

Reported median and range in the percentage of patients experiencing this outcome from identified studies: 1.1% (0.0% to 5.8%).

Discussion: Of the 24 studies identified from the systematic reviews providing evidence on erosion following TVT surgery, eleven provided information for 100 or more women undergoing the procedure.

The largest study was based in Australia and included 301 women aged 19 years of over with SUI or mixed incontinence, who were not pregnant and had no major voiding dysfunction or prolapse. This study reported a rate of erosion of 0.3%, by six weeks, compared with the highest reported rate of 6.0% at three months in another study, by an Australian research team. The latter study assessed 182 patients with USI who had failed conservative management or required prophylactic incontinence surgery whilst having surgery for prolapse.

Two of the studies with 100 or more patients and six studies with fewer than 100 patients found no cases of erosion with TVT.

The findings from the included studies show that vaginal/mesh erosion can occur with TVT surgery. The risk of erosion is most likely small, with a minority of women experiencing erosion following the procedure. The balance of evidence from the median of all trials suggests that the risk is around one in 83 women, but there is evidence that it may be occur in as many as one in 17 women or as few as one in 301 women.

The wide range of risk identified from the studies in these systematic reviews may be the result of differences in the ways the studies defined, diagnosed and recorded erosion. The duration of follow up in the studies does not appear to be a factor as six of the studies reporting no cases of erosion had follow up for one year.

It is possible that other factors, such as surgical skill and/or individual patient characteristics, play a significant role in an individual woman's likelihood of experiencing erosion with TOT surgery.

Study details of the eleven studies with more than 100 women are presented in Table 2.3. The * indicates that the country is the country of the lead author and it is uncertain whether this is also the country in which the study was conducted. NR indicates that the information was not reported in the review. However, this information may be reported in the original study report.

Table 2.3: TVT Outcome/adverse events (AE): erosion

Systematic Review	Study	Year	Type of study	No. of patients	Country	Mean age	Type of incontinence	Additional patient inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
											No.	%
Ogah 2010	Lord	2006	RCT	301	Australia	NR	SUI or MUI	NR	<18 years of age, pregnant, major voiding dysfunction (urinary flow rate<10ml/s or residual volume >150ml)	6 weeks	1	0.3%
Ogah 2010	Meschia	2006	RCT	296	Italy*	NR	USI	USI and urethral hypermobility	Previous anti incontinence surgery, vaginal prolapse, detrusor overactivity	NR	8	2.7%
Ogah 2010	Lim	2005	RCT	182	Australia*	58.4	USI	Failed conservative management or required prophylactic incontinence surgery during prolapse repair	Women were excluded with a past history of urogenital malignancy, fistula or pelvic radiotherapy	3	11	6.0%
Cody 2003	Ward	2001	RCT	175	UK and Republic of Ireland	49	USI	Completed family	Detrusor instability, vaginal prolapse requiring treatment, previous prolapse or incontinence surgery, major degree of voiding dysfunction	24	1	0.6%
Novara 2010	Wang W	2009	RCT	154	China	NA	SUI	NR	NR	NR	3	1.9%

Systematic Review	Study	Year	Type of study	No. of patients	Country	Mean age	Type of incontinence	Additional patient inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
											No.	%
Ogah 2010	Rechberger	2007	RCT	140	Poland*	NR	SUI	NR	Mixed urinary incontinence, VLPP<60, prolapse>Stage II	12	4	2.9%
Ogah 2010	Rinne	2008	RCT	134	Finland*	NR	SUI	History of stress urinary incontinence, indication for surgical treatment of stress incontinence, positive cough-stress test, Detrusor Instability Score (DIS) 7 or less	Previous incontinence surgery, PRV>100ml, more than 3 UTIs in past year, BMI>35, prolapse>second degree, malignancy of the pelvis past or present	12	0	0.0%
Novara 2010	Naumann	2006	RCT	123	Germany*	NR	SUI	NR	NR	NR	3	2.4%
Ogah 2010	Araco	2008	RCT	108	Italy*	54	SUI	Symptomatic SUI Grade 1 and 2a	ISD, overactive bladders, prolapse, recurrent SUI	12	1	0.9%
Cody 2003	Fynes	2000	Case series	103	Australia	60	USI/MUI	NR	NR	6	1	1.0%
Cody 2003	Niemczyk	2001	Case series	100	USA	61.8	SUI	Failed PFMT, oestrogen replacement or urinary sphincter tone-enhancing medication	Active UTI	2	0	0.0%

2.1.4 Outcome/Adverse Events (AE): Repeat Operation on Tape/Mesh/Sling

Number of systematic reviews reviewed for this outcome: Three (Cody, Rehman, Latthe).

Number of unique studies identified within the reviews: Six (One RCT, five case series).

Reported median and range in the percentage of patients experiencing this outcome from identified studies: 1.6% (0.5% to 6.0%)

Discussion: Six studies were identified that provided evidence for at least 50 patients on repeat operations on TVT following implantation. Follow up in all studies was for at least 12 months. The studies ranged in size from 62 to 404 patients.

The largest study also reported the lowest rate of repeat operation – specifically, cutting of the tape – of 0.5% of patients. This study was a case series of 402 women with USI or mixed urinary incontinence, with a mean age of 57, who were followed for 12 months.

The highest reported rate was in a French study of 100 women with USI and without urge incontinence, and with a mean age of 60, who were followed for 12 months. This study reported 6.0% of women required tape resection or ablation.

The findings from the included studies show that reoperation on tape can occur with TVT surgery. The risk of reoperation is most likely small, affecting a minority of women. The balance of evidence from the median of all trials suggests that around one in 63 women will require some form of operation on the tape, but there is evidence that it may be as many as one in 17 women or as few as one in 202 women.

The wide range of risk identified from the studies in these systematic reviews may be the result of differences in the ways the studies defined, diagnosed and recorded reoperation. Some of the studies looked at tape cutting and/or removal whilst others looked at repositioning. However, both the highest and lowest reported rates were for tape cutting or removal so this is unlikely to explain the difference.

It is possible that the variation in the evidence is due to other factors, such as surgical skill and/or individual patient characteristics. These factors may play a significant role in an individual woman's likelihood of requiring reoperation on the tape.

Study details are presented in Table 2.4. NR indicates that the information was not reported in the review. However, this information may be reported in the original study report.

Table 2.4: TVT Outcome/adverse events (AE): reoperation on tape/mesh/sling

Systematic Review	Study	Year	Type of study	Type of operation	No. of patients	Country	Mean age	Type of incontinence	Additional patient inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
												No.	%
Cody 2003	Meschia	1999, 2000, 2001	Case series	Tape cut	404	Italy	57	USI, MUI	NR	NR	12	2	0.5%
Cody 2003	Lebret	2001	Case series	Tape resection or surgical ablation	100	France	60.2	USI	Failed PFMT	Urge incontinence	12	6	6.0%
Cody 2003	Kinn	2001	Case series	Tape cut	75	Sweden	59.8	SUI	Failed PFMT, urge incontinence, could have had previous incontinence surgery	Neurological conditions	24	1	1.3%
Rehman 2011	Arunkalaivanan	2003	Case series	Sling release	68	NR	NR	USI	NR	Detrusor overactivity	12	2	2.9%
Latthe 2007	Riva	2006	RCT	Sling repositioning	66	NR	No mean. Range 40-85	USI	USI with urethral hypermobility age 40–85, urethra cystocele grade 0–2	Previous prolapse or continence surgery or vaginal wall repair with mesh	12	1	1.5%
Cody 2003	Haab	2001	Case series	Sling release	62	France	62.8	SUI	Urethral hypermobilty	Urge incontinence, detrusor overactivity,	16	1	1.6%

Systematic Review	Study	Year	Type of study	Type of operation	No. of patients	Country	Mean age	Type of incontinence	Additional patient inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
												No.	%
										sphincter deficiency, prolapse			

2.2 TRANSOBTURATOR (TOT) IN-OUT (INCLUDING TVT-O)

2.2.1 Outcome/Adverse Events (AE): Postoperative Pain/Discomfort after Six Months

Number of systematic reviews reviewed for this outcome: Two (Madhuvrata, Ogah).

Number of unique studies identified within the reviews: Four (Two RCTs, two prospective cohorts).

Reported median and range in the percentage of patients experiencing this outcome from identified studies: 0.90% (0.6% to 5.1%).

Discussion: Four studies were identified that provided evidence for at least 50 patients on postoperative pain lasting at least six months for patients undergoing a TOT procedure. The studies ranged in size from 100 to 161 patients.

The largest study with the longest follow up (mean of 38 months) reported the lowest rate of pain (groin or thigh) at 0.6%. This study was of Dutch women with SUI undergoing no concomitant procedures at the time of the TOT procedure. Two other studies with over 100 patients and follow up at 12 months reported rates of persistent groin and/or thigh pain of 1.0% or less.

The highest rate of persistent pain was reported in a study of 117 women undergoing TOT with USI and urethral hypermobility. Women were excluded if they had undergone previous incontinence surgery or had coexisting pelvic pathology. This study reported a rate of persistent groin pain at six months' follow up of 5.1%.

The included evidence suggests that persistent pain at six months is a potential outcome with TOT and the risk to an individual woman with the same characteristics as women in the identified studies and treated in a similar clinical setting is not insignificant. The risk may be as high as one in 20 at six months postoperatively. However, the evidence also suggests that by 12 months postoperatively the risk falls significantly, and at this point the rate is at most one in 100 women suffering from persistent pain.

Study details are presented in Table 2.5. The * indicates that the country is the country of the lead author and it is uncertain whether this is also the country in which the study was conducted. NR indicates that the information was not reported in the review. However, this information may be reported in the original study report.

Table 2.5: TOT Outcome/adverse events (AE): groin or thigh pain from all identified studies

Systematic Review	Study	Year	Type of study	No. of patients	Country	Type of pain	Mean age	Type of incontinence	Additional patient inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
												No.	%
Madhuvrata 2012	Debodinance	2007	Prospective cohort	100	France	Groin or thigh pain	NA	USI	Urodynamic stress incontinence corrected by TVT test	No concomitant procedures	12	1	1.0%
Ogah 2010	Meschia	2007	RCT	117	Italy*	Groin pain	NR	USI	USI and urethral hypermobility	Previous incontinence surgery, vaginal prolapse, coexisting pelvic pathology, detrusor overactivity	6	6	5.1%
Ogah 2010	Rinne	2008	RCT	131	Finland*	Groin pain	NR	SUI	History of stress urinary incontinence, indication for surgical treatment of stress incontinence, positive cough-stress test,	Previous incontinence surgery, PRV>100ml, more than 3 UTIs in past year, BMI>35, prolapse >second degree, past or present	12	1	0.8%

Systematic Review	Study	Year	Type of study	No. of patients	Country	Type of pain	Mean age	Type of incontinence	Additional patient inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
												No.	%
									Detrusor Instability Score (DIS) 7 or less	pelvic malignancy			
Madhuvrata 2012	Houwert	2009	Prospective Cohort	161	Netherlands	Groin / thigh pain	NR	SUI	Women with indication for surgical treatment of SUI.	No concomitant procedures. Recurrent UTI, significant urge incontinence, post voiding retention >150ml or bladder capacity <100ml	38	1	0.6%

2.2.2 Outcome/Adverse Events (AE): Deterioration of Sexual Function 6 Months Postoperatively

Number of systematic reviews reviewed for this outcome: One (Jha).

Number of unique studies identified within the reviews: Two (One prospective cohort study and one retrospective cohort study).

Reported median and range in the percentage of patients experiencing this outcome from identified studies: 2.5% (1.9% to 3.2%)

Discussion: Two studies were identified that provided evidence for at least 50 patients on deterioration of sexual function lasting at least six months following the insertion of TOT.

The highest reported rate of 3.2% (groin pain) was in the smaller of the two studies, which was conducted by a research team based in Egypt. This study followed up 62 women with SUI and an average age of 41 for a mean of 12 months.

The lowest rate of 1.9% (at a mean follow up of 14.7 months) was reported in a US study of 103 women with USI, with a mean age of 55, who explicitly did not have prolapse or require concomitant surgery at the time of TOT insertion.

Findings from the included studies show that deterioration of sexual function at six months appears to be low and occur in a minority of women undergoing a TOT procedure. Whilst there is no direct evidence of the outcome at six months, the evidence suggests that the rate 12 months postoperatively could be as high as one in 31 women but could be as low as one in 53 women. The evidence base is relatively weak being based on one study of just over 100 women and one of just over 60 women, with no evidence directly from a UK setting.

It must also be noted that each of the included studies specifically included *de novo* or worsening coital incontinence as a cause of deterioration of sexual functioning. The studies therefore did not solely look at painful sex that occurred or worsened after the operation, which was the focus for some studies for other procedures. The exception was the TVT procedure where studies looked at the identical outcome. This should be kept in mind when comparing the rates of sexual deterioration for TVT or TOT with other procedures.

Study details are presented in Table 2.6. The * indicates that the country is the country of the lead author and it is uncertain whether this is also the country in which the study was conducted. NR indicates that the information was not reported in the review. However, this information may be reported in the original study report.

Table 2.6: TOT Outcome/adverse events (AE): deterioration of sexual function six months postoperatively

Systematic Review	Study	Year	Type of study	Description of sexual difficulties	No. of patients	Country	Mean age	Type of incontinence	Additional patient inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
												No.	%
Jha 2012	Murphy	2008	Retrospective cohort	Deterioration of sexual function, including coital incontinence	103	USA*	54.8	USI	NR.	Prolapse, concomitant surgery	14.7	2	1.9%
Jha 2012	El Enen	2009	Prospective cohort	Deterioration of sexual function, including coital incontinence	62	Egypt*	40.5	SUI	Neurologically intact	No other surgical diseases	12	2	3.2%

2.2.3 Outcome/Adverse Events (AE): Erosion

Number of systematic reviews reviewed for this outcome: Four (Ogah, Cody, Novara, Latthe).

Number of unique studies identified within the reviews: Twenty-five (23 RCTs, two prospective cohort studies).

Reported median and range in the percentage of patients experiencing this outcome from identified studies: 2.4% (0.0% to 5.9%).

Of the 25 studies identified from the systematic reviews providing evidence on erosion following TOT surgery, eleven provided information for 100 or more women undergoing the procedure.

The largest study was based in the UK and included 341 women with USI or MUI and no prolapse. Women could have had previous incontinence surgery. This study reported a rate of erosion by 12 month follow up of 2.3%, compared with the highest reported rate of 5.6% in a German study of 125 patients with SUI.

Two of the studies with 100 or more patients and three studies with fewer than100 patients found no cases of erosion with TOT.

The findings from the included studies show that vaginal/mesh erosion can occur with TOT surgery. The risk of erosion is most likely small with a minority of women experiencing erosion following the procedure. The balance of evidence from the median of all trials and from the largest UK study suggests that this risk is around one in 40 women, but there is evidence that it may be occur in as many as one in 18 women or fewer than one in 114 women.

The wide range of risk identified from the studies in these systematic reviews may be the result of differences in the ways the studies defined, diagnosed and recorded erosion. Duration of follow up in the studies does not appear to be a factor as two of the studies which reported no cases of erosion had follow up for one year.

It is possible that other factors, such as surgical skill and/or individual patient characteristics, play a significant role in an individual woman's likelihood of experiencing erosion with TOT surgery.

Study details of the eleven studies with more than 100 women are presented in Table 2.7. The * indicates that the country is the country of the lead author and it is uncertain whether this is also the country in which the study was conducted. NR indicates that the information was not reported in the review. However, this information may be reported in the original study report.

Table 2.7: TOT Outcome/adverse events (AE): erosion (ten largest studies shown)

Systematic Review	Study	Year	Type of study	No. of patients	Country	Mean age	Type of incontinence	Additional patient inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
											No.	%
Madhuvrata 2012	Abdel-Fattah	2010	Prospective Cohort	341	UK	NA	USI/Mixed incontinence	USI or mixed incontinence but predominant SI, previous incontinence surgery, failed or declined PFMT.	Predominant overactive bladder symptoms, diabetes or pelvic organ prolapse, neurological conditions	12	8	2.3%
Novara 2010***	Rechberger	2009	RCT	197	Poland*	NR	SUI	NR	Prolapse >stage I	NR	5	2.5%
Madhuvrata 2012	Houwert	2009	Prospective Cohort	161	Netherlands	NR	SUI	Women with indication for surgical treatment of SUI.	No concomitant procedures. Recurrent UTI, significant urge incontinence, post voiding retention >150ml or bladder capacity <100ml	38	5	3.1%
Ogah 2010	Rechberger	2007	RCT	156	Poland*	NR	SUI	NR	Mixed urinary incontinence, VLPP<60, prolapse>	12	4	2.6%

Systematic Review	Study	Year	Type of study	No. of patients	Country	Mean age	Type of incontinence	Additional patient inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
											No.	%
									Stage II			
Novara 2010***	Wang W	2009	RCT	146	China	NA	SUI	NR	NR	NR	3	2.1%
Ogah 2010	Rinne	2008	RCT	131	Finland*	NR	SUI	History of stress urinary incontinence, indication for surgical treatment of stress incontinence, positive cough-stress test, Detrusor Instability Score (DIS) 7 or less	Previous incontinence surgery, PRV>100ml, more than 3 UTIs in past year, BMI>35, prolapse>second degree, malignancy of the pelvis past or present	12	1	0.8%
Novara 2010***	Naumann	2006	RCT	125	Germany*	NR	SUI	NR	NR	NR	7	5.6%
Latthe 2007	Meschia	2007	RCT	117	Italy*	NR	USI and urethral hypermobility	Primary USI and urethra hypermobility	NR	9	1	0.9%
Ogah 2010	Liapis	2008	RCT	114	Greece	NR	USI	Concomitant gynaecological operations were allowed	Detrusor overactivity, previous anterior vaginal wall surgery, prolapse greater than	12	0	0.0%

Systematic Review	Study	Year	Type of study	No. of patients	Country	Mean age	Type of incontinence	Additional patient inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
											No.	%
									stage 1, MUCP<20			
Ogah 2010	Araco	2008	RCT	100	Italy*	54	SUI	Symptomatic SUI Grade 1 and 2a	ISD, overactive bladders, prolapse, recurrent SUI	12	3	3.0%
Ogah 2010	Lee	2008	RCT	100	NR	NR	USI	USI	NR	12	0	0.0%

2.2.4 Outcome/Adverse Events (AE): Repeat Operation on Tape/Mesh/Sling

Number of systematic reviews reviewed for this outcome: One (Latthe).

Number of unique studies identified within the reviews: One (RCT).

Reported median and range in the percentage of patients experiencing this outcome from identified studies: 0% (N/A).

Discussion: One study of 50 or more patients was identified which reported reoperation rates on slings after a traditional sling operation. This study was an RCT which included 65 women aged between 40 and 85 with USI and no previous prolapse or incontinence surgery. Patients were followed up for 12 months and 3.1% required repeat surgery during that time to reposition the sling.

The available evidence indicates that repeat sling operations on a patient with a traditional sling within 12 months postoperatively is a potential outcome, but the risk to an individual woman with the same characteristics as women in the identified study and treated in a similar clinical setting is low.

The available evidence suggests that one in every 32 to 33 women having TOT implanted will require a further operation to reposition the sling within 12 months.

The evidence is limited, based upon fewer than 100 operations and potentially just from one surgical centre. The study also looked solely at repositioning rather than removal, as is the case for other studies for other procedures. As such, this finding should be treated with caution; comparison with other procedures is problematic.

The study details are presented in Table 2.8. NR indicates that the information was not reported in the review. However, this information may be reported in the original study report.

Table 2.8: TOT Outcome/adverse events (AE): reoperation on tape/mesh/sling

Systematic Review	Study	Year	Type of study	Type of operation	No. of patients	Country	Mean age	Type of incontinence	Additional patient inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
												No.	%
Latthe 2007	Riva	2006	Prospective RCT	Sling repositioning	65	NR	No mean. Range 40-85	USI	USI with urethral hypermobility, urethra cystocele grade 0–2	Previous prolapse or continence surgery or vaginal wall repair with mesh	12	2	3.1%

2.3 SINGLE INCISION SYSTEM (INCLUDING TVT-SECUR)

2.3.1 Outcome/Adverse Events (AE): Postoperative Pain/Discomfort after 6 Months

Number of systematic reviews reviewed for this outcome: One (Walsh).

Number of unique studies identified within the reviews: Three (Two RCTs, one case series).

Reported median and range in the percentage of patients experiencing this outcome from identified studies: 1.1% (0% to 1.9%).

Discussion: Three studies were identified that provided evidence for at least 50 patients for postoperative pain lasting at least six months for patients undergoing a single incision procedure. All three studies collected data on persistent pain 12 months after the initial operation. The studies ranged in size from 52 to 115 patients.

The highest reported rate of 1.9% (groin pain) was in a French study of 52 patients with USI. The largest study of 115 patients in Korea reported no patients suffering from persistent groin/thigh pain at 12 months post operatively.

Findings from the included studies show that cases of persistent postoperative pain with single incision appear rare, with the available evidence suggesting that no more than one in 52 women will experience persistent pain 12 months after the procedure. The available evidence suggests that the rate may be far lower and affect fewer than one in 115 women. The evidence therefore suggests that persistent pain at 12 months is a potential outcome with single incision, but the risk to an individual woman with the same characteristics as women in the identified studies and treated in a similar clinical setting is low.

Study details of are presented in Table 2.9. The * indicates that the country is the country of the lead author and it is uncertain whether this is also the country in which the study was conducted. NR indicates that the information was not reported in the review. However, this information may be reported in the original study report.

Table 2.9: Single incision systems: Outcome/adverse events (AE): groin or thigh pain from all identified studies

Systematic Review	Study	Year	Type of study	Number of patients	Country	Type of pain	Mean age	Type of incontinence	Additional patient inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
												No.	%
Walsh 2011	Kim	2010	RCT	115	Korea	Groin or thigh	56	USI	Could include detrusor overactivity	NR	12	0	0.0%
Walsh 2011	Neuman	2008	Case series	90	Israel*	Thigh	54	USI	NR	NR	12	1	1.1%
Walsh 2011	Debodiance	2008	Case series	52	France*	Groin	56	USI	NR	NR	12	1	1.9%

2.3.2 Outcome/Adverse Events (AE): De Novo Sexual Difficulties

Number of systematic reviews reviewed for this outcome: Zero.

Number of unique studies identified within the reviews: Zero.

Reported median and range in the percentage of patients experiencing this outcome from identified studies: N/A.

Discussion: No studies were found that provided evidence for this adverse event for this procedure.

2.3.3 Outcome/Adverse Events (AE): Erosion

Number of systematic reviews reviewed for this outcome: One (Abdel-Fattah).

Number of unique studies identified within the reviews: One (RCT).

Reported median and range in the percentage of patients experiencing this outcome from identified studies: 0% (N/A).

Discussion: One study of 50 or more patients was identified which reported rates of erosion of patients undergoing a single incision procedure. This study was an RCT that included 86 women with USI receiving a TVT-Secur sling in Belgium and the Netherlands. The review provided limited evidence about the patients included in the trial. The rate of erosion was reported to be 8.1%.

The available evidence suggests that fewer than one in 12 women having a single incision procedure suffer from erosion within the first 12 months following operation. The evidence is very limited, however, being based upon a single study of fewer than 100 patients. As such, this finding should be treated with caution.

Whilst the evidence is limited to one study, this study does indicate that erosion is a potential outcome for women undergoing a single incision procedure and may occur in a minority of patients.

Study details are presented in Table 2.10. NR indicates that the information was not reported in the review. However, this information may be reported in the original study report.

Table 2.10: Single incision systems: Outcome/adverse events (AE): erosion

Systematic Review	Study	Year	Type of study	Number of patients	Country	Mean age	Type of incontinence	Additional patient inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
											No.	%
Abdel-Fattah 2011a	Hinoul	2010	RCT	86	Netherlands and Belgium	NR	USI	Positive stress test	NR	12	7	8.1%

2.3.4 Outcome/Adverse Events (AE): Repeat Operation On Tape/Mesh/Sling

Number of systematic reviews reviewed for this outcome: Zero.

Number of unique studies identified within the reviews: Zero.

Reported median and range in the percentage of patients experiencing this outcome from identified studies: N/A.

Discussion: No studies were found that provided evidence for this adverse event for this procedure.

2.4 FASCIAL OR PUBOVAGINAL SLING

2.4.1 Outcome/Adverse Events (AE): Pain/Discomfort

Number of systematic reviews reviewed for this outcome: Zero.

Number of unique studies identified within the reviews: Zero.

Reported range in the percentage of patients experiencing this outcome from identified studies: N/A.

Discussion: No studies were found that provided evidence for this adverse event for this procedure.

2.4.2 Outcome/Adverse Events (AE): Deterioration in Sexual Function Six Months Post Operatively

Number of systematic reviews reviewed for this outcome: Zero.

Number of unique studies identified within the reviews: Zero.

Reported range in the percentage of patients experiencing this outcome from identified studies: N/A.

Discussion: No studies were found that provided evidence for this adverse event for this procedure.

2.4.3 Outcome/Adverse Events (AE): Erosion

Number of systematic reviews reviewed for this outcome: One (Ogah).

Number of unique studies identified within the reviews: One (RCT).

Reported range in the percentage of patients experiencing this outcome from identified studies: 0% (N/A).

Discussion: One RCT of more than 50 patients was identified that provided evidence on the rate of erosion following traditional sling surgery. The country in which the RCT was performed could not be identified from the systematic review.

The patients in the RCT had SUI but 61% of patients also had urge incontinence. Patients were excluded for a range of urological conditions. There were no reported instances of erosion.

The available evidence suggests that erosion is rare with traditional sling and no instance could be found in a trial of 67 patients who underwent the procedure. The evidence base is weak, being limited to this one study that may have been conducted in a single surgical centre.

Study details are presented in Table 2.11. NR indicates that the information was not reported in the review. However, this information may be reported in the original study report.

Table 2.11: Fascial or pubovaginal slings: outcome/adverse events (AE): erosion

Systematic Review	Study	Year	Type of study	Number of patients	Country	Mean age	Type of incontinence	Patient criteria	Follow up (Mean months)	Number of patients with AE	Percentage patients with AE
Ogah 2010	Basok	2008	RCT	67	NR	NR	SUI (but mixed with urge incontinence in 61% of patients)	Patients with ISD, prolapse or grade III or IV cystocele were excluded	12	0	0.0%

2.4.4 Outcome/Adverse Events (AE): Reoperation Rates on Mesh/Tape/Sling

Number of systematic reviews reviewed for this outcome: Zero.

Number of unique studies identified within the reviews: Zero.

Reported range in the percentage of patients experiencing this outcome from identified studies: N/A.

Discussion: No studies were found that provided evidence for this adverse event for this procedure.

Section 3: Pelvic Organ Prolapse: Anterior/Posterior

We identified two systematic reviews that evaluated the efficacy and safety of mesh or grafts in surgery for pelvic organ prolapse. Each of the reviews had different objectives: Jia reported the results by the type of repair: anterior, posterior, or both (Jia 2007) and Maher (2010; 2011) compared all types of surgical management for pelvic organ prolapse.

3.1 NON- ABSORBABLE SYNTHETIC MESH

3.1.1 Outcome/Adverse Events (AE): Postoperative Pain/Discomfort after 6 Months

Number of systematic reviews reviewed for this outcome: One (Jia).

Number of unique studies identified within the reviews: One (Case series).

Reported median and range in the percentage of patients experiencing this outcome from identified studies: 5.5%.

Discussion: One study of 50 or more patients was identified which reported rates of postoperative pain 6 months after non-absorbable synthetic mesh repair for anterior/posterior prolapse. This study was a case series of 56 women in France with a mean age of 63 who required repair of grade II to IV cystocele. After follow up for a mean of 37 months, 5.5% reported localised pain related to mesh shrinkage.

The available evidence suggests that one in 18 women having non-absorbable synthetic mesh repair for anterior/posterior prolapse will experience post-operative pain at least six months after surgery and possibly for significantly longer.

The evidence is limited, being based on around 50 operations potentially from just one surgical centre. As such, this finding should be treated with caution; comparison with other procedures is problematic.

Study details of presented in Table 3.1. NR indicates that the information was not reported in the review. However, this information may be reported in the original study report.

Table 3.1: Non-absorbable synthetic mesh: outcome/adverse events (AE): postoperative pain/discomfort after six months

Systematic Review	Study	Year	Type of study	Number of patients	Country	Type of pain	Mean age	Additional patient inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
											No.	%
Jia 2007	De Tayrac	2006	Case series	55	France	Local pain around mesh shrinkage	62.7	Women with symptomatic stage 2 to 4 cystocele	NR	37 months	3	5.50 %

3.1.2 Outcome/Adverse Events (AE): Deterioration of Sexual Function Six Months Postoperatively

Number of systematic reviews reviewed for this outcome: Two (Jia, Maher).

Number of unique studies identified within the reviews: Two (One RCT, one case series).

Reported median and range in the percentage of patients experiencing this outcome from identified studies: 15.3% (12.8% to 17.7%).

Discussion: Two studies were identified that provided evidence for at least 50 patients on deterioration of sexual function lasting at least six months after non-absorbable synthetic mesh repair for anterior/posterior prolapse. Both studies reported rates of *de novo* dyspareunia.

The highest reported rate of 17.7% was in the smaller of the two studies. This study was of 62 women in Australia with symptomatic prolapse of at least grade II, who were followed up for 12 months postoperatively.

The lowest rate of 12.8% (at a mean follow up of 13 months) was reported in a French study of 78 women with a mean age of 63, also with prolapse of at least grade II.

Findings from the included studies show that deterioration of sexual function in the form of new onset of painful sex at six months postoperatively appears to occur in a significant minority of women undergoing non-absorbable synthetic mesh repair for anterior/posterior prolapse. Whilst there is no direct evidence of the outcome at six months, the evidence suggests that the rate 12 months postoperatively could be between around one in six and one in eight women.

The evidence base is relatively weak, being based on two studies of just under 80 women, with no evidence directly from a UK setting. As such, this finding should be treated with caution.

Study details of are presented in Table 3.2. NR indicates that the information was not reported in the review. However, this information may be reported in the original study report.

Table 3.2: Non-absorbable synthetic mesh: outcome/adverse events (AE): deterioration of sexual function 6 months postoperatively

Systematic Review	Study	Year	Type of study	Description of sexual difficulties	No. of patients	Country	Mean age	Inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
											No.	%
Jia 2007	De Tayrac	2007	Case series	Dyspareunia (de novo)	78	France	63	Symptomatic vaginal wall prolapse at stage 2 to 4	NR	13	10	12.8%
Maher 2010	Lim	2007	RCT	Dyspareunia (de novo)	62	Australia	NR	Symptomatic prolapse >=stage 2	NR	12	11	17.7%

3.1.3 Outcome/Adverse Events (AE): Erosion

Number of systematic reviews reviewed for this outcome: Two (Jia, Maher).

Number of unique studies identified within the reviews: Thirteen (Five RCTs, eight case series)

Reported median and range in the percentage of patients experiencing this outcome from identified studies: 6.5% (0.9% to 19.6%).

Discussion: Of the 13 studies identified from the systematic reviews providing evidence on erosion following non-absorbable synthetic mesh repair for anterior/posterior prolapse, six provided information for more than 100 women undergoing the procedure. Limited information on the patients included in most of the studies was provided in the systematic reviews.

The largest study was based in France and included 325 women with a mean age of 63. This study reported a rate of erosion of 0.9% over a mean 14.6-month follow up. This was the lowest rate reported across all studies.

The highest reported rate of erosion, 19.6%, was in another French study of 138 women with a mean age of 62 who were followed up for a median of 32 months.

The findings from the included studies show that vaginal/mesh erosion can occur following non-absorbable synthetic mesh repair for anterior/posterior prolapse. The balance of evidence from the median of all trials suggests that this risk is around 1 in 15 women, but there is evidence that it may occur in as many as 1 in 5 women or fewer than 1 in 111 women.

The wide range of risk identified from the studies may be the result of differences in the ways the studies defined, diagnosed and recorded erosion, and in the severity of erosion recorded. Duration of follow up in the studies does not appear to be a significant factor, as the study with the longest follow up of over three years had one of the lowest reported rates of erosion at 2.1%.

It is possible that the wide variance in reported rates means that other factors, such as surgical skill and/or individual patient characteristics, play a significant role in an individual woman's likelihood of experiencing erosion following non-absorbable synthetic mesh repair for anterior/posterior prolapse.

Study details of the ten largest studies are presented in Table 3.3. NR indicates that the information was not reported in the review. However, this information may be reported in the original study report.

Table 3.3: Non-absorbable synthetic mesh: outcome/adverse events (AE): erosion (ten largest studies only)

Systematic Review	Study	Year	Type of study	No. of patients	Country	Mean age	Inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
										No.	%
Jia 2007	Rozet	2004	Case series	325	France	63	NR	NR	14.6	3	0.9%
Jia 2007	Collinet	2006	Case series	277	France	64	Pelvic prolapse	NR	NR	34	12.3%
Jia 2007	Flood	1998	Case series	142	Canada	65	Women undergoing extended anterior colporrhaphy reinforced	NR	3.2 years	3	2.1%
Jia 2007	Deffieux	2007	Case series	138	France	62	NR	NR	32	27	19.6%
Jia 2007	Fatton	2007	Case series	106	France	63.2	Recurrent vaginal prolapse or primary cases with significant prolapse. All had a prolapse with at least a >=3 component	NR	3	5	4.7%
Maher 2010	Nieminen	2008	RCT	104	NR	NR	Post-menopausal	NR	24	18	17.0%
Jia 2007	Dwyer	2004	Case series	97	Australia	61	Recurrent or large anterior and posterior compartment vaginal prolapse (Baden-Walker >=2) large fascia defect unsuitable for standard repair alone	NR	29	9	9.3%
Maher 2010	Natale	2009	RCT	96	NR	NR	Recurrent, symptomatic stage 2 or greater anterior vaginal wall prolapse (point Ba >/= -1) planning to undergo secondary pelvic reconstructive surgery	NR	24	6	6.3%

Systematic Review	Study	Year	Type of study	No. of patients	Country	Mean age	Inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
										No.	%
Jia 2007	Cervigni	2007	RCT	93	Italy	NR	Recurrent POP stage ≥2	NR	6-28	6	6.5%
Jia 2007	Hiltunen	2006	RCT	92	Finland	NR	Symptomatic cystocele of stage ≥II (POP-Q)	NR	12	17	18.5%

3.1.4 Outcome/Adverse Events (AE): Repeat Operation on Tape/Mesh/Sling

Number of systematic reviews reviewed for this outcome: One (Jia).

Number of unique studies identified within the reviews: Nine (One RCT, eight case series).

Reported median and range in the percentage of patients experiencing this outcome from identified studies: 4.8% (0.9% to 10.9%).

Discussion: Nine studies with 50 or more patients were identified that provided evidence on repeat operations on mesh following non-absorbable synthetic mesh repair of anterior/posterior prolapse. Specifically, all studies reported rates of operation on mesh following erosion. Follow up was for at least a mean of 12 months in the eight studies that reported duration of follow up. The studies ranged in size from 55 to 325 patients.

The largest study was based in France and included 325 women with a mean age of 63. This study reported a rate of erosion of 0.9% over a median 14.6-month follow up. This was the lowest rate reported across all of the studies.

The highest reported rate of reoperation due to erosion, 10.9%, was in another French study of 138 women with a mean age of 62 who were followed up for a median of 32 months.

The findings from the included studies show that reoperation on mesh does occur following non-absorbable synthetic mesh repair for anterior/posterior prolapse. The balance of evidence from the median of all trials suggests that around one in 21 women will require some form of operation due to mesh erosion, but there is evidence that it may be as many as one in nine women or as few as one in 111 women.

The wide range of risk identified from the studies may be the result of differences in the ways the studies defined, diagnosed and recorded erosion repair. Duration of follow up in the studies does not appear to be a significant factor, as the study with the longest follow up of over three years had one of the lowest reported rates of repair at 2.1%.

It is possible that the wide variance in reported rates means that other factors, such as surgical skill and/or individual patient characteristics, play a significant role in an individual woman's likelihood of requiring reoperation due to erosion following non-absorbable synthetic mesh repair for anterior/posterior prolapse.

Study details of are presented in Table 3.4. NR indicates that the information was not reported in the review. However, this information may be reported in the original study report.

Table 3.4: Non-absorbable synthetic mesh: outcome/adverse events (AE): reoperation on tape/mesh/sling

Systematic Review	Study	Year	Type of study	No. of patients	Country	Mean age	Additional patient inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
										No.	%
Jia 2007	Rozet	2004	Case series	325	France	63	Genito-urinary prolapse	NR	14.6	3	0.9%
Jia 2007	Collinet	2006	Case series	277	France	64	Pelvic prolapse	NR	NR	25	9.0%
Jia 2007	Flood	1996	Case series	142	Canada	65	Women undergoing extended anterior colporrhaphy reinforced	NR	3.2 years	3	2.1%
Jia 2007	Deffleux	2007	Case series	138	France	62	NR	NR	32	15	10.9%
Jia 2007	Fatton	2007	Case series	106	France	63.2	Recurrent vaginal prolapse or primary cases with significant prolapse. All had a prolapse with at least a >=3 component	NR	3	2	1.9%
Jia 2007	Dwyer	2004	Case series	97	Australia	61	Recurrent vaginal prolapse or a large fascia defect unsuitable for standard repair alone	NR	29	6	6.2%
Jia 2007	Cosson	2002	Case series	83	France	47	Symptomatic prolapse of the uterus who underwent	NR	6	1	1.2%

Systematic Review	Study	Year	Type of study	No. of patients	Country	Mean age	Additional patient inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
										No.	%
							laparoscopic sacral colpopexy				
Jia 2007	Lim	2007	RCT	62	Australia	NR	Symptomatic prolapse >=stage 2	NR	12	3	4.8%
Jia 2007	De Tayrac	2006	Case series	55	France	63	Symptomatic stage 2 to 4 cystocele	NR	37	4	7.3%

3.1.5 Outcome/Adverse Events (AE): Organ Damage

Number of systematic reviews reviewed for this outcome: One (Jia).

Number of unique studies identified within the reviews: Four (Case series).

Reported median and range in the percentage of patients experiencing this outcome from identified studies: 2.1% (0.9% to 2.8%).

Discussion: Four studies were identified that provided evidence for at least 50 patients for organ damage following non-absorbable synthetic mesh repair for anterior/posterior prolapse. Studies ranged in size from 83 to 277 patients and all were conducted in France.

The largest study of patients with pelvic prolapse, with a mean age of 64, reported a rate of organ damage of 1.8%.

The highest rate of organ damage of 2.8% was reported in a study of 143 women with a mean age of 63, with vaginal wall prolapse stage II to IV. The lowest rate of 0.9% was in 100 women, also of mean age 63, but with at least stage III recurrent or new prolapse.

The included evidence suggests that organ damage is a potential outcome for women following non-absorbable synthetic mesh repair for anterior/posterior prolapse. The risk may be as high as one in 36 women or as low as one in 111 women.

This wide range of risk identified may be the result of differences in the ways the studies defined, diagnosed and recorded organ damage.

It is also possible that the wide variance in reported rates means that other factors, such as surgical skill and/or individual patient characteristics, play a significant role in an individual woman's likelihood of experiencing organ damage following non-absorbable synthetic mesh repair for anterior/posterior prolapse.

Study details of are presented in Table 3.5. NR indicates that the information was not reported in the review. However, this information may be reported in the original study report.

Table 3.5: Non-absorbable synthetic mesh: outcome/adverse events (AE): organ damage

Systematic Review	Study	Year	Type of study	No. of patients	Country	Mean age	Inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
										No.	%
Jia 2007	Collinet	2006	Case series	277	France	64	Pelvic prolapse	NR	NR	5	1.8%
Jia 2007	De Tayrac	2007	Case series	143	France	63	Symptomatic vaginal wall prolapse at stage 2 to 4	NR	13	4	2.8%
Jia 2007	Fatton	2007	Case series	110	France	63.2	Recurrent vaginal prolapse or primary cases with significant prolapse. All had a prolapse with at least a >=3 component	NR	25 weeks	1	0.9%
Jia 2007	Cosson	2002	Case series	83	France	47	Patients with symptomatic prolapse of the uterus who underwent laparoscopic sacral colpopexy	NR	NR	2	2.4%

3.2 ABSORBABLE BIOLOGICAL GRAFTS

3.2.1 Outcome/Adverse Events (AE): Postoperative Pain/Discomfort after Six Months

Number of systematic reviews reviewed for this outcome: One (Jia).

Number of unique studies identified within the reviews: Three (One RCT, two case series).

Reported median and range in the percentage of patients experiencing this outcome from identified studies: 2.7% (0.8% to 7.5%).

Discussion: Three studies were identified that provided evidence for at least 50 patients for postoperative pain lasting at least six months following insertion of absorbable biological mesh during anterior/posterior prolapse surgery. All three studies were conducted in the USA.

The largest study reported the lowest rate of persistent pain, with 0.8% of 132 women with a mean age of 62 and grade II-IV cystoceles suffering from suprapubic pain at a mean of 12.4 months follow up after the procedure.

The highest rate of 7.5% was reported in an RCT of 67 women with a mean age of 65 after 13 months' follow up.

Findings from the included studies show that postoperative pain at six months and beyond appears to occur in a minority of women undergoing absorbable biological mesh repair for anterior/posterior prolapse. Whilst there is no direct evidence of the outcome at six months, the evidence suggests that the rate 12 months postoperatively could be as high as one in 13 women but could also be as low as one in 125 women. The evidence base is relatively weak, being based on three studies from the USA and with no evidence directly from a UK setting.

The range of risk identified across the three studies may be the result of differences in the ways the studies defined, diagnosed and recorded pain.

It is also possible that the variance in rates means that other factors, such as surgical skill and/or individual patient characteristics, play a significant role in an individual woman's likelihood of experiencing prolonged postoperative pain and discomfort when undergoing absorbable biological mesh repair for anterior/posterior prolapse.

Study details of are presented in Table 3.6. NR indicates that the information was not reported in the review. However, this information may be reported in the original study report.

Table 3.6: Absorbable biological mesh: Outcome/adverse events (AE): Postoperative pain/discomfort after six months

Systematic Review	Study	Year	Type of study	Number of patients	Country	Type of pain	Mean age	Additional patient inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
											No.	%
Jia 2007	Kobashi	2002	Case series	132	USA	Suprapubic pain	62	Grade 2-4 cystoceles	NR	12.4	1	0.8%
Jia 2007	Kobashi	2005	Case series	73	USA	Prolonged postoperative pain	31-86	Patients with symptomatic rectoceles	NR	13.7	2	2.7%
Jia 2007	Ghandi	2005	RCT	67	USA	Pelvic pain	64.9	Anterior vaginal wall prolapse to the hymen or beyond while straining, 18 years or older	NR	13	5	7.5%

3.2.2 Outcome/Adverse Events (AE): Deterioration of Sexual Function 6 Months Post Operatively

Number of systematic reviews reviewed for this outcome: Zero.

Number of unique studies identified within the reviews: Zero.

Reported median and range in the percentage of patients experiencing this outcome from identified studies: N/A.

Discussion: No studies were found that provided evidence for this adverse event for this procedure.

3.2.3 Outcome/Adverse Events (AE): Erosion

Number of systematic reviews reviewed for this outcome: Two (Jia, Maher).

Number of unique studies identified within the reviews: Seven (Three RCTs, three case series, one non-randomised comparative study).

Reported median and range in the percentage of patients experiencing this outcome from identified studies: 1.2% (0.0% to 21.4%).

Discussion: Of the seven studies identified from the systematic reviews providing evidence on erosion following absorbable biological mesh repair for anterior/posterior prolapse, all provided information for fewer than 100 women undergoing the procedure.

The largest study was of 98 women with at least stage II primary anterior prolapse. Limited information was available on the patients in this study, which reported one case (1.0%) of erosion during two years of follow up. The highest rate of 21.4% at 17 months was reported in a US study of 56 patients undergoing cystocele repair.

Two studies found no cases of erosion: one study was of 85 women in Italy with at least grade II recurrent prolapse, and the other was of 70 women in the USA with high grade cystocele (grade III and above).

The findings from the included studies show that vaginal/mesh erosion can occur following absorbable biological mesh repair for anterior/posterior prolapse. The balance of evidence from the median of all included trials and the largest study suggests that the risk is around one in 83 to one in 100 women, but there is evidence that it may occur in over one in five women.

The wide range of risk identified may be the result of differences in the ways the studies defined, diagnosed and recorded erosion. Duration of follow up in the studies does not appear to be a factor, as the studies with the highest and lowest reported rates of erosion had the same follow up of two years.

It is possible that the wide variance in reported rates means that other factors, such as surgical skill and/or individual patient characteristics, play a significant role in an individual woman's likelihood of experiencing erosion following absorbable biological mesh repair for anterior/posterior prolapse.

Study details of are presented in Table 3.7. NR indicates that the information was not reported in the review. However, this information may be reported in the original study report.

Table 3.7: Absorbable biological mesh: Outcome/adverse events (AE): Erosion

Systematic Review	Study	Year	Type of study	No. of patients	Country	Mean age	Inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
										No.	%
Maher 2010	Meschia	2007	RCT	98	NR	NR	Primary anterior prolapse POP-Q Point Ba -1 (>=stage II)	NR	24	1	1.0%
Jia 2007	Simsiman	2006	Case series	89	USA	59.5	Advanced >=stage II anterior vaginal wall prolapse	NR	24	15	16.8%
Jia 2007	Cervigni	2007	RCT	87	Italy	NR	Recurrent POP stage ≥2	NR	6-28	0	0.0%
Jia 2007	Kocjancic	2007	RCT	85	Italy	NR	Primary anterior vaginal wall prolapse >stage II	NR	14	1	1.2%
Jia 2007	Gomelsky	2004	Case series	70	USA	NR	Women underwent surgical correction of high grade cystocele (Baden-Walker and POP-Q grading system), i.e. grade III: Aa+1 and Ba+2, or at rest, grade IV: Aa+3 and Ba+4	NR	24	0	0.0%
Jia 2007	Powell	2004	Case series	58	USA	63.7	Stage 2 or greater anterior vaginal compartment relaxation	NR	24.7	6	10.3%
Jia 2007	Handel	2007	Non-randomised comparative study	56	USA	NR	Patients underwent cystocele repair	NR	17	12	21.4%

3.2.4 Outcome/Adverse Events (AE): Repeat Operation on Tape/Mesh/Sling

Number of systematic reviews reviewed for this outcome: One (Jia).

Number of unique studies identified within the reviews: Two (One RCT, one non-randomised comparative study).

Reported median and range in the percentage of patients experiencing this outcome from identified studies: 3.2% (1.0% to 5.4%).

Discussion: Two studies were identified that provided evidence for at least 50 patients for repeat operation on mesh following insertion of absorbable biological mesh during anterior/posterior prolapse surgery. Both studies reported rates of reoperation due to mesh erosion.

The largest study was of 98 women with at least stage II primary anterior prolapse. This study reported one case (1.0%) of surgical correction of erosion during two years of follow up, compared with a rate of 5.4% at 17 months in a US study of 56 patients undergoing cystocele repair. Limited information was provided by the reviews about the patients in both trials.

Findings from the included studies show that repeat operation on mesh occurs in a minority of women undergoing absorbable biological mesh repair for anterior/posterior prolapse. The evidence suggests that the rate could be as high as one in 19 women but could be as low as one in 100 women. The evidence base is relatively weak, being based on one study of just under 100 women and one of fewer than 60 women and with no evidence directly from a UK setting.

The wide range of risk identified may be the result of differences in the ways the studies defined, diagnosed and recorded the severity of mesh erosion requiring repair.

It is possible that the variance in reported rates between the two studies means that other factors, such as surgical skill and/or individual patient characteristics, play a significant role in an individual woman's likelihood of mesh erosion requiring surgical repair when undergoing absorbable biological mesh repair for anterior/posterior prolapse.

Study details of are presented in Table 3.8. NR indicates that the information was not reported in the review. However, this information may be reported in the original study report.

Table 3.8: Absorbable biological mesh: outcome/adverse events (AE): reoperation on tape/mesh/sling

Systematic Review	Study	Year	Type of study	No. of patients	Country	Mean age	Additional patient inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
										No.	%
Jia 2007	Mechia	2007	RCT	98	NR	NR	Primary anterior prolapse POP-Q Point Ba -1 (>=stage II)	NR	24	1	1.0%
Jia 2007	Handel	2007	Non-randomised comparative study	56	NR	NR	Patients underwent cystocele repair	NR	17	3	5.4%

3.2.5 Outcome/Adverse Events (AE): Organ Damage

Number of systematic reviews reviewed for this outcome: One (Jia).

Number of unique studies identified within the reviews: One (Case series).

Reported median and range in the percentage of patients experiencing this outcome from identified studies: 0% (N/A).

Discussion: One study of 50 or more patients was identified which reported rates of organ damage following absorbable biological mesh repair for anterior/posterior prolapse. This study was a case series of 70 women in the USA with high grade cystocele (grade III or above) who were followed for 24 months. The study found no cases of organ damage.

The available evidence indicates that organ damage occurs in fewer than one in 70 women undergoing absorbable biological mesh repair for anterior/posterior prolapse.

The evidence is limited, being based on fewer than 100 operations potentially from just one surgical centre and for a group of patients with significant prolapse. As such, this finding should be treated with caution; comparison with other procedures is problematic.

Study details of are presented in Table 3.9. NR indicates that the information was not reported in the review. However, this information may be reported in the original study report.

Table 3.9: Absorbable biological mesh: outcome/adverse events (AE): organ damage

Systematic Review	Study	Year	Type of study	No. of patients	Country	Mean age	Inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
										No.	%
Jia 2007	Gomelsky	2004	Case series	70	USA	NR	High grade cystocele (Baden-Walker and POP-Q grading system), i.e. grade III: Aa+1 and Ba+2, or at rest, grade IV: Aa+3 and Ba+4	NR	24 months	0	0.0%

Section 4: Uterine/Vault Prolapse

We identified two systematic reviews that evaluated the efficacy and safety of mesh or grafts in surgery for uterine/vault prolapse. Each of the reviews had different objectives: one aimed to demonstrate differences in women undergoing surgery for uterine or vault prolapse (Jia 2008; 2010) and the other review, Feiner (2008), compared transvaginal mesh kits.

4.1 NON-ABSORBABLE SYNTHETIC MESH

4.1.1 Outcome/Adverse Events (AE): Postoperative Pain/Discomfort after 6 Months

Number of systematic reviews reviewed for this outcome: One (Feiner).

Number of unique studies identified within the reviews: Three (unspecified study design).

Reported median and range in the percentage of patients experiencing this outcome from identified studies: 2.0% (1.2% to 2.3%).

Discussion: Three studies were identified that provided evidence for at least 50 patients on postoperative pain lasting at least 6 months for patients undergoing non-absorbable synthetic mesh repair for uterine/vault prolapse. The studies ranged in size from 85 to 349 patients. Limited information on patients in the studies was provided in the review in which the studies were identified.

The largest study reported a rate of postoperative vaginal pain at a mean of six months of 2.0% with the lowest rate of 1.2% being reported in a study of 85 women with 12 months' mean follow up.

Findings from the included studies show that pain at least six months postoperatively occurs in a minority of women undergoing non-absorbable synthetic mesh repair for uterine/vault prolapse. The evidence suggests that the rate could be as high as one in 43 women but could be as low as one in 83 women.

The range of risk identified between the studies may be the result of differences in the ways the studies defined, diagnosed and recorded pain.

It is also possible that the variance in rates means that other factors, such as surgical skill and/or individual patient characteristics, play a significant role in an individual woman's likelihood of experiencing prolonged postoperative pain and discomfort when undergoing non-absorbable synthetic mesh repair for uterine/vault prolapse.

Study details of are presented in Table 4.1. NR indicates that the information was not reported in the review. However, this information may be reported in the original study report.

Table 4.1: Non-absorbable synthetic mesh: Outcome/adverse events (AE): Groin or thigh pain from all identified studies

Systematic Review	Study	Year	Type of study	Number of patients	Country	Type of pain	Mean age	Additional patient inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
											No.	%
Feiner 2008	Van Raalte	2007	NR	349	NR	Vaginal pain	NR	NR	NR	6	7	2.00%
Feiner 2008	Riva	2005	NR	172	NR	Prolonged pain	NR	NR	NR	12	4	2.3%
Feiner 2008	Miller	2006	NR	85	NR	Pain	NR	NR	NR	12	1	1.20%

4.2 NON-ABSORBABLE SYNTHETIC/ABSORBABLE BIOLOGICAL COMBINED

4.2.1 Outcome/Adverse Events (AE): Deterioration of Sexual Function Six Months Postoperatively

Number of systematic reviews reviewed for this outcome: One (Jia).

Number of unique studies identified within the reviews: One (Case series).

Reported median and range in the percentage of patients experiencing this outcome from identified studies: 14.5%.

Discussion: There was one study of more than 50 patients that reported on deterioration of sexual functioning following mesh repair for uterine/vault prolapse. The study reported on a combined synthetic/biological mesh. No studies were found of more than 50 patients that reported solely on absorbable biological or non-absorbable synthetic mesh for uterine/vault prolapse repair.

The identified study found a rate of *de novo* dyspareunia of 14.5% in 76 patients in the USA with a mean age of 55. Patients had stage II to IV prolapse without stress urinary incontinence and were followed up for a mean of 12 months.

The available evidence suggests that around one in seven women having mesh repair for vault/uterine prolapse will experience de novo sexual pain at least six months after surgery and possibly for significantly longer.

The evidence is limited, being based on around 75 operations potentially from just one surgical centre. As such, this finding should be treated with caution; comparison with other procedures is problematic.

Study details are presented in Table 4.2. NR indicates that the information was not reported in the review. However, this information may be reported in the original study report.

Table 4.2: Absorbable biological or non-absorbable synthetic mesh: outcome/adverse events (AE): deterioration of sexual function six months postoperatively

Systematic Review	Study	Year	Type of study	Description of sexual difficulties	No. of patients	Country	Mean age	Inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
											No.	%
Jia 2008	Bradley	2007	Case series	Dyspareunia (de novo)	76	USA	54.8	Stage II-IV prolapse	Stress urinary incontinence	12	11	14.5%

4.3 NON-ABSORBABLE SYNTHETIC MESH

4.3.1 Outcome/Adverse Events (AE): Erosion

Number of systematic reviews reviewed for this outcome: Three (Jia, Feiner, Maher).

Number of unique studies identified within the reviews: Thirty-one (One RCT, five non-randomised comparative studies, 12 case series, 13 unknown).

Reported median and range in the percentage of patients experiencing this outcome from identified studies: 5.5% (0.0% to 25.6%).

Discussion: Of the 31 studies identified from the systematic reviews providing evidence on erosion following non-absorbable synthetic mesh repair for uterine/vault prolapse, thirteen provided information for more than 100 women undergoing the procedure.

The largest study of 349 women reported 1.1% experienced erosion by six month mean follow up, compared with the highest reported rate of 25.6% over 120 weeks post operatively in an Israeli study of 79 patients with stage III or IV prolapse from a vaginal apical support defect.

Two studies found no cases of erosion: one of these studies followed patients for a mean of almost four years.

The findings from the included studies show that vaginal/mesh erosion can occur following non-absorbable synthetic mesh repair for uterine/vault prolapse, affecting a minority of women. The balance of evidence from the median of all trials is that around one in 18 women will experience erosion, but there is evidence that it may occur in as many as one in four women or fewer than one in 149 women.

The wide range of risk may be the result of differences in the ways the studies defined, diagnosed and recorded erosion. Duration of follow up in the studies does not appear to be a factor, as one of the studies reporting no cases of erosion had the longest follow up of all studies.

It is possible that the wide variance is evidence that other factors, such as surgical skill and/or individual patient characteristics, play a significant role in an individual woman's likelihood of experiencing erosion following non-absorbable synthetic mesh repair for uterine/vault prolapse.

Study details of the ten largest studies are presented in Table 4.3. NR indicates that the information was not reported in the review. However, this information may be reported in the original study report.

Table 4.3: Non-absorbable synthetic mesh: outcome/adverse events (AE): erosion (ten largest studies only)

Systematic Review	Study	Year	Type of study	No. of patients	Country	Mean age	Additional patient inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
										No.	%
Feiner 2008	Van Raalte	2007	NR	349	NR	NR	NR	NR	6	4	1.1%
Jia 2008	Visco	2001	Non-randomised comparative study	273	USA	60.6	NR	NR	7	15	5.5%
Feiner 2008	Meschia	2007	NR	228	NR	NR	NR	NR	32 weeks	11	4.8%
Jia 2008	Wu	2006	Case series	212	USA	65.5	Prior hysterectomy. Underwent abdominal sacral colpopexy	NR	15	10	4.7%
Jia 2008	Griffis	2006	Case series	196	USA	NR	All had prior hysterectomy	NR	10.4	16	8.2%
Feiner 2008	Abdel-fattah	2008	NR	181	NR	NR	NR	NR	12 weeks	21	11.6%
Feiner 2008	Davila	2006	NR	177	NR	NR	NR	NR	19 weeks	24	13.6%
Feiner 2008	Riva	2005	NR	172	NR	NR	NR	NR	12	6	3.5%
Jia 2008	Fedorkow	1993	Case series	149	Canada	58.4	Prior hysterectomy and abdominal sacrovaginopexy	NR	NR	0	0.0%
Jia 2008	Elneil	2005	Case series	128	UK	62	Patients had open or laparoscopic sacrocolpopexy (n=121), hysteropexy (n=6), or cervicopexy (n=1)	NR	19	3	2.3%

4.3.2 Outcome/Adverse Events (AE): Repeat Operation on Tape/Mesh/Sling

Number of systematic reviews reviewed for this outcome: Two (Jia 2007, 2008).

Number of unique studies identified within the reviews: Twelve (Eight case series, four non-randomised comparative studies).

Reported median and range in the percentage of patients experiencing this outcome from identified studies: 4.0% (0.8% to 7.1%).

Discussion: Twelve studies with 50 or more patients were identified that provided evidence on repeat operations on mesh following non-absorbable synthetic mesh repair for uterine/vault prolapse. Specifically, all studies reported rates of operation on mesh following erosion. The studies ranged in size from 62 to 300 patients.

The largest study was based in the USA and included 300 women, all of whom had prior hysterectomy. This study reported a rate of reoperation due to erosion of 3.0% over a mean 10.4 month follow up.

The highest reported rate of reoperation due to erosion, 7.1%, was in another US study of 98 women undergoing abdominal sacral suspension followed for at least nine months.

The findings from the included studies show that reoperation on mesh does occur following non-absorbable synthetic mesh repair for uterine/vault prolapse. The balance of evidence from the median of all trials and suggests that around 1 in 25 women will require some form of operation due to mesh erosion but there is evidence that it may be as many as one in 14 women or as few as one in 125 women.

The wide range of risk identified from the studies may be the result of differences in the ways the studies defined, diagnosed and recorded erosion repair.

It is possible that the wide variance in reported rates means that other factors, such as surgical skill and/or individual patient characteristics, play a significant role in an individual woman's likelihood of requiring reoperation due to erosion following non-absorbable synthetic mesh repair for vault/uterine prolapse.

Study details of the ten largest studies are presented in Table 4.4. NR indicates that the information was not reported in the review. However, this information may be reported in the original study report.

Table 4.4: Non-absorbable synthetic mesh: outcome/adverse events (AE): reoperation on tape/mesh/sling (ten largest studies only)

Systematic Review	Study	Year	Type of study	Type of operation	No. of patients	Country	Mean age	Additional patient inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
											No.	%
Jia 2008	Griffis	2006	Non-randomised comparative study	Erosion requiring surgery	300	USA	NR	All had prior hysterectomy	NR	10.4	9	3.0%
Jia 2008	Visco	2001	Non-randomised comparative study	Erosion requiring surgery	273	USA	65.5	Prior hysterectomy and underwent abdominal sacral colpopexy	NR	15	13	4.8%
Jia 2008	Lindeque	2002	Case series	Erosion requiring surgery	262	South Africa	28-79	Good vaginal wall support, typically after recent anterior and posterior colporrhaphy, who were diagnosed with vaginal vault prolapse (stage II) and enterocele. Patients with massive enterocele with the uterus in situ were rarely seen but were included.	NR	16	10	3.8%
Jia 2008	Elneil	2005	Case series	Erosion requiring surgery	128	UK	62	Open or laparoscopic sacrocolpopexy (n=121),	NR	19	3	2.3%

Systematic Review	Study	Year	Type of study	Type of operation	No. of patients	Country	Mean age	Additional patient inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
											No.	%
								hysteropexy (n=6), or cervicopexy (n=1) using non absorbable mesh for vault prolapse				
Jia 2008	Brizzolaraara	2003	Case series	Erosion requiring surgery	124	USA	65.1	NR	NR	36	1	0.8%
Jia 2008	Paraiso	2005	Non-randomised comparative study	Erosion requiring surgery	117	USA	62	Post hysterectomy vaginal prolapse	NR	15	3	2.6%
Jia 2008	Higgs	2005	Case series	Erosion requiring surgery	103	UK	58	Received laparoscopic sacrocolpopexy	NR	66	5	4.9%
Jia 2008	Begley	2005	Non-randomised comparative study	Erosion requiring surgery	98	USA	66	Received abdominal sacrocolpopexy	NR	9.8-29.3	7	7.1%
Jia 2007	Amrute	2007	Case series	Erosion requiring surgery	76	USA	69.3	Received tension-free 4-point fixation	NR	30.7	2	2.6%
Jia 2008	Petros	2001	Case series	Erosion requiring surgery	75	Australia	54	At least Stage II following abdominal or vaginal hysterectomy	NR	54	4	5.3%

4.3.3 Outcome/Adverse Events (AE): Organ Damage

Number of systematic reviews reviewed for this outcome: Two (Jia, Feiner).

Number of unique studies identified within the reviews: Sixteen (Two RCTs, 10 case series, three non-randomised comparative studies, one unknown).

Reported median and range in the percentage of patients experiencing this outcome from identified studies: 1.8% (0.0% to 7.9%).

Discussion: Sixteen studies with 50 or more patients were identified that provided evidence on organ damage during non-absorbable synthetic mesh repair for uterine/vault prolapse. Specifically, all studies reported rates of operation on mesh following erosion. The studies ranged in size from 52 to 262 patients.

The largest study was based in South Africa and included women aged 28 to 79 with stage II prolapsed and enterocele. The study reported a rate of organ damage of 1.5%.

The highest reported rate of organ damage, 7.9%, was in a Dutch study of 101 women undergoing abdominal colposacropexy with a mean age of 59.

Three UK studies were identified reporting rates of organ damage from 0.0% to 1.9%. The UK study which found no instances of organ damage was the only study to report zero instances (from the included studies): it studied 127 women with a mean age of 59.

The findings from the included studies show that organ damage does occur following non-absorbable synthetic mesh repair for uterine/vault prolapse. The balance of evidence from the median of all trials suggests that around one in 56 women suffer organ damage during the procedure, but there is evidence that it may be as many as one in 13 women or fewer than one in 127 women.

The wide range of risk identified from the studies may be the result of differences in the ways the studies defined, diagnosed and recorded organ damage.

It is possible that the wide variance in reported rates means that other factors, such as surgical skill and/or individual patient characteristics, play a significant role in an individual woman's likelihood of suffering organ damage during non-absorbable synthetic mesh repair for vault/uterine prolapse.

Study details for the ten largest studies are presented in Table 4.5. NR indicates that the information was not reported in the review. However, this information may be reported in the original study report.

Table 4.5: Non-absorbable synthetic mesh: outcome/adverse events (AE): organ damage (ten largest studies only)

Systematic Review	Study	Year	Type of study	No. of patients	Country	Mean age	Inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
										No.	%
Jia 2008	Lindeque	2002	Case series	262	South Africa	28-79	Patients with good vaginal wall support, typically after recent anterior and posterior colporrhaphy, who were diagnosed with vaginal vault prolapse (stage II) and enterocele. Patients with massive enterocele with the uterus in situ were rarely seen but were also included	NR	16	4	1.5%
Jia 2008	Culligan	2002	Case series	245	USA	61.2	Patients underwent sacral colpopexy	NR	48	1	0.4%
Feiner 2008	Abdel-fattah	2008	NR	143	NR	NR	NR	NR	12 weeks	2	1.40%
Jia 2008	Elneil	2005	Case series	128	UK	62	Open or laparoscopic sacrocolpopexy (n=121), hysteropexy (n=6), or cervicopexy (n=1) using nonabsorbable mesh for vault prolapse	NR	19	2	1.60%

Systematic Review	Study	Year	Type of study	No. of patients	Country	Mean age	Inclusion criteria	Exclusion criteria	Follow up (Mean months)	Patients with AE	
										No.	%
Jia 2008	Hefni	2007	Case series	127	UK	59	NR	NR	14	0	0.0%
Jia 2008	Brizzolara	2003	Case series	124	USA	65.1	NR	NR	36	1	0.8%
Jia 2008	Besinger	2005	Case series	121	USA	53.3	Women underwent abdominal sacral suspension	NR	12.5	3	2.5%
Jia 2008	Ng	2004	Non-randomised comparative study	113	Singapore	60	Women with at least grade 4 uterovaginal prolapse or grade 3 vault prolapse	NR	18.1	1	0.9%
Jia 2008	Higgs	2005	Case series	103	UK	58	Women who had laparoscopic sacrocolpopexy	NR	66	2	1.9%
Jia 2008	De Vries	1995	Case series	101	The Netherlands	59	Women underwent abdominal colposacropexy	NR	48 months (median)	8	7.9%

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Y O R K

Health Economics

C O N S O R T I U M

University of York
Market Square
Vanbrugh Way
Heslington
YORK YO10 5NH

Tel: +44 (0) 1904 323620
Fax: +44 (0) 1904 323628
Email: yhec@york.ac.uk
Web: www.yhec.co.uk