Table 1a: International Agency Reviews of Transvaginal Mesh Safety

Author(s)	**Review type & Level of evidence**	**Purpose of Review**	**Findings**	**Conclusions**
European Commission Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) Preliminary Opinion on the safety of surgical meshes used in urogynaecological surgery (2015)	Preliminary Opinion on the safety of surgical meshes used in urogynaecological surgery Draft for public consultation, based on a comprehensive safety review. Narrative review reporting on evidence in a range from SIGN 1++ to SIGN 4 .	To provide a scientific opinion on the safety of surgical meshes used in "contemporary pelvic surgery". The specific issues addressed, within the scope of this review, were: 1. Risks associated with the use of surgical meshes for treating SUI & POP; 2. Identification of high-risk patient groups; 3. Need for further assessment in this field; 4. The scientific rationale for the use of synthetic surgical mesh for the management of SUI	The SCENIHR is of the opinion that: 1. Risks associated with the use of synthetic surgical meshes for treating SUI & POP Types of synthetic mesh: • synthetic mesh type 1 (polypropylene monofilament, macroporous >75µm) is the "most appropriate" synthetic mesh for vaginal use and ; • synthetic mesh type 1 & synthetic mesh type 3 (polyester ,multifilament , microporous <10µm) are the "most appropriate" synthetic meshes for insertion via the abdominal route; and • synthetic mesh type 2 (mono and multifilament, microporous,) is "not appropriate" for this clinical use; • synthetic mesh type 4 (monofilament, nanoporous <1µm) is "not appropriate" for this clinical us; and • there is insufficient evidence on which to base an opinion regarding other synthetic materials. Factors to consider in assessing the risk	*"Review of the current literature and experience from clinical practice suggests that the use of surgical mesh in this context is associated with both benefits and risks. However, only a few randomised controlled studies have been published until now. The use of such mesh in repair surgery may lead to various complications of poor tissue integration, such as tissue erosion, exposure of the mesh and shrinkage of the mesh. The success of mesh interventions varies depending on the type of anatomical defect, its severity, the*

		& POP	associated with mesh insertion: • overall surface area of material used, (which is > for POP than for SUI); • Mesh design (mono- multifilament, pore size directionality); • predisposing factors for infection 9e.e pore <75µn); • material characteristics (e.g. long-term stability, biocompatibility, flexibility, elasticity, aging, etc.); • physical properties and durability of the materials in the context of long-term indwelling of the device in human tissue; the material within the tissue on a long-term basis; and • recognition that mesh exposure is only seen with a non-absorbable material such as synthetic mesh. Are certain surgery techniques of higher risk? • the available evidence (to 2 year follow up) suggests that all synthetic materials are associated with the risk of mesh exposure; • generally vaginal surgery is associated with a higher risk of mesh- related morbidity than abdominal mesh insertion; • the complications associated with mesh insertion are related to the route of insertion; • risk assessment of the use of mesh	*presence of risk factors, the rationale for the use of mesh and the skill and experience of surgeons." (Pg 7)* *"The SCENIHR acknowledges the efficacy and use of implanted meshes for SUI in the majority of patients with moderate to severe SUI. It considers that the associated risk is limited, but recognises the absence of long-term data. Most complications associated with mesh insertion are related to the route of insertion." (pg 9)* *"The SCENIHR acknowledges that vaginally implanted mesh for POP is associated with increased risks compared to mesh*

			needs to differentiate between its use in SUI and POP: • the evidence indicates the efficacy and use of implanted meshes for SU, that the risk associated with this use is low, recognising, however, that in the absence of long-term data, (5-10 year follow up) this assessment has its limitations; • the evidence suggests that vaginally implanted mesh for POP is associated with increased risks compared to mesh implantation for SUI. The use vaginally implanted mesh for POP should be restricted; • vaginal insertion of non-absorbable synthetic mesh with a large surface area is associated with the highest incidence of complications; and • vaginal insertion of non-absorbable synthetic mesh is associated with a higher complication rate than trans-abdominal insertion. Factors associated with clinical experience: • there is a learning curve for MUS procedures for SUI and for POP surgery procedures, especially in relation to: operation duration; and surgical experience; • the evidence would suggest only experienced surgeons (such as > 20 cases performed under supervision of an	*implantation for SUI. Its use should be restricted to patients selected according to established evidence based clinical guidelines" (Pg 9)* *"Recommendations:* • *Ensure the patients are correctly and comprehensively informed on the benefits and risks associated with the use of synthetic non-absorbable meshes.* • *Establish European implant registries.* • *Establish scientific studies to assess the long-term (at least 5 years) safety and performance of synthetic non-absorbable meshes.* • *Encourage further research into novel design and*

			experienced surgeon should perform this kind of surgery unsupervised; • the learning curve for MUS surgery may vary from one trainee to another, and may be longer than expected. Factors affecting this include: trainee's prior experience; the difficulty of the procedures; and the level/quality of the supervision; and • the importance of adherence with clinical guidelines. 2. The Identification of high-risk patient groups Patent selection issues: • In the case of mesh devices, there is at present very little robust evidence available to inform patient selection when used for POP or SUI procedures; • the identification of high-risk patient groups is of importance, More needs to be known, but at present it is recognised that: ○ smoking is statistically associated with an increased risk of mesh exposure; and ○ factors such as age & obesity may also be important; ○ SCENIHR recommends being "more reluctant" to use mesh devices for POP in younger age groups;	*materials, in particular absorbable meshes, and improved technologies for manufacturing meshes, such as electrospining.* • *Encourage further research into the application of regenerative medicine technology, such as the cellular seeding of graft materials.* • *Establish evidence-based European Guidelines.* • *Develop training programs for surgeons in association with European medical associations. (Pg 11).*

			Patient consent:
			• Appropriately informed patient consent should be the result of a wide-ranging discussion regarding the patient's specific situation. It should cover:
			  ○ the availability of robust data on the efficacy and safety of many of the transvaginal mesh products:
			  ○ there is considerably more robust evidence on the safety and efficacy of polypropylene mesh use for SUI than for POP procedures;
			  ○ that long-term follow-up is currently not available, which makes a balanced estimate of the risk/benefit ratio of mesh devices difficult;
			• the potential benefits and complications of POP surgery in general versus status quo or use of conservative treatments:
			  ○ the potential benefits & complications of transvaginal mesh implants and when clinically indicated;
			  ○ the alternatives to surgical management;
			  ○ the alternative surgical treatments;
			• the potential complications of transvaginal mesh:
			  ○ adverse outcomes including mesh exposure/ erosion, vaginal scarring/stricture, fistula formation, dyspareunia, urinary problems,	

			infection, perforation and/or pelvic pain; ○ that complications may lead the need for additional intervention, but may not be completely resolved even with mesh removal. ○ pain and/or dyspareunia caused by POP surgery with or without mesh should be discussed based on the available scientific evidence; • Provision of written documentation, including device documentation (PIL) when available; • If mesh procedure is considered, patients should also be informed of, and discuss, the following issues: ○ the route by which the mesh will be placed; ○ that a mesh is considered a permanent implant; ○ that removal of mesh or correction of mesh-related complications may involve subsequent surgery, which may not fully correct some complications; ○ that complete removal of mesh may not be possible; and ○ patients should be encouraged to ask their doctor questions on why he/she thinks that mesh implantation is particularly beneficial for her and what the evidence or level of experience of	

			the doctor is who is supposed to perform the procedure as well as what particular risks are involved in the proposed procedure. 3. Need for further assessment in this field. • There is a lack of long-term data on performance and safety of the use of synthetic non-absorbable mesh for POP repair; • the increasing literature on complications and on successful outcomes for patients will support a meta-analysis of patient selection to avoid poor outcomes; • longer term, post procedure follow up studies (5-10 years) are needed; 4. The scientific rationale for the use of synthetic surgical mesh for the management of SUI & POP For SUI procedures: • the amount of synthetic mesh used for the treatment of SUI is far less compared to the use of such mesh in POP repair; • there is robust evidence to support the use of MUS, it is “the most extensively reviewed and evaluated procedure for female SUI now in use”;	

			• any operation can cause complications, for MUS these include bleeding, damage to the bladder and bowel, voiding difficulty, mesh tape exposure and pelvic pain; • all these complications may require repeated surgery, but this is uncommon; • the evidence suggests that there are “excellent and equivalent outcomes” between a retropubic and a transobturator sling procedures with low complication rates; • treatment success decreases over 5 years for both retropubic and transobturator slings, with retropubic slings demonstrating a slight benefit, though satisfaction with both types of slings remained high; • women undergoing a transobturator sling procedure reported more sustained improvement in urinary symptoms and sexual function; • new mesh erosions occurred in both types over time at a similar rate; • long-term effectiveness of up to 80% has been demonstrated in studies including one that has followed up a small group of patients for 17 years, though most for much shorter times than this. For POP procedures • there is convincing evidence that the use	

			of a synthetic mesh to repair a prolapsed anterior vaginal wall is subjectively and objectively superior to a native tissue repair; • however, there is no evidence for any difference in health related quality of life between mesh and native tissue repair; • the rate of new pelvic organ prolapse in the untreated vaginal compartment is significantly higher when synthetic mesh is used, though there is no evidence for a difference in the need for subsequent operations for POP or the occurrence of new dyspareunia or sexual function; • the use of mesh results in higher rates of reported SUI, although this was not reflected in a higher rate for SUI surgery; • mesh exposure is reported frequently. • for the posterior vaginal compartment, there is moderate evidence that the use of mesh results in higher rates of objective cure; • higher rates of new POP of the anterior vaginal compartment are seen, but no differences in subjective cure or new SUI. • Mesh exposures are reported frequently; • for the treatment of more than one vaginal compartment, the meta-analysis showed that the use of mesh resulted in higher rates of subjective and objective	

			‘cure’, but also in significantly higher rates of new POP of the untreated vaginal compartments; • there were no differences in patient satisfaction, health related quality of life, subsequent operations for POP; new dyspareunia, sexual function scores or new SUI; • mesh exposures were frequently reported; • the follow-ups of selected papers for that meta-analysis were mainly short (12 months) and sometimes medium-term (36 months). Long-term results (5-10 years) of RCT’s are not yet published and, thus, are yet unavailable for analysis; • common adverse events: ○ mesh exposure (complication rates 4-19%).Exposures can cause additional symptoms or be asymptomatic; ○ dyspareunia (complication rate 9%) Studies comparing vaginal mesh versus native tissue repair did not demonstrate a difference in new dyspareunia, nor in postoperative dyspareunia; ○ Pain can occur after any surgical repair of vaginal prolapse (reported in 3-10% of cases in a small trial (n-20). Randomised studies however could not demonstrate a difference between	

			a mesh augmented and native tissue repair of POP; and • other complications that can occur after vaginal mesh surgery are haemorrhage, bowel and or rectal injury, urinary infection and postoperative retention. These complications also occur after native tissue surgery.	
Accident Compensation Corporation (2015) New Zealand	Review of national "no-fault" personal compensation claims Non Analytic Study SIGN 3 (*NB Data considered in this review included data supplied by MedSafe – see below).*	Retrospective audit review of treatment injury claims. Considered Hernia, SUI, and POP. procedures Focus on: • Characteristics of injury claims • Analysis of surgical procedures & Mesh use	Between July 2005 and June 2014, ACC considered 466 individual treatment injury claims for mesh-related injuries. This represented 0.7% of all treatment injury claims and 0.002% of all ACC claims Of these claims: • 54 individual female SUI procedures, • 131 individual POP procedures • 79 combines SUI & POP procedures Claim rate for individual & combined mesh procedures: • SUI 0.7% (133 / 17094 mesh used) • POP 3.3% (329/ 6197 mesh used) (NB Analysis used numerator period 1/7/2005 to 30/6/2014 and mesh supply denominator 1/1/2005 to 31/10/2014) Overall 81% (%=213/264) of all urogynaecological mesh surgeries resulting in a treatment injury claim were transvaginal repairs and only 5% (14/264).were	*"Post-surgery complications* • *Treatment injury claims for mesh complications made up 0.7% of all treatment injury claims and 0.002% of all ACC claims.* • *The claim rate is 5 times higher in using mesh for POP repair than SUI….* • *The most common claims for urogynaecological procedures using mesh was mesh erosion (65%)….* • *In the majority of cases where the*

			abdominal repairs. Some 14% (37/264) were unknown. This result indicates that abdominal mesh repair (sacrocolpopexy) of POP or/and SUI resulted in lower claim rates for mesh-related complications compared to transvaginal repair with mesh. POP mesh repairs were more likely to result in an injury claim for located on the vaginal wall, irrespective of being placed on the anterior wall (65%) or posterior wall (61%). Other sites combined accounted for fewer than 26% of injury claims. SUI repairs leading to injury claim were slightly more likely following retropubic urethral insertion (55%) compared with transobturator urethral insertion (45%), Other surgical factors such as whether the mesh was used with or without modification, and whether, and if so how, it was secured had some association with injury claims. The most common injury types were: • Mesh erosion/exposure/extrusion (SUI 85%, POP 63%, Combined 73%) • Dyspareunia (SUI 24%, POP 26%, Combined 20%) • Voiding symptoms (SUI 35%, POP 9%, Combined 22%) All other symptoms < 20%	*surgical mesh failed, subsequent surgery was required"* *"The health sector could discuss the possibilities of whether:* • *a postmarket surveillance study would provide information regarding the surgical mesh complications for each specific mesh product already marketed in New Zealand.* • *a multi-agency registry would provide a better means of tracking surgical mesh used and the associated complications to address mesh-related public health concerns.* • *a full evidence-based review could*

			The review found that in those urogynaecology mesh procedures which had resulted in a treatment injury claim, 92% of them required additional surgery. .	*identify or evaluate the effectiveness and safety of using surgical mesh in urogynaecologic surgeries and general surgeries. It could also possibly determine whether the evidence is directly applicable or generalisable to the New Zealand health sector.*
Medical Devices and Healthcare Regulatory Authority (2014) (MHRA) United Kingdom	Safety Review – Summary of available evidence. Evidential level: Narrative review reporting on evidence in a range from SIGN 1++ to SIGN 4	Assess the benefits and risks of Mesh Implant, given safety concerns. Considered SUI & POP Focus on: • Implant safety • Adverse outcomes • Patient experience	Generally concluded Mesh implants are safe. Adverse outcomes are highly variable in rate of occurrence (primarily based on Health Economics Consortium "York Review" 2012) *"Data for vaginal mesh implants for SUI indicate that the overall benefit outweighs the relatively low rate of reported complications"* (Pg. 76) Factors associated with surgical practice seem to be more important than the device itself. *"MHRA's current position is that for the majority of women, the use of vaginal mesh*	*"From our review of the information available to us, there appears to be no evidence that vaginal mesh implants are unsafe, which would justify MHRA taking enforcement action to take them off the market, or remove them from use."* (Pg. 5)

			implants is safe and effective. However, as with all surgery, there is an element of risk to the individual patient. This conclusion is entirely dependent on compliance with the National Institute for health and Care Excellence (NICE) and other sources of guidance which emphasise the caution that should be exercised prior to surgery being considered." (Pg. 87) The impact on individual patients with adverse outcomes can be significant. *"Whilst some women have experienced distressing and severe effects, the current evidence shows that when these products are used correctly they can help alleviate the very distressing symptoms of SUI and POP and as such the benefits still outweigh the risks."* (Pg. 87) *"Given the benefits seen with vaginal mesh implants for POP, the overall benefits appear to outweigh the risks. However, further work is needed to characterise long-term safety in relation to different surgical procedures and vaginal mesh types."* (Pg. 76) However, data on longer term outcomes is not available. *"The MHRA fully recognises that there is little*	

			systematic collated information available about patient experience of surgical implantation of these devices, and there appears to be little available evidence of long-term clinical follow up. The only outcomes we are typically made aware of are from those individuals who have experienced adverse effects." (Pg. 85)	
Medsafe (2014) New Zealand	Review of adverse outcomes reported. Evidential level: Non Analytic Study SIGN 3	To make publically available data on adverse outcomes with Mesh Implants.in the light of international concerns. Considered SUI & POP	No formal data analysis undertaken, reported data tables from January 2004 (first surgery) to June 2014 (last outcome). There were 66 reported adverse outcomes from any source, not differentiated by SUI / POP No clear pattern of Mesh implant involvement Range of implant to outcome report intervals from 1 day to over 9 years (NB excess of reports from 2013 onwards (38/66 = 58%)	There are no conclusions.
Therapeutic Goods Administration (2014) (TGA) Australia *[NB Based on website report NOT full review*	Safety Review – Summary of available evidence. Evidential level: Not identifiable.	To review the safety and use of Mesh Implants. Considered SUI & POP	The Review highlighted the importance of: • appropriate patient selection • experience of the surgeon • need for fully informed consent. The Review found the level of evidence poor and that there was little evidence of effectiveness in the type of device.	*"The TGA has completed a review of urogynaecological surgical mesh implants and found that, while there may be a benefit in certain patients there is little evidence to support the overall*

unpublished]			Specially, “adequate” evidence for the use of Mesh implants for SUI, Abdominal POP, but not trans-vaginal POP. All Mesh products to be reassessed for device compliance. Adverse outcomes are not specified but were concluded to low – even accepting under-reporting	*effectiveness of these surgical meshes as a class of products.”* (Website)
Health Canada (2014) Canada ***(****NB Based on website news report)*	News alert – Hospital and patient advice note. Evidential level: Not identifiable.	To provide updated safety advice / recommendations for patients and healthcare providers.	Routine, ongoing device safety assessment is happening and device labelling under review. Healthcare providers should consider the following in determining appropriate surgical intervention: • Single-incision mini sling procedures are novel techniques for the treatment of SUI and may carry higher risk of complications than the traditional mid-urethral sling procedures; • Transvaginal mesh procedures for the treatment of POP are evolving procedures that may carry higher risk of complications than established traditional abdominally-placed mesh or native tissue repair procedure; • Clinicians should be aware of the complications associated with transvaginal implantation of surgical mesh for the treatment of SUI or POP. Some of these complications may require additional surgery which may not fully	*Health Canada is informing patients about the potential risk of complications associated with transvaginal implantation of surgical mesh devices for the treatment of pelvic organ prolapse (POP) and stress urinary incontinence (SUI). Although many women treated with these devices have had good outcomes, Health Canada continues to receive reports of complications.* *The use of transvaginal mesh devices for POP and SUI repair has been*

			correct them; • Surgeons performing transvaginal mesh procedures should have adequate training specific to the devices used and be aware of the specific device information, in particular, sections concerning warnings and implantation technique; Pre-surgery information should include: • Pre surgery counselling to inform patients about all treatment options; • Ensure patients are fully aware of the potential risks and benefits of each treatment option and provide patients with written documentation including specific device information; • If mesh procedure is considered, patients should be informed about:: ○ The route by which the mesh will be placed (abdominal or transvaginal); ○ The potential complications of mesh placement; ○ That a mesh is considered a permanent implant; removal of mesh or correction of mesh-related complications may involve subsequent surgery which may not completely remove mesh implants and/or fully correct some complications. • Healthcare professionals are encouraged	*associated with reports of acute or chronic pain, pain during sexual intercourse, mesh erosion and shrinkage, infection, urinary problems, organ or blood vessel perforation, nerve damage, bleeding, vaginal tightness and/or shortening, and recurrent POP and SUI. Additional surgery may be required and may not fully correct some complications."*

			to: ○ Update their knowledge by reviewing relevant scientific literature and clinical guidelines regarding techniques, effectiveness and complications; ○ Develop / maintain clinical competencies by attending relevant training courses related to the use of Mesh devices. • Ongoing monitoring of the complications associated with the use of transvaginal surgical mesh devices and to work with manufacturers to evaluate device safety and effectiveness data as they become available. • Device regulation requires ongoing reporting of adverse outcomes. Reporting rates determined on the basis of spontaneously reported post-marketing adverse incidents are generally presumed to underestimate the risks. Cases of serious or unexpected adverse incidents in patients implanted with transvaginal surgical mesh devices for POP and SUI repair should be reported. Advice to patients: • Before surgery, check about all POP and SUI treatment options and understand the pros and cons of each option; • Ask for and review a copy of the patient	

			information that comes with the mesh product; • Discuss any questions and/or concerns with your health care professional; • Following POP or SUI mesh implant: ○ without complications or symptoms – continue with routine follow-up; ○ with complication or symptoms – see your surgeon .	
Health Care Inspectorate of the Ministry of Health, Welfare and Sport (2013) Netherlands	Safety Review of available evidence Evidential level: Narrative review reporting on evidence in a range from SIGN 3 to SIGN 4 The format of the investigation was set in a context of fulfilling legal requirements for device safety	The main question posed was whether the reported complications were serious enough to: warrant taking devices off the market, banning the intervention or taking other measures. Considered POP only SUI not considered by the review, but subject to ongoing consideration.	The review concluded that patient reporting highlighted: • serious complications do exist • patients felt ill-informed and did not understand what specific risks the procedures carried • Patients their post-surgery complaints/ bad experiences went unheard. Overall the evidence of the effectiveness of transvaginal Mesh over traditional treatment, in respect of failure rates, was considered to have been established. Clinical introduction of devices was swift and without clear criteria regarding indications of its effectiveness and safety. A professional quality standard was developed by the professional body that permits use with repeat prolapse or clinical studies. The standard requires that a registry to log the interventions and possible complications of	*"The application of mesh may lead to serious complications, but in many cases also benefits patients. Very few alternatives to conventional surgery are available without the use of mesh, and therefore a ban on mesh is considered not to be in the interest of patients." (Pg. 20).*

			transvaginal mesh is maintained. The investigation found the device had been introduced in line with legal requirements, albeit there had been administrative problems. In assessing device safety, manufacturers were noted as having conducted little clinical research on use for POP before the market introduction. Evidence from other applications of Mesh was permitted in its assessment for POP. However, the evidence was still was still sufficient to permit valid introduction to the market at that time. The review of the device safety agency found that whilst there were shortcomings in the process of assessing device safety, the agency had complied with the legal framework in operation at the time of the assessment. The investigation found evidence that healthcare professionals rarely reported post implant complications. The Vigilance and Post-market Surveillance System was considered to be insufficient to provide feedback on experiences. The Dutch Inspectorate recommended a number of specific actions. • the requirements for clinical evaluation of	

			devices should be stricter; • the Vigilance and Post-Marketing Surveillance System needs to be strengthened in European legislation; and • the creation of a central, independent registry for implants, recording product information and patient information as a minimum. The registry should include all implants, across all specialties. A number of practical, enforcement actions are also noted to reduce the risk of complications. These cover clinicians, professional associations, industry and the health ministry.	
Danish Health & Medicines Authority (2012) Denmark *[NB Based on website summary report]*	News alert – Hospital and patient advice note. Evidential level: Not identifiable.	To advise Danish hospitals to recall women with synthetic Mesh implants for POP repairs for consultation and evaluation. Women with Mesh implants for SUI specifically excluded from review.	Patient recall for clinical assessment recommended in the light of FDA report from 2011 and subsequent regulatory changes. Advice for women issued to recommend seeking clinical review if received a POP synthetic mesh For SUI mesh patients, recommended seeing primary care physician if they experienced problems. .	*"The Danish Health and Medicines Authority now advises hospitals in Denmark to call in women for consultation in response to concerns raised by the authorities in other countries which currently follow the complications closely. Synthetic mesh has been used in Denmark since the mid-1990s to the benefit of*

				thousands of women who suffer from urinary incontinence. The current concerns do not involve surgery for urinary incontinence, and it is important to stress that these women do not have to worry. *The Danish Health and Medicines Authority reminds treating physicians that they are obliged to report serious adverse events involving the use of mesh, because mesh is a medical device."*
York Health Economics Consortium (2012) ("York Review") For the MHRA United Kingdom	Safety and Adverse Outcome Review Evidential Level: SIGN 1+	To summarise the findings of the major systematic review of the safety/adverse events of vaginal tapes/slings/meshes for SUI and POP.	The Review published a useful summary of the reported risk (and possible risk range) of adverse outcomes by procedure, type of implant, of surgical approach: • Generally found that the risk of adverse events included were low. • Where there were variations in reported risks, identified the potential for differences in "surgical skill" and "patient characteristics". • Reported risk variation was also noted as potentially due to heterogeneity in the definitions of adverse events was also	*"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*

			noted for some outcomes. • Was clear variation in the number of included studies by type of adverse outcome (range from 0 to 25). Erosion associated with TVT/SPARC (n=24) and TOT (n=25) most researched. • Patient outcomes measured at 6 months, not longer.	*been reported in individual study reports."* (Pg. 2)
Food and Drug Administration (2011) United States of America	Safety Review – Summary of available evidence Evidential level: Narrative review reporting on evidence in a range from SIGN 1++ to SIGN 4 Only focussed on POP evidence.	To update on advice to the public and the medical community on the reported complications related to transvaginal POP repair with mesh. Considered POP only.	The 2011 review found evidence of adverse outcomes associated with both POP repairs and SUI repairs. Adverse POP outcomes included: erosion; pain; sexual dysfunction; infection; urinary problems; bleeding; organ perforation; recurrent prolapse; neuro-muscular problems; vaginal scarring/shrinkage; and emotional problems. Many recorded need for additional intervention. *"Between 2008 and 2010, there were seven reported deaths associated with POP repairs. Follow-up investigation on the death reports revealed that three of the deaths associated with POP repair were related to the mesh placement procedure (two bowel perforations, one hemorrhage). Four deaths were due to post-operative medical complications not directly related to the mesh placement procedure." (Pg. 7).* Safety concerns identified in the literature	Safety review concluded: *"Based on evaluation of adverse event reports and assessment of the scientific literature, the FDA has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk…Compounding the concerns regarding adverse events are*

			included: • Patients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh. Such adverse events can be life-altering for some women. These may persist despite mesh removal. • Mesh complications are not rare. The most common mesh-related complication experienced by patients undergoing POP repair is vaginal mesh erosion. More than half of the women who experienced erosion from non-absorbable synthetic mesh required surgical excision. • Transvaginal surgery with mesh to correct vaginal apical prolapse is associated with a higher rate of complication requiring reoperation and reoperation for any reason compared to traditional vaginal surgery or sacral colpopexy. • Abdominal POP surgery using mesh (sacral colpopexy) appears to result in lower rates of mesh complications compared to transvaginal POP surgery with mesh. In regard of efficacy, the literature review found that: *"while transvaginal POP repair with mesh often restores anatomy, it has not been shown to improve clinical benefit over traditional non-mesh repair". (Pg. 8)*	*performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair, particularly for transvaginal apical and posterior repair. While the literature suggests an anatomic benefit to anterior repair with mesh augmentation, this anatomic benefit may not result in superior clinical outcomes… Based on these findings, the FDA is considering regulatory changes that may improve our understanding of the safety and effectiveness of these devices and has specific recommendations for patients and healthcare providers." (Pg9-10)* Reclassification of device risk level (2014)

			A number of limitations of the existing literature were identified. These affect the interpretation of the available data: • Many studies are poorly designed and/or conducted, are underpowered, use incompletely documented inclusion/exclusion criteria, use variable lengths of patient follow-up without adequate justification; • Very few studies extend past 2 years; • The majority of studies use an “ideal” effectiveness outcome which is not necessary for most women to achieve symptomatic relief; • Study results often combine primary and repeat prolapse repairs Often patients also undergo additional POP procedures and/or combined POP-SUI procedures; and • Adverse events are inconsistently defined and reported. Generally the FDA made recommendations for patients and for healthcare providers to improve communication, understanding of risks and complications, and better informed consent before surgery and effective follow up after POP with Mesh surgery. For patients before transvaginal POP repair surgery:	

			• Be aware of the risks associated with transvaginal POP repair, including that mesh surgery may increase the risk for needing additional surgery due to complications and that repeat surgery may not resolve complications for a small number of patients; • Consider with clinical teams all POP treatment options, both surgical and non-surgical, and repair with or without mesh. Seek to understand why they may be recommending treatment of POP with mesh. After surgery: • Continue with annual / routine check-ups and follow-up care. Be clear if you did or did not have Mesh implants; • Notify health care providers if they develop complications or symptoms that last after the last follow-up appointment; • Talk to the health care providers about any questions or concerns. For health care provides: • Recognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications. Ensure that the patient understands the postoperative risks and complications of mesh surgery as well as limited long-term outcomes data.	

			• Inform the patient about the benefits and risks of non-surgical options, non-mesh surgery, surgical mesh placed abdominally and the likely success of these alternatives compared to transvaginal surgery with mesh. • Choose mesh surgery only after weighing the risks and benefits of surgery with mesh versus all surgical and non-surgical alternatives. Factors to consider include: surgical mesh is a permanent implant that may make future surgical repair more challenging; a mesh procedure may put the patient at risk for requiring additional surgery or for the development of new complications; removal of mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life; complete removal of mesh may not be possible and may not result in complete resolution of complications, including pain; and Mesh placed abdominally for POP repair may result in lower rates of mesh complications compared to transvaginal POP surgery with mesh; • Notify the patient if mesh will be used in her POP surgery and provide the patient with information about the specific product used. Subsequent regulatory and advisory changes	

			relating to POP with Mesh repair include requiring post marketing surveillance (Jan 2012) and have proposed a reclassification of risk of POP Mesh to “high risk” (class III) which creates a requirement for pre-market assessment (April 2014). These broadly bring the FDA in line with UK / EU device regulation.
			
			The last update by the FDA in relation to SUI Mesh surgery seems to have been In March 2013. This recommends healthcare providers to:
			• Obtain specialized training for each SUI mesh placement technique;
			• Monitor potential adverse events from the mesh sling, such as erosion, and complications associated with the use of the tools used in transvaginal placement of the mesh sling during the surgical procedure, such as bladder perforations;
			• Before surgery inform the patient about her choice to have incontinence repair with or without a mesh sling. The patient should understand:
			  ○ the likely success of transvaginal SUI surgery with mesh compared to non-surgical treatment options and non-mesh surgery based on the individual patient factors;
			  ○ the potential postoperative complications of a mesh sling surgery	

			compared to non-mesh surgery and their effect on quality of life; ○ that there is limited information about outcomes after one year; ○ whether or not mesh will be used in the repair, and if so, which specific product will be used; that a mesh sling is a permanent implant; and that ○ as with any SUI surgery, the use of surgical mesh for SUI can make any future surgical repairs more difficult and can put the patient at risk for additional complications and surgeries. • Ensure that the patient understands the postoperative risks and potential complications of mesh sling surgery.	

Table 1b International Agency Safety Reviews – General Observations

Document	Safety of Mesh Implant	Conclusions	Actions
Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) European Commission	Preliminary Opinion on the safety of synthetic surgical meshes used in urogynaecological surgery. NB This is a **consultation** and the final findings may change. SCENIHR *"deals with questions related to emerging or newly identified health and environmental risks and on broad, complex or multidisciplinary issues requiring a comprehensive assessment of risks to consumer safety or public health and related issues not covered by other Community risk assessment bodies."*	Generally conclude: • There is a scientific case for the use of mesh in both SUI and POP; • Adverse outcomes do occur and create real problems for those affected. • SUI procedures are less prone to adverse outcome than POP procedures; • Other factors associated with poor outcomes include: ○ the type of anatomical defect and severity; ○ the presence of risk factors; and ○ the skill and experience of surgeons.	Recommended actions focus on: • Accurate and comprehensive informed consent; • Registration of implants; • Mesh research into: ○ improved, long-term (at least 5 years) safety and performance research of synthetic non-absorbable meshes; ○ novel design and materials (absorbable meshes); and ○ improved technologies for mesh manufacture; • Wider research into the application of regenerative medicine technology e.g, cellular seeding of graft materials; • Establish evidence-based European Guidelines; and • formal training programs for surgeons.
Accident Compensation	Analysis of injury claims by NZ	Broadly speaking conclude	Actions needed on improving

Corporation (2015) New Zealand	"no fault" injury claims system. Primarily focuses on what can be learned from injury data available. NB this data cannot say anything about mesh effectiveness Includes hernia data.	that: • POP is more likely to lead to injury claim that SUI • POP – Mesh siting on vaginal wall, using unmodified mesh and secured using sutures more likely to lead to an injury claim, • SUI – retropublic • urethral insertion of unsecured mesh without modification for likely to lead to an injury claim. • For both, transvaginal more problematic than abdominal.	data collection and how surgical follow up data is generated. Data on surgical approaches and demographics of claimants identified as possible sources of information to assess suitability of mesh surgery for specific patients.
Medical Devices and Healthcare Regulatory Authority (2014) (MHRA) United Kingdom	Primarily based on the York Review (2012), and own data analysis, linked to all other safety review work – found little evidence of safety issues over and above the normal risk of surgical interventions. Acknowledged that patient adverse outcomes are real and severe, but the assessed benefits outweigh the risks.	Surgical procedures are fine if carried out in line with NICE guidance. Four deaths in UK associated with Mesh procedures consistent with complications of surgery and not implant failures.	Further action needed on: • Improved patient selection • (Better) Informed patient consent. • Comprehensive (long term) information on patient outcomes. • National Mesh Register with Unique Identifier Code for individual implants.
Medscape (2014)	Simply reported data on reported adverse outcomes.	N/A	Not a formal action from the review, but the interval

New Zealand	No clear suggestion of a single type of implant associated with problems. The excess of reports from 2013 and 2014 mean it is not possible to exclude reporting bias.		between event (surgery) and reported outcome does suggest longer-term post-operative follow up is warranted. Even accepting the risk of reporting bias.
Therapeutic Goods Administration (2014) (TGA) Australia (NB Based on website news report NOT the full review)	The Review found the level of evidence poor and that they was little evidence of effectiveness in the type of device. Effectiveness is not clearly defined. Specifically, the website noted there was "adequate" evidence for the use of Mesh implants for SUI, Abdominal POP, but not trans-vaginal POP. The website noted **All** Mesh products to be reassessed for device compliance.	The findings from the review highlighted the importance of: • appropriate patient selection • surgeon experience • the need for fully informed patient consent.	Difficult to assess this website update fully. The surgical practice findings are in line with other reviews. BUT the conclusion that the class of products was ineffective is somewhat out of step with other reviews. Reconciling that to the finding of adequate evidence for some uses also doesn't sit easily with the overall finding.
Health Canada (2014) Canada	News alert – Hospital and patient advice note. To provide updated safety advice / recommendations for	Recommendations focus on: • pre-surgical considerations; • good practice in information / communication in considering options;	This is more of a response to externally driven concerns. There does not seem to have been any reassessment of the approach to establishing

	patients and healthcare providers.	• developing and maintaining clinical competencies • Device adverse event reporting	device safety.
Health Care Inspectorate of the Ministry of Health, Welfare and Sport (2013) Netherlands	The format of the investigation was set in a context of fulfilling legal requirements for device safety Only considered POP applications.	Findings of the investigations highlighted: • serious complications are real; • device safety assessment processes could / should be improved; and • need for appropriate follow up post implant.	The Dutch Inspectorate recommended a number of specific actions. • the requirements for clinical evaluation of devices should be stricter; • the Vigilance and Post-Marketing Surveillance System needs to be strengthened in European legislation; and • the creation of a central, independent registry for implants, recording product information and patient information as a minimum.
Danish Health & Medicines Authority (2012) Denmark Based on website news report	News alert – Hospital and patient advice note.	To advise Danish hospitals to recall women with synthetic Mesh implants for POP repairs for consultation and evaluation. Women with Mesh implants for SUI specifically excluded from review.	Patient recall for clinical assessment recommended in the light of FDA report from 2011 and subsequent regulatory changes.
York Health Economics Consortium (2012) (“York Review”)	Safety and Adverse Outcome Review	To summarise the findings of the major systematic review	Generally found that the risk of adverse events included were low.

For the MHRA United Kingdom			Where there were variations in reported risks, identified the potential for differences in “surgical skill” and “patient characteristics”. Reported risk variation was also noted as potentially due to heterogeneity in the definitions of adverse events, noted for some outcomes.
Food and Drug Administration (2011) United States of America	Primary aimed at assessing the device safety. NB POP only. SUI subject to ongoing consideration	The 2011 review found evidence of adverse outcomes. Between 2008 & 2010 there were 2874 reports, 52.3% associated with POP repairs and 47.7% with SUI The 7 POP deaths were associated with surgical procedure or complications. Evidence for POP repair effectiveness and safety low Limitations of literature articulated. Recommendations updated for	Generally the FDA and MHRA data is broadly similar in its conclusions. There are effectiveness issues and safety concerns, but not sufficient to warrant device withdrawal – more regulation needed. NB the regulatory changes have largely brought the US in line with the UK / EU approach to device assessment and regulation.

		POP and SUI (2013) for patients and healthcare providers	

Table 2a: Systematic Reviews of SUI Procedures

Title & Author(s)	**Purpose of Review & Review type,**	**Level of evidence included & Quality of evidence**	**Findings** • **Surgical Outcomes** • **Adverse Outcomes** • **Quality of Life (QoL)**	**Conclusions**
Anterior vaginal repair for urinary incontinence in women. Glazener CMA & Cooper K. (2001) Cochrane Database of Systematic Reviews. 2001; Issue 1 DOI: 10.1002/14651858. CD001755. Last assessed as up-to-date: September 2009.	To determine the effects of surgical anterior vaginal wall repair (AVR) on stress or mixed urinary incontinence (SUI or MUI) in comparison with other management options. Cochrane Systematic Review	Systematic Review based on evidence ranging from SIGN 1++ (High quality meta-analysis, systematic reviews of Randomised Controlled Trials (RCTs) ,or RCTs with a very low risk of bias) to SIGN 1+.(Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias) Review included 10 RCTs / quasi-RCTs in which 385 women had anterior vaginal repair for SUI (7 trials) / MUI (3 trials) as a primary procedure. Women with prolapse were included in of the	***AVR versus no treatment or mock operation*** No trials identified. ***AVR versus conservative interventions*** Only 1 small trial (n-16) compared AVR to pelvic floor muscle training – no useful data reported; ***AVR versus open abdominal retropubic suspension (ARS) in all women*** Eight trials identified. **Surgical Outcomes** • AVR was less effective than abdominal suspension, based on subjective outcomes: ○ < 1 year follow up (8 trials) – AVR 29% (82/279) of women still incontinent compared with 14% (50/346) ARS women still reporting incontinence [Relative Risk (RR) of failure: 1.89, 95% CI 1.39 to 2.59] ○ 1 year to 5 year follow up (6 trials) – AVR 38% (97 of 259) compared with	*"The limited evidence indicates that the open abdominal approach (retropubic suspension) is better than anterior vaginal repair for the treatment of primary urodynamic stress incontinence. The effect was longer lasting, whether or not the women had associated prolapse.(Pg 10)* *"Although there were no direct comparisons between anterior vaginal repair and suburethral slings, evidence from a Cochrane review comparing abdominal retropubic suspension with slings in six trials suggested that they were broadly equally effective."*

		7 trials. Previous UI surgery was a reason to exclude women from participating in 9 of the trials. Overall, the authors concluded that, on the basis of the number of participants included in the review and the research methods used by the trials that the overall quality of the evidence was "poor".	ARS 17% (57 of 327) still incontinent. [RR of failure 2.29 95% CI 1.7 to 3.08] ○ > 5 year follow up (4 trials) – AVR 38% (49/128 compared with 21% (31/145); [RR of failure 2.02, 95% CI 1.36 to 3.01] **Adverse outcomes** • Perioperative complications (urinary tract infections; bladder perforation; raised temperature, & bleeding) were reported in 3 trials. There was no observed difference between AVR and ARS [RR of perioperative complications 1.57. 95% CI 0.84 to 2.95] • New or recurrent prolapse was less likely after AVR (4%, 48/197) than ARS (17%, 43/251). [RR of new or recurrent prolapse 0.24, 95%CI 0.12 to 0.47]) • More women required repeat surgery for recurrent incontinence after AVR (23%, 25/107) than women who had ARS (2%, 4/164 [RR of repeat surgery 8.87, 95% CI 3.28 to 23.94]) • No differences were found for any other adverse outcomes including: death; urge incontinence / overactive bladder syndrome; voiding problems; prolapse repair rates; and pain on sexual intercourse **QoL** • Measure in only 1 small trial (n=35), marginal improvement in reported "incontinence impact" for ARS over AVR.	*(Pg 9)*

			AVR versus open ARS in trials including women with co-existing prolapse
			Six trials identified.
			
			Surgical Outcomes
			• When these trials were considered alone open ARS was better than AVR in terms of subjective failure rates in both:
			  ○ 1 year to 5 year follow up: [RR 2.49, 95% CI 1.83 to 3.39] Comparison
			  ○ > 5 year follow up – [RR 3.39, 95%CI 1.4 to 8.22].
			
			Adverse outcomes
			• There was a greater need for repeat continence surgery after AVR (23%, 25/ 107) compared with ARS (2%, 4/164) [RR 8.87, 95% CI 3.28 to 23.94]
			• In the ARS group, continuing or recurrent prolapse was higher than for AVR [RR in favour of AVR 0.12, 95% CI 0.05 to 0.32].Though overall there was no difference between AVR or ARS aggregated in having further prolapse surgery.
			• There were no significant differences in voiding dysfunction, perioperative surgical complications, length of hospital stay,
			• subsequent urge incontinence, overactive bladder syndrome or death.
			
			QoL
			• None of the 6 trials collected QoL data.	

			AVR compared with needle suspension Three trials identified. **Surgical Outcomes & Adverse Outcomes** • No differences were reported between the two procedures. **QoL** • None of the 3 trials collected QoL data ***AVR versus suburethral sling operations*** No trials identified. ***AVR versus Laparoscopic Colposuspensions*** No trials identified ***One type of anterior vaginal repair versus another*** No trials identified.	
Systematic review of the clinical effectiveness and cost-effectiveness of tension-free vaginal tape for treatment of urinary stress incontinence Cody J et al. (2003) Health Technol. Assess 2003;7 (21).	To evaluate the effectiveness (and cost-effectiveness) of tension-free vaginal tape (TVT) in comparison with the standard surgical interventions. Health Technology Assessment. ***[NB Only***	Systematic Review based on evidence ranging from SIGN 1++ (High quality meta-analysis, systematic reviews of Randomised Controlled Trials (RCTs) ,or RCTs with a very low risk of bias) to SIGN 2+.(Well conducted case control or cohort studies with a	The main findings on the surgical effectiveness elements of the review were: **Surgical Outcomes** • Two year subjective cure rates for TVT procedures compared with existing surgical procedures (laparoscopic colposuspension and traditional slings) were broadly similar. (RCT / Comparative studies: TVT – 64% to 93%; Comparator surgery – 53% to 100%). • Evidence for subjective improvement without cure was uncertain. (RCT /	*"Judging how well TVT performs in comparison with other surgical procedures for stress incontinence is difficult because there are few randomised controlled trials." (Pg x)* *"Laparoscopic colposuspension and traditional slings have broadly similar cure rates*

	effectiveness data reviewed]	low risk of confounding or bias and a moderate probability that the relationship is causal) Review included 80 studies: five RCTs or quasi-RCTs; nine non-randomised comparative studies; 66 case series (17 with >2 year; & 49 with <2 year follow up); and six reports from two population-based TVT registries. Variation in the quality of the included in the review was observed. The RCT data included in this review were mainly derived from a single clinical trial. This may be a source of bias. Overall, the authors considered that there was "limited" data on which to base the review.	Comparative studies: TVT – 5% to 11%; Comparator surgery – 0% to 36%). • TVT is less invasive than comparative procedures, is usually performed under regional or local anaesthesia, and is followed by a shorter stay in hospital **Adverse Outcomes** • Principal operative complication is bladder perforation. . (RCT / Comparative studies: TVT – 4% to 22%; Comparator surgery – 0% to 10%). Case series data suggests the complication rate is around 4% for TVT. • Three month complications include: new urge symptoms, voiding dysfunction, & post-op pain. Data is – however – described as unreliable. • No RCT data included follow up to 2 years, though the case series data includes studies with up to 4 year follow up. **QoL** • Two RCTs consider QoL measures. At 6 months the TVT group scored significantly better for the SF-36 subscales on role imitation due to emotional problems, social functioning vitality and mental health • Case series data show improvements in post-operative QoL scores compared to pre-operation levels.	*to TVT and open colposuspension based on limited data from direct comparisons with TVT and from systematic reviews."* *(Pg x)* *"There are currently no RCT data beyond 2 years post-surgery. Although the case series with more than 4 years of follow-up suggest sustained cure rates, there are only three such studies, and they include only around 300 women. Long-term continence rates are therefore currently not known reliably, nor are the effects of TVT on the outcome of future problems such as prolapse and recurrent stress incontinence." (Pg x)*
Laparoscopic	To determine the	Systematic Review	***Laparoscopic colposuspension (LC) v no***	***"****Like other laparoscopic*

colposuspension for urinary incontinence in women. Dean N et al (2006) Cochrane Database of Systematic Reviews. 2006; Issue 3: DOI:10.1002/14651858.CD002239.pub2 Last assessed as up-to-date: December 2009.	effects of laparoscopic colposuspension for the treatment of urinary incontinence in women. Cochrane Systematic Review	based on evidence ranging from SIGN 1++ (High quality meta-analysis, systematic reviews of Randomised Controlled Trials (RCTs) ,or RCTs with a very low risk of bias) to SIGN 1+.(Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias) Review included 22 RCT studies where women were treated for SUI with laparoscopic colposuspension in at least one arm of the trial, with sample size range between 20 and 300. Trials excluded women with: previous incontinence surgery (15 trials); previous retropubic surgery (12 trials); history of mixed urinary incontinence (9 trials); history of POP (10 trials); patients requiring concurrent gynaecological	***treatment or mock operation*** No trials identified ***LC v conservative management*** No trials identified ***LC v Open Colposuspension (OC)*** Ten trials identified. Outcome data for 'six to 18 months were available for eight studies. Longer-term data, over five years, were only available for two studies. **Surgical outcomes** • Subjective cure rates from trials ranged from 58% to 96% for OC and 62% to 100% for LC in < 18 months follow up, but the overall subjective cure rate was not significant between LC and OC (RR = 0.95, 95% CI 0.90 to 1.00).This analysis was subject to statistically significant heterogeneity in the pooled meta-analysis. This was due to one trial. • Incontinence symptoms were recorded in two trials. Initial significant improvement for both LC and OC declined over time with the LC group showed marked deterioration over time in this group with 1 trial showing LC approaching preoperative levels of incontinent episodes by five years and the other trial showing no apparent difference between LC and OC at 18 months. • Objective (clinician) cure rate <18 months showed a statistically significant reduction of RR in LC, compared with OC (RR =	*operations, laparoscopic colposuspension appears to have short-term benefits over open surgery, such as quicker recovery, less pain and perioperative complications; but it appears to be more costly and takes longer to perform." (Pg 15)* *"If laparoscopic colposuspension is performed, two paravaginal sutures appear to be more effective than one suture or the use of mesh and staples. It is unclear whether an extraperitoneal approach has advantages over a transperitoneal method. The place of laparoscopic colposuspension in clinical practice should become clearer when ongoing trials with longer-term data are reported." (Pg 15)* *"Surgical trials related to urinary incontinence should systematically address surgical morbidity*

		procedures (8 trials); Ten studies compared laparoscopic colposuspension with open colposuspension but none were not consistent in either the number, type of mesh used, or type of sutures used. Other trials were also variable in types of Mesh and sutures used. The surgeons in three studies had performed fewer than 20 laparoscopic colposuspensions before starting the trial. Other studies reported surgeons as being senior gynaecologists with extensive experience in both procedures. Just over half stated the method of approach used for the laparoscopic colposuspension. Ten studies used the	0.91, 95%CI 0.86 to 0.96). Between 18 months and five years, no significant differences between LC and OC observed (RR = 1.01, 95% CI 0.88 to 1.16) • No significant differences observed in comparisons for: de novo detrusor overactivity or voiding dysfunction **Adverse outcomes** • Overall, there were significantly fewer perioperative complications for LC compared with OC (RR = 0.74, 95% CI 0.58 to 0.96), though there were numerically more bladder injuries with LC (4%) compared with OC (2%) • Women who had LC appeared to have significantly less pain and needed less postoperative analgesia, but pooling of the quantitative data was not possible • All but one trial reported hospital length of stay to be longer for OC, pooled data analysis was possible for six studies suggesting LC procedure stays were shorter than OC stays though there was significant variation in the data. **QoL** • Six studies reported use of QoL scales, but indexes were so varied no pooled data analysis was possible. Improvements noted for both LC and OC in the year following surgery, with no suggestion of difference between operative approaches ***LC v needle suspension***	*outcomes such as adverse perioperative events, pain scores, length of hospital stay, time to return to normal activities, development of urge symptoms or detrusor overactivity and, especially, the need for repeat surgery or alternative interventions." (Pg 15)* *"Long-term follow up is essential for the proper evaluation of incontinence treatments, and this should be included in all trials of laparoscopic colposuspension." (PG 15)*

		transperitoneal approach The authors assessed the risk of bias associated trial allocation as being adequate in 13 trials and inadequate in a single trial, However it was unclear for the remaining 8 trials.	No trials identified ***LC v traditional sling procedures*** No trials identified ***LC v'self-fixing' sling procedures*** Eight trials with different types of Mesh and sutures used for both operative approaches **Surgical outcomes** • Overall, there was no statistically significant difference in subjective cure rates between LC and vaginal sling procedures (VS) within 18 months (RR = 0.91, 95% CI 0.80 to 1.02). In 1 trial, this effect remained the case in 4-8 year follow up as TVT was reported to have similar subjective cure rates as LC (RR = 1.18, 95% CI 0.36 to 3.81) • Objective (clinical) cure rates within 18 months were assessed in all but one study, but with varying definitions of cure. Taken together, LC had statistically significantly lower objective cure rates than VS using Mesh (RR = 0.88, 95% CI 0.81 to 0.95) • Urge symptoms were reported in two studies that showed that urgency was more common with VS • No other differences in surgical outcome measures were observed **Adverse outcomes** • Seven trials reported on the perioperative complication rates between LC and VS	

			and found no difference in rates (RR = 0.99, 95% CI 0.60 to 1.64) • Two studies assessed pain and pain relief. One reported analgesics used to be lower with VS using TVT. The second reported that the length of time that patient-controlled analgesia was used post-surgery was equal in both groups. • The length of inpatient stay differed between the two groups although by only one day, with VS providing the shorter stay (Mean difference (days) = 1.10 95% CI 0.79 to 1.41) • Re-operation rates at one year were reported in one study. For the VS with TVT group the rate was 8% (3/38) compared with the LC group 3%(1/32) requiring repeat surgery for non-cure **QoL** • Five studies assessed quality of life. These studies each used a variety of validated questionnaires. No pooling of data for analysis was possible. • Three trials reported significant improvement in QoL measures for both LC and VS, but no differences between them at one year post-surgery. One further study which only reported QoL scores, noted them to be similar in each group at one year post-surgery. • Only one study reported a significant difference between the two procedures with VS using TVT show better QoL at one year post-surgery.	

			LC v anterior repair No trials identified ***LC v periurethral injections*** No trials identified ***LC v LC: one versus two sutures*** **Surgical outcomes** • One trial reported a significantly greater number of women felt subjectively cured (89%) in the two-suture compared to the one-suture group (RR = 1.37, 95% CI 1.14 to 1.64) • A similar result was observed for episodes of incontinence reported by patients for the two suture group (83% cure rate) compared to the one suture group (58%) (RR = 1.42, 95% CI 1.14 to 1.77) • Objective (clinical) cure rates were reported to be better for the two suture group, but numbers were very small **Adverse outcomes** • In the one-suture group 18% (14/78)had a perioperative surgical complication, which was equal to the 18% (15/83) observed for the two-suture group (RR = 0.88, 95% CI 0.45 to 1.70) • One woman in the two-suture group had repeat incontinence surgery. ***LC v LC: sutures versus mesh and staples***	

			Surgical outcomes • Three trials were identified, of which two reported subjective cure rates with sutures than with mesh within 18 months (RR = 1.28, 95% CI 1.11 to 1.47) • Significantly better objective (clinical) cure rate in the suture group < 18 months (RR = 1.20, 95%CI 1.07 to 1.35 **Adverse outcomes** • Across the three trials, there were significantly fewer complications in the mesh group (RR = 1.94, 95% CI 1.09 to 3.48), but this may be due to the bias from one study as there were no statistical significant differences between the number of postoperative complications in two of the three studies • One woman in the mesh group and two women in the suture group had repeat incontinence surgery. ***LC v LC: transperitoneal v extraperitoneal*** **Surgical outcomes** • One study compared a transperitoneal LC approach with an extraperitoneal LC approach. Detail in the trial was sparse • Overall, 18 out of 22 women were subjectively and objectively cured, one was unchanged and one was worse. **Adverse outcomes** • One woman had postoperative detrusor over activity	

			• Two perioperative complications were reported, one a bladder injury.	
Traditional suburethral sling operations for urinary incontinence in women. Rehman H (2011), Cochrane Database of Systematic Reviews. 2011 Issue1. DOI: 10.1002/14651858.CD001754.pub3 Last assessed as up-to-date:June 2010	To determine the effects of traditional suburethral slings on stress or mixed incontinence in comparison with other management options. Cochrane Systematic Review	Systematic Review based on evidence ranging from SIGN 1++ (High quality meta-analysis, systematic reviews of Randomised Controlled Trials (RCTs) ,or RCTs with a very low risk of bias) to SIGN 1+.(Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias) Twenty-six randomised or quasi randomised trials were identified that met the inclusion criteria of women with urodynamic stress incontinence (urodynamic diagnosis), or symptoms of stress or mixed urinary incontinence (clinical diagnosis), in which at least one trial arm involves traditional suburethral sling	The main findings on the review were: ***Traditional suburethral sling operation (TSS) v no treatment or mock operation***. No trials identified. **TSS v conservative management (e.g. pelvic floor muscle training, electrical stimulation, cones, biofeedback)** No trials identified. ***TSS v pharmaceutical drugs*** One trial studied patients with mixed urinary incontinence treated with oxybutynin or surgery **Surgical outcomes** • TSS observed to be significantly better for treating mixed UI for patient reported incontinence within one year (RR = 0.18; 95% CI 0.08 to 0.43) • Also fewer women had persistent urgency urinary incontinence after TSS (RR = 0.29; 95% CI 0.09 to 0.94) **TSS v injectables** One small trial was identified which compared TSS with injectable Macroplastique. **Surgical outcomes** • The only statistically significant outcome was in clinician observed incontinence	*"Evidence relating to primary outcome, was available but limited in determining the effectiveness of traditional suburethral sling operations in the treatment of urinary incontinence. The limited evidence suggests that traditional slings may be equally as effective as other surgical treatments currently available, but variability in the quality of trials is a major limiting factor." (Pg 29)* *".Traditional slings seemed to be as effective as minimally invasive slings, but had higher rates of adverse effects. This should be interpreted with some caution however, as the quality of evidence in the studies was variable, follow-up short and randomised trials do have inherent limitations in identifying complication rates." (Pg*

		procedures. These trials included 2284 women (1287 with traditional slings) and sample sizes ranging from 20 to 655). Ten different materials were used for the sling procedure across the 26 studies. The scientific quality of the trials was low or moderate. Most did not give sufficient detail about the method of patient allocation and blinding. Only two trials used an adequate randomisation method. This means that, generally, it is the author's judgment that there is an "unclear" risk of bias in the trials.	within the first year. TSS related incontinence 19% (4/21) compared to injectable group 90% (20/22), (RR = 0.21; 95% 0.09 to 0.21) • No statistically significant differences between groups found for patient reported incontinence; voiding dysfunction; de novo detrusor overactivity; or urinary tract infection ***TSS v open abdominal retropubic colposuspension*** Seven trials identified. The extent to which the trials could be considered together was limited, because of differences in the procedures compared, the populations studied, the outcomes assessed, and the length of follow-up. **Surgical outcomes** • Patient reported incontinence was found to be not significantly different between the two approaches <1 year post-surgery and after five years follow up. • Five trials considered incontinence at one to five year follow-up. Analysis combining urodynamic and symptom only diagnosis, showed a lower incontinence rate with TSS (RR = 0.75; 95% CI 0.62 to 0.90, • No statistically significant differences in clinically-assessed incontinence rates at one year. **Adverse outcomes** • Four trials reported were statistically	*30)* *"There is a need for further trials of adequate power, better quality and reporting standard to assess the effectiveness of suburethral slings in comparison with other surgical techniques and different types of slings, and in specific situations such as women who have already had." (Pg 30)* *"Outcomes should be relevant to women who have incontinence and are seeking treatment, and policy makers commissioning treatment, in order to allow comparison between treatments. In particular, quality of life, psychological and economic outcomes should be incorporated. Surgical trials related to urinary incontinence should systematically address surgical morbidity outcomes such as adverse peri- and post-operative events, length of*

			significantly fewer perioperative complications in the open colposuspension group (RR = 1.31; 95% CI 1.14 to 1.51). However, this finding was mostly due to data from only one, large, trial which included data on bladder perforation and urinary tract infection. This trial reported a 20% lower risk of bladder perforation with TSS and a 50% increase in urinary tract infection with TSS as compared with colposuspension • Five trials showed significantly more women had voiding dysfunction after TSS (13%) versus open colposuspension (2%),(RR = 6.08; 95% CI 3.10 to 11.95) • No trials showed significant differences between groups for de novo urge symptoms or incontinence, detrusor overactivity, or new or recurrent prolapse. Though numerically more women had new or recurrent prolapse after open colposuspension (15%) compared to TSS (2%) **QoL** • Pooled data analysis was not possible, but 1 trial reported a significantly greater improvement in QoL for those receiving the open colposuspension compared TSS ***TSS v bladder neck needle suspension (abdominal and vaginal)*** One small trial compared a biological sling with needle suspension	*hospital stay, time to return to normal activities, development of urge symptoms or detrusor overactivity and especially the need for repeat surgery or alternative interventions. Long-term follow-up (at least one year, preferably five years or more) is essential for the proper evaluation of incontinence treatments." (Pg 30)*

			Surgical outcomes • No significant differences in patient reported incontinence rates between the groups in the short or longer term; however the numbers in the trial (n=10 in each trial arm) were too small to address such differences **Adverse outcomes** • Significantly more women who had TSS had post-operative complications (40%) compared with those who had needle suspension (20%) (RR 4.50 = 95% CI 1.28 to 15.81). • Data reported for urge incontinence, late voiding dysfunction and detrusor overactivity showed no statistically significant differences, ***TSS v anterior repair.*** No trials identified. ***TSS v laparoscopic procedures*** No trials identified. ***TSS v a minimally invasive sling*** Twelve trials addressed this comparison Surgical outcomes • Patient reported Incontinence <12 months post-surgery was reported by eight RCTs (pooled n = 693). No significant difference between TSS and minimally invasive sling groups (RR = 0.97; 95% CI 0.78 to 1.20). • No improvement was reported by 11% of	

			women with TSS v 15% of those with minimally invasive sling operations (Pooled n = 432), though the CI are wide. (RR = 0.78; 95% CI 0.48 to 1.27) • No significant differences for TSS or minimally invasive sling operations were reported by 6 studies in patient reported incontinence over 1 year • Objective (clinical) cure rates were not found to be significant between groups for < 1 year or > 1 year follow up. **Adverse outcomes** • Perioperative complication. Pooled data from three trials showed TSS was associated with had a statistically significant higher risk.(RR = 1.59; 95% CI 1.03 to 2.44) • De novo detrusor overactivity was significantly less after minimally invasive synthetic suburethral sling operations (RR = 3.21; 95% CI 1.29 to 8.03).Though this was principally due to the higher influence of one largest trial • No statistical significant differences were found between TSS and minimally invasive slings for: ○ bladder perforation (Seven RCTs) (RR = 0.62; 95% CI 0.34 to 1.11) ○ de novo urgency symptoms or urgency. (Three pooled trials) (RR = 3.13; 95% CI 0.96 to 10.24) ○ postoperative voiding dysfunction (Four pooled trials) (RR = 1.60 95% CI 0.94 to 2.71)	

			○ release of sling (Two trials) (RR = 3.67; 95% CI 0.95 to 14.22) ○ urinary retention up to 6 weeks. (1 trial) (RR 5.51; 95% CI 0.68 to 44.63) ○ vaginal erosion (1 trial) (RR = 0.35; 95% CI 0.02 to 8.10) **QoL** • Seven studies, four of which used a variety of validated questionnaires. The data were reported in different ways so that pooled data meta-analysis was not possible • No specific pattern of statistical significant differences between groups was identified. ***One type of TSS v another TSS*** Five trials included, the majority of the trials compared different biological materials with each other. **Surgical outcomes** • No significant differences were found in patient reported incontinence in the short, medium or long term **Adverse outcomes** • No statistically significant differences were observed, though significant data heterogeneity was reported in the two trials considering post-operative complications	
Open retropubic	To assess the effects	Systematic Review	The main results were:	*"The evidence available*

colposuspension for urinary incontinence in women.
 	
Lapitan MCM et al (2012)
 	
Cochrane Database of Systematic Reviews. 2012; Issue 6.
 	
DOI: 10.1002/14651858.CD002912.pub5
 	
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	of open retropubic colposuspension for the treatment of urinary incontinence.
	
	Cochrane systematic review
		based on evidence ranging from SIGN 1++ (High quality meta-analysis, systematic reviews of Randomised Controlled Trials (RCTs) ,or RCTs with a very low risk of bias) to SIGN 1+.(Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias)
		
		The review included 53 studies (and 2 ongoing studies) which were either randomised or quasi-randomised controlled trials which involved open retropubic colposuspension in at least one arm of the trial. Of these, 49 were suitable for pooled data analysis
		
		Risk of bias in included studies was assessed. However almost all studies were classed as being of at an "unclear" risk for bias.
			Open retropubic colposuspension (RC) V no treatment or mock operation
			No trial identified
			
			RC v conservative treatment
			Two small trials compared RC with forms of conservative treatment with pelvic floor muscle training (with or without electrical stimulation) (PFMT)
			
			Surgical outcomes
			• RC was found to be significantly better that PFMT in the short-term (< 1year) for both
			  ○ Patient reported incontinence (1 trial) (RR = 0.24 95% CI 0.08 to 0.71) and
			  ○ Objective (clinical) incontinence (1 trial) (RR = 0.26 95% CI 0.13 to 0.53)
			
			• No formal comparisons were made between the two treatment groups in terms of surgical parameters, quality of life, or health economics.
			
			RC v drug therapy
			One small trial – RC v anticholinergic treatment
			
			Surgical outcomes
			• Patient reported, subjective cure rates showed that 100% of patients reported drug therapy to have failed to provide a cure compared with13% of RC patients
			• A quantitative symptom scoring system
				indicates that open retropubic colposuspension is an effective treatment for stress urinary incontinence, especially in the long term. Within the first year of treatment, the overall continence rate is approximately 85% to 90%. After five years, approximately 80% patients can expect to be dry " (Pg 25)
				
				"Sling procedures (both traditional and minimally invasive) confer similar success rates in comparison with open colposuspension. The long-term adverse event profile of the sling procedure, in particular with the use of the TVT, is still unclear." (Pg 26)
				
				"There is an urgent need for trials of adequate power to assess the effectiveness, safety and cost-effectiveness of open retropubic colposuspension in

		(>80%, present author's assessment) .	was also used as a means of assessing improvement. The subjective symptom scores showed improvement in both treatment groups, with the RC group having a greater improvement ($P < 0.05$). • Post-treatment subjective and objective symptom scores after RC showed significantly better scores than drug treatment. • Objective cure rates were not reported. Quality of life measures, adverse events, and health economic measures were not reported ***RC v anterior colporrhapy (repair) (AC)*** A total of eight trials, methodologically, the quality of the studies was generally satisfactory **Surgical outcomes** • Evidence from seven trials evaluating a total of 695 women (with assessments available at different time periods) showed a lower incontinence rate for subjective cure after RC that after AC: o incontinence rates RC (9%) compared with AC (19%) < 1 year (RR = 0.46 95% CI 0.30 to 0.72) o incontinence rate RC (14%) compared with AC (36%) at one to five years (RR = 0.37 95% CI 0.27 to 0.51) o incontinence rate RC (28%) compared with AC (53%) over five years (RR = 0.49; 95% CI 0.32 to 0.75) • Objective cure rates were found to be:	*comparison with (a) suburethral slings, particularly the self-fixing sling procedures such as TVT, and (b) the laparoscopic technique." (Pg 26)*

			○ incontinence rates RC (9%) compared with AC (25%) < 1 year (RR = 0.36 95% CI 0.22 to 0.58) ○ incontinence rate RC (16%) compared with AC (44%) at one to five years (RR = 0.34 95% CI 0.25 to 0.47) ○ incontinence rate RC (26%) compared with AC (54%) over five years (RR = 0.48 95% CI 0.31 to 0.73) • Data from one small trial showed a longer operating time for RC over AC (Weighted Mean Difference (WMD) 14 minutes; 95% CI 5 to 23) **Adverse outcomes** • Based on the two trials with data perioperative complications was significantly lower for RC than AC (RR = 0.39 95% CI 0.19 to 0.83) • Estimates of the risk for de novo urge symptoms and urge incontinence (3 trials) and risk for detrusor overctivity (4 trials) showed no statistically significant differences • In 5 trials, more women with prolapse were observed in RC than AC groups (16% versus 5%), this was not statistical significant even when a random-effects analysis was used to address data heterogeneity • Fewer women in the RC (63%) group had repeat anti-incontinence surgery compared with AC (23%) in three trials (RR = 0.11 95% CI 0.04 to 0.30)	

			QoL
			• One small trial investigated both types of surgery on the quality of life through an incontinence rating score. Scores improved in both treatment groups, with a small difference between them.
			
			RC v traditional or self-fixing sling procedures
			Twenty trials identified, of which 14 used TVT (1 trial TVT v TOT v RC) and 6 traditional suburethral slings, of various types. Data was of sufficient quality and size to allow sub-group analysis for traditional sling (TS) patients and TVT patients.
			
			Surgical outcomes
			• Patient reported, short term subjective cure rate (< 1 year)
			  ○ TVT & TS (8 trials) – no significant difference with RC (RR = 0.90 95% CI 0.69 to 1.18)
			  ○ TS only (6 trials) – no significant difference (RR = 1.92 95% CI 0.57 to 6.50)
			  ○ TVT only (5 trials) – no significant difference (RR = 0.88 95% CI 0.67 to 1.16)
			• Patient reported, medium term subjective cure rate (1 to 5 years)
			  ○ TVT & TS (6 trials) – showed a lower incontinence rate with sling procedures over RC (RR = 1.18; 95%CI 1.01 to 1.39)
			  ○ TS only (1 trial) – showed a lower	

			incontinence rate with sling procedures over RC ○ TVT only (5 trials) – showed no clear differences between TVT and RC for the subjective incontinence rate or subjective improvement rate • Patient reported, long term subjective cure rate (> 5 years) ○ TS & TVT (2 trials) – showed no significant difference between groups • Objective (clinical) cure rates show no significant differences between RC and sling procedures over any time period • The 6 trials that compared RC with TCT showed shorter hospital stays for the TVT group (WMD = 3.99 95% CI 3.71 to 4.28) **Adverse outcomes** • Perioperative surgical complications ○ TS & TVT (8 trials) – statistically significantly fewer complications in the RC group (RR = 0.76; 95% CI 0.66 to 0.87). Again this showed the effect of the large TS study ○ TVT only (4 trials) – no significant difference in the perioperative complications rates between procedures (RR = 1.11 95% CI 0.66 to 1.87) • Developing voiding difficulties: ○ TS & TVT (11 trials) – this showed nearly 40% lower risk of developing voiding difficulties after RC v sling procedures (RR = 0.41 95% CI 0.26 to 0.67). This again showed the influence	

			of the large TS trial ○ TVT only (7 trials) – no significant difference in the risk of voiding dysfunction between the two groups. • New or recurrent prolapse ○ TS & TVT (3 trials) – showed greater risk for new or recurrent prolapse amongst RC patients (9%) compared to sling procedures (0.5%) (RR = 8.18 95% CI 1.96 to 34.19) ○ TVT only (1 trial) – found no significant difference between RC and TVT groups if only symptomatic prolapse was considered. However, a significant reduction in objective cystocoele but more enterocoele and vault or cervical prolapse cases were observed in the RC group compared with theTVT group up to 2 years post-surgery • Bladder perforation ○ TS only (1 trial) – showed higher risk of sutures passing through the bladder during RC (3%) compared sling procedure (0.06%) (RR = 4.95 95%CI 1.09 to 22.44) ○ TVT only (8 trials) – in contrast, data showed a higher risk for TVT (6.3%) compared to RC (0.9%) (RR = 0.20; 95% CI 0.08 to 0.49) • There was insufficient evidence to assess whether or not there were differences in the risks of de novo urge symptoms and de novo detrusor overactivity between the two treatment procedures. • Other significant complications reported	

			during individual TVT trials were: ○ one patient suffered a non-serious, but significant vascular injury ○ one patient undergoing urethrolysis for persistent urinary retention ○ two patients suffering from partial erosion during long-term follow-up ○ six patients with not defined tape complications at five-year follow-up **QoL** • TS (1 trial) – no significant differences between TS and RC groups in two validated QoL measures • TVT (1 trial) – no significant difference between TVT and RC in health dimensions in three validated QoL measures. RC group showed lower scores for the emotional and social functioning, vitality and mental health dimensions of the SF 36 to 2 years. ***RC v needle suspension (NS)*** Seven trials identified with methodological qualities of assessed as generally satisfactory, albeit with small sample sizes in all save one trial **Surgical outcomes** • Patient-reported subjective cure rate ○ < 1 year incontinence rate RC (11%) v NS (15%) (RR = 0.66 95% CI 0.42 to 1.03) (5 trials)) ○ 1 to 5 years incontinence rate RC (14%) v NS (23%) (RR = 0.56 95% CI 0.39 to 0.81) (6 trials)	

			○ > 5 years incontinence rate RC (18%) v NS (57%) (RR = 0.32 95% CI 0.15 to 0.71) (1 trial) • Objective (clinical) cure rate ○ < 1 year incontinence rate RC (9%) v NS (14%) (RR = 0.56 95% CI 0.32 to 0.97) (3 trials) ○ 1 to 5 year incontinence rate RC (13%) v NA (21%) (RR = 0.59 95% CI 0.40 to 0.88) (5 trials) ○ >5 year incontinence rate RC (18%0 v NS (57%) (RR = 0.32 95% CI 0.15 to 0.71) (1 trial) **Adverse outcomes** • Pooled data from three trials suggested that perioperative complications for RC (30%) were a lower that for NS (48%), though there was substantial data heterogeneity (RR = 0.66 95% CI 0.46, 0.94) • No significant differences between RC and NS were observed in relation to the occurrence of de novo urge symptoms, • de novo detrusor instability, voiding difficulty, or new prolapse ***Open retropubic colposuspension versus laparoscopic colposuspension (LC)*** There were 12 trials, though the comparability of outcome data was low **Surgical outcomes** • Pooled analysis of differing trials indicated there was no statistically significant	

			difference in patient reported subjective cure rates in any of the short-, medium-, or long-term • Objective (clinical) cure rates for the short- and medium-term follow up periods were not found to be significant. A single trial over the long-term (> 5 years) suggested LC was significantly better than RC; however, this trial was of low quality **Adverse outcomes** • Four provided evidence that LC (3%) may produce more bladder perforation that RC (0.6%) (RR = 0.22 95% CI 0.06 to 0.87) • No significant differences in the risk were observed for perioperative complications, de novo urge symptoms or urge incontinence, de novo detrusor overactivity, voiding difficulties, or new or recurrent prolapse **QoL** • In two trials quality of life was measured using the SF-36 physical and mental sub-scales. Both trials demonstrated significant improvement in both sub-scales after RC and LC, with LC having a worse post-operative mental sub-scale scores compared with OC (WMD = 3.94 95% CI 1.07 to 6.81) ***RC versus periurethral (collagen) injection*** One small trial identified **Surgical outcome**	

			• Of 66 women receiving collagen injections and 67 surgery, a reported 19% of women were more likely to be cured with surgery than injections **Adverse outcomes** • There were reported to be significantly fewer and less severe complications with collagen injection than surgery. ***RC v RC: Burch versus Marshall-Marchetti-Krantz procedures*** Four trials identified of sufficient methodological quality. **Surgical outcomes** • For patient reported subjective cure, pooled data for the 1 to 5 year follow up period showed a significant difference and suggested that women treated with a Burch procedure were less likely to be incontinent (RR = 0.72 95%CI 0.52 to 0.99) • No significant differences were found on objective (clinical) cure rates **Adverse outcomes** • One trial reported a lesser risk for voiding difficulties after Burch procedure (RR = 0.27; 95% CI 0.08 to 0.90) • There was insufficient evidence to determine whether or not there were any differences between the procedures in terms of perioperative complications, de novo urge symptoms or urge	

			incontinence, detrusor overactivity, repeat anti-incontinence surgery, or new or recurrent prolapse ***RC v RC: Burch procedure versus paravaginal defect repair*** One small trial identified – insufficient data to allow meaningful interpretation ***RC v RC: Marshall-Marchetti-Krantz versus paravaginal defect repair or vaginal obturator shelf repair*** No trials identified	
Urethral injection therapy for urinary incontinence in women. Kirchin V (2012) Cochrane Database of Systematic Reviews. 2012; Issue 2. DOI: 10.1002/14651858. CD003881.pub3 Last assessed as up-to-date: May 2011	To assess the effects of periurethral or transurethral injection therapy on the cure or improvement of urinary incontinence in women. Cochrane systematic review	Systematic Review based on evidence ranging from SIGN 1++ (High quality meta-analysis, systematic reviews of Randomised Controlled Trials (RCTs) ,or RCTs with a very low risk of bias) to SIGN 1+.(Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias) Fourteen trials were included in this review. In addition four ongoing trials were	***Injection versus no or mock treatment*** One trial identified. Patients received either autologous fat injection or saline placebo injection **Surgical outcomes** • Patient reported subjective cure / improvement reported by 22% of women receiving fat injection compared with 78% showing no improvement or deterioration. However this was comparable with rates for placebo injection (RR = 0.98 95% CI 0.75 to 1.29) • No differences in post treatment, clinically observed symptom rates were observed **Adverse outcomes** • Complication rate was higher for fat injection (32%, 29 out of 91) compared	*"This updated review still provides an unsatisfactory basis for practice. Injection therapy with silicone particles shows a short-term advantage over home pelvic floor muscle training with a reduction in pad use and an increase in disease-specific quality of life; but it is not known if this is maintained beyond three months" (Pg 19)* *"Injection therapy appears inferior to open surgery at 12 months but has a better safety profile." (Pg 19)*

		noted. All were randomised or quasi-randomised controlled trials of treatment for urinary incontinence in which at least one management arm involved periurethral or transurethral injection therapy. Risk of bias was assessed as either "low" or "unclear" in the majority of trials. One trail was assessed at "high" risk of bias.	with placebo injections and (11%, 11 out of 98) (RR = 2.84, 95% CI 1.51 to 5.35) • Other adverse events reported included: ○ Urinary retention: fat injection, 6 patients; placebo, 0 patients ○ urinary tract infections: fat injection, 6 patients; placebo, 3 patients ○ infection at the liposuction site; placebo, 2 patients. • Of the 91 fat injections, 17 (19%) were injected into the wrong site, 6 of the 98 (6%) placebo injections were at the wrong site • There was one death in fat injection group (due to fat migration and subsequent lung embolism). No deaths were reported in the placebo group ***Injection versus conservative management*** One trial identified. Compared silicone particle injection with a pelvic floor exercise programme **Surgical outcomes** • At three month follow up treatment failure was lower in the injection group for both complete cure (RR = 0.7 95%CI 0.52 to 0.94) and cure or marked improvement (RR = 0.22 95% CI 0.03 to 1.81). **Adverse outcomes** • There were 37 episodes of urinary retention was reported in the injection group compared with none in the pelvic	*"The treatment-related death of a patient in a single trial is sufficient evidence to recommend that autologous fat should not be used as a bulking agent." (Pg 19)*

			floor exercise group • Other side effects in the injection group included: dysuria (47%); de novo urgency (21%); mild pain, haematuria, and implant leakage (all at 8%) • Dysuria and retention were transient in all but one patient, who had a new onset of anterior vaginal wall prolapse and persistent retention. **QoL** • Quality of life was assessed using the validated I-QoL questionnaire. The changes in mean score at baseline to three months were: injection 2.59 to 3.03; and pelvic floor exercise 2.96 to 3.2. There was a significant difference between the two groups in terms of change from baseline (RR = 0.54, 95% CI 0.16 to 0.92) ***Injection versus other surgical management*** Two trials compared injection therapy (one collagen, one silicone) with open surgery ***1. Collagen injection trial*** Companion was made to three types of open surgery: Burch procedure; open sling procedure; or open bladder neck suspension. **Surgical outcomes** • Patient satisfaction with treatment outcome was reported to be not significant.	

			• Objective (clinical) cure was reported as more likely following surgery (RR = 1.69 95% CI 1.02 to 2.79) However, this was significant if an intention-to-treat analysis was performed. **Adverse outcomes** • Overall, 36 (unspecified) complications occurred in the 64 injection patients (56%) compared with 84 complications amongst the 54 surgery patients (64%) ***2. Silicon Injection trial*** In the silicone injection trial 23 women received injections compared with 22 who were treated with a pubovaginal sling. Outcomes were assessed at six weeks and six-monthly intervals. Cochrane analysis focussed on 6 month outcomes **Surgical outcomes** • No statistically significant difference was reported in patient satisfaction rates post treatment • For objective (clinical) cure rates at six months 91% of injection patients were not cured compared 19%) of pubovaginal sling patients (RR = 4.77 95% CI 1.96 to 11.64) **Adverse outcomes** • Formal analysis was not undertaken as the number of adverse events was very low (5 UTI & 1 hernia)	

			One type injection material v another Eight trials identified. ***1. Carbon particles versus collagen*** (Two trials) • Surgical outcomes: no statistically significant differences were found for patient reported subjective cure or for objective (clinical) outcomes • Adverse outcomes: only transient effects noted for 1 trial **2. *Silicone particles versus collagen*** (Two trials) • Surgical outcomes: silicone injections were found in 1 trial to be more likely to show an objective (clinical) cure rate at 12 months (RR = 0.84 95% CI 0.71 to 0.99), using an intention to treat analysis • Adverse outcomes: no differences reported. ***3. Calcium hydroxylapatite (CaHA) versus collagen*** (One trial) • Surgical outcomes: no significant differences reported • Adverse outcomes: De novo urge incontinence was reported to be significantly higher in the collagen group: (12.3%) compared to the CaHA group (5.7%). Two CaHA patients had specific treatment related events – vaginal erosion and tracking of injectable under trigone obscuring the ureteric orifice	

			4. Ethylene vinyl alcohol copolymer (EVOH) versus collagen (One trial) • Surgical outcomes: No significant differences observed • Adverse outcomes; no analysable data 5. ***Porcine dermal implant injection versus silicone particles*** (One trial) • Surgical outcomes: an improvement at six months was see in objective (clinical) cure rate with 62% (15 / 24) in the pordine dermis implant group compared with 40% (10 / 24) in the silicone injection group (RR = 0.60 95% CI 0.33 to 1.10) • Adverse outcomes: Urinary retention occurred in 2 out of 25 in the porcine dermis implant group and 3 out of 25 in the silicone group (RR = 0.67, 95% CI 0.12 to 3.65) 6. ***Dextranomer and hyaluronic acid versus collagen*** (One trial) • Surgical outcome: in objective (clinical) cure tests dextranomer and hyaluronic acid was found to be less effective in reducing leakage from baseline by 50% or more (RR for non-improvement = 2.14, 95% CI 1.37 to 3.36; Analysis 4.3.5) and for loss on provocation. Urine loss on the pad test was higher with dextranomer and hyaluronic acid (43.7 g of urine) v (18.3g)	

			with collagen (18.3 g, SD3.5) (MD = 25.40 95% CI 24.27 to 26.53) • Adverse outcomes: reported that events were more frequent in the dextranomer and hyaluronic acid group (68% v 50%) (RR = 1.35, 95% CI 1.1 to 1.64) ***One route of injection versus another*** Three trials identified 1. ***Periurethral versus transurethral injection*** (One trial) • Surgical outcomes: no significant differences • Adverse outcomes: data insufficient to assess differences 2. ***Bladder neck versus mid-urethral injection*** (One trial) • Surgical outcomes no significant differences were observed in objective (clinical) cure rate • Adverse outcomes: no statistically significant difference reported in the number of women who experienced postoperative retention lasting < 48 hours	
Treatment of recurrent stress urinary incontinence after failed minimally invasive	To obtain and examine evidence supporting different management strategies for recurrent	Systematic Review based on evidence ranging from SIGN 1++ (High quality meta-	*"Among the literature of non-randomised studies, the data suggest that repeat suburethral tape surgery is less effective than for primary surgery, and there is some*	"*To date there is no high-quality, trial-based evidence that can inform treatment decisions on the*

synthetic suburethral tape surgery in women Bakali E et al (2013) Cochrane Database of Systematic Reviews. 2012; Issue 2. DOI:10.1002/14651858.CD009407.pub2. Last assessed as up-to-date: December 2012	/ persistent stress urinary incontinence (SUI) in women after failed suburethral tape surgery. Cochrane systematic review	analysis, systematic reviews of Randomised Controlled Trials (RCTs) ,or RCTs with a very low risk of bias) to SIGN 1+.(Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias) Twelve studies were identified, but all excluded because they did not meet the eligibility criteria. Six were RCTs but were not eligible because the previous incontinence surgery was not a suburethral tape. One RCT may have been eligible for inclusion because some of the women were having repeat surgery, but the data were unsuitable for further analysis.	*evidence that retropubic suburethral tapes are superior to trans-obturator tapes as secondary procedures.* *"In view of the absence of any evidence comparing the alternative management options for failed primary suburethral tape surgery, clinicians must rely largely on expert opinion or personal experience when advising patients about treatment options." (Pg 9)*	*management of recurrent SUI after a failed suburethral tape. No randomised comparison studies exist. Conservative treatment options include lifestyle advice, pelvic floor muscle training, bladder training and drugs (medication). Surgical treatment options may include retropubic colposuspension, urethral bulking agents, a fascial sling procedure, artificial urethral sphincter or repeat suburethral tape." (Pg 9)*
Single-incision sling operations for urinary incontinence in women.	To assess the effectiveness of mini-sling procedures in	Systematic Review based on evidence ranging from SIGN 1++	The general findings may be summarised as: ***Single-incision slings versus***	*"Women were more likely to remain incontinent after surgery with single-*

Nambiar A (2014) Cochrane Database of Systematic Reviews. 2014 Issue 6: DOI:10.1002/14651858.CD008709.pub2 Last assessed as up-to-date February 2013	women with urodynamic clinical stress or mixed urinary incontinence in terms of improved continence status, quality of life or adverse events. Cochrane systematic review	(High quality meta-analysis, systematic reviews of Randomised Controlled Trials (RCTs) ,or RCTs with a very low risk of bias) to SIGN 1+.(Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias) In all, 31 trials met the inclusion criteria. These include 19 published research trials, one academic thesis and 11 abstracts. All were RCTS of quasi-randomised trials. In all cases at least one trial arm involved one single-incision slings. The risk of bias in included trials was variable, with about half of the trials using adequate methods, while in the other half, the methods	1. ***No treatment*** No trials identified 2. ***Conservative treatment*** No trials identified 3. ***Colposuspension*** No trials identified . 4. ***Laparoscopic procedures*** No trials identified 5. ***Traditional sub-urethral slings*** No trials identified 6. ***Retropubic minimally invasive slings*** Five trials were identified which used a "bottom up" approach. These included MiniArc sling against TVT (1 trial) and TVT-Secur against TVT (4 trials). No trials were found to have used a "top down" approach. **Surgical outcomes** • Patient reported subjective cure rates were found to better after retropubic slings. Persistent urinary incontinence was reported more for single-incision surgery (41%, 121/292) than for retropublic slings (26%, 72/281) (RR = 2.08 95% CI 1.04 to 4.14) (5 trials) • For women reporting no improvement, there was no statistically significant differences between treatment groups (3	*incision slings than after use of inside-out transobturator (TVT-O) tapes... They were more likely to need further continence surgery and had mesh exposure more often." (Pg 26)* *"TVT-Secur is inferior to TVT and has already been withdrawn from clinical use." (pg 26)* *"Not enough evidence was found for the review authors to conclude whether single-incision slings were different from outside-in transobturator (TOT) tapes in terms of efficacy, but some evidence suggests that they… had a slightly lower risk of postoperative pain." (Pg 26)* *"Evidence was insufficient to suggest that one type of single-incision sling is superior to another in direct comparisons, in terms of efficacy or a more favourable adverse event profile. " (Pg 26)*

		used were not considered to be inadequate or were not described. Overall, only two trials were identified as showing a generally "high" risk of bias with the majority assessed as showing "unclear" bias.	trials) • Overall, objective (clinical) outcomes were found to be statistically significant with retropubic slings being better than single-incision slings in reducing SUI (RR = 4.44, 95% CI 2.06 to 9.56) (2 trials) **Adverse outcomes** • De novo urgency was reported in three trials, all of which compared TVT-Secur versus TVT. It was found to be more common in the single-incision group (27/125, 22%) than the retropubic TVT group (11/123, 9%) (RR = 2.39 95% CI 1.25 to 4.56) • Repeat stress incontinence surgery was reported in two trials. In one, which compared single-incision surgery with retropubic sling, 9 women required repeat surgery with single–incision compared with none in the TVT group. However in the other trial, no statistically significant difference in the comparison between retropubic slings versus a single-incision sling. • No statistically significant differences were observed between groups, though small numbers of cases were reported for vaginal wall perforation; bladder or urethral perforation; urinary retention and the need for catheterisation; vaginal mesh exposure; mesh extrusion into bladder or urethra; long-term pain or discomfort;; and new-onset detrusor overactivity • No difference was found in the number of	*"Additional high-quality trials are required to definitively answer the question whether single-incision slings are equivalent to standard mid-urethral slings for the treatment of stress urinary incontinence in women." (Pg 27)* *"Long-term follow-up of at least five years is required for assessment of long-term benefits and, particularly, risks. (Pg 27)* *"The woman's report of cure of stress incontinence is generally the desired outcome of sling surgery and should be the primary outcome of any efficacy trial." (Pg 27)* *"Another consideration is to identify whether niche group of patients may benefit from this particular type of sling surgery, who may not be suitable for other forms of open or minimally invasive surgery." (Pg 27)*

			women who needed new surgical procedures to deal with complications of the index surgery between groups (2 trials) **QoL** • One trial measured condition-specific quality of life at one year using a validated instrument. QoL was reported to be statistically significantly better in the retropubic group ***7. Single-incision slings versus obturator minimally invasive slings*** Twenty trials were found. Of these 13 trials made comparison to the medial-to-lateral 'inside out' approach (TVT-O) and 7 trials to the lateral-to-medial 'outside-in' approach (TOT) **Surgical outcomes** • Patient reported subjective cure o TVT-O compared to single-incision slings were found that more women had urinary incontinence in the single-incision sling (172/572, 30%) than the women with TVT-O slings (55/481, 11%) over 12 month follow up period (RR = 2.55, 95% CI 1.94 to 3.36) (10 trials) o TOT compared to single-incision slings were found to be not different statistically in terms of incontinence. Individual comparison by subtype of single-incision sling (5 types) was also	

			found to be no statistically different (7 trials). ○ TVT-O & TOT combined analysis showed that transobturator slings were significantly better that single-incision slings to reduce incontinence (RR = 1.91 95% CI 1.53 to 2.39). However, this analysis shows a high degree of heterogeneity • Objective (clinical) cure rates ○ TVT-O compared to single-incision slings were found to be statistically significantly better are reducing incontinence (RR = 2.91 95% CI 2.00 to 4.25) (7 trials) ○ TOT were found not to be statistically differed from single-incision slings in terms of incontinence cure (5 trials) ○ TVT-O 7 TOT combined were still statistically significantly better that single-incision slings in reducing incontinence (RR = 1.88 95% CI 1.49 to 2.36) **Adverse outcomes** • Vaginal mesh exposure (erosion) ○ TVT-O when compared with single-incision sling (TVT-Secur) was found to have a significantly lower risk of mesh erosion. More women in the single-incision groups had exposure (18/284, 6%) than the TVT-O group (4/278, 1%) (RR = 3.75 95% CI 1.42 to 9.86) (5 trials) ○ TOT was compared in four trials to	

			differing types of single-incision slings. No comparison suggested a statistically significant difference between the treatment groups. ○ TVT-O & TOT combined analysis was found to be still significantly in favour of transobturator slings having a lower risk of mesh erosion (RR = 2.59 95% CI 1.21 to 5.56) • Post-operative pain or discomfort ○ TVT-O patients were found to have more post-operative pain and discomfort. Pain was reported for TVT-O more often (90/391, 23%) than for single-incision slings (27/415, 7%) (RR = 0.29 95% 0.20 to 0.43) (8 trials, TVT-Secur (4 trials), Ajust (2 trials), MiniArc (1 trial), Contasure Needleless (1 trial)) ○ TOT slings (39/148, 26%) was also found to be worse than single-incision slings (7/148, 5%) in resulting in reported pain (RR = 0.19, 95% CI 0.09 to 0.40) (2 trials with different single incision slings) ○ TVT-O & TOT combined analysis result showed that women had less post-operative pain or discomfort after a single-incision sling (RR = 0.26 95% CI 0.19 to 0.37) • Long-term pain or discomfort ○ TVT-O compared with single-incision sling was found to be not statistically different in risk of long term pain between treatment groups (3 trials).	

			○ TOT compared with single-incision slings did show a statistically significant difference favoured single-incision slings (RR 0.12, 95% CI 0.02 to 0.82 (2 trails) ○ TVT-O & TOT combined analysis showed that there were more likely to be associated with long term pain (11/155, 7.1%) than single-incision slings (1/196, 0.5%) (RR = 0.14, 95% CI 0.04 to 0.54) • Repeat stress incontinence surgery ○ TVT-O compared with single-incision slings found that women were nearly six times more likely to need further stress incontinence surgery after single- incision, TVT-Secur sling surgery (28/240,12%) than a TVT-O procedure (3/180, 2%) (RR = 5.86, 95% CI 2.0 to 17.21) (3 trials, all TVT-Secur) ○ TOT slings when compared with single-incision slings provided no evidence for statistical differences between treatment groups in the need for repeat surgery when using either MiniArc single-incision slings (2 trials) or the tissue fixation system single-incision sling (1 trial) ○ TVT-O & TOT combined analysis found that, overall, there was a statistically significant difference with fewer women having a transobturator sling procedure (33/412, 8.0%) needing repeat surgery than after a	

			single-incision sling (8/352, 2.3%) (RR = 3.09, 95% CI 1.48 to 6.49). However, this result was driven by the two trials that used TVT-Secur as the single-incision sling, if these are removed from the analysis no significant difference in repeat surgery rates was observed
			• Need for any other additional or new surgical procedure to treat complications
			  ○ TVT-O was found to be associated with a statistically lower chance of needing surgery to deal with new complications than single-incision surgery (RR = 2.15 95% CI 1.04 to 4.43) (5 trials, ll TVT-Secur)
			  ○ TOT compared with single-incision slings was found to be not significantly different in risk for new surgery (RR= 1.75 96% CI 0.52 to 5.85) (3 trials)
			  ○ TVT-O & TOT combined analysis showed twice as many women required surgery for complications after a single-incision sling (28/541, 5.2%) than TVT-O or TOT procedures (11/448, 2.5%) (RR = 2.03 95% CI 1.09 to 3.78)
			• Data relating to mesh extrusion into bladder or urethra was found to be significantly worse for single-incision surgery in 1 trial. The review team considered this to be a spurious finding given the low number of cases in the single treatment arm
			• No statistical differences between	

			treatment groups were observed in relation to: major vascular or visceral injury; bladder or urethral perforation; vaginal wall perforation; Urinary retention and the need for catheterisation; Infection related to the use of synthetic mesh; or de novo urgency **8. One single-incision sling versus another** Nine trials identified, only one of which was considered to be methodologically robust. Because of the numerous types of slings compared, very few data could be combined in meta-analysis and evidence was insufficient to allow the review authors to confidently identify any differences between any of the different types of single-incision sling.	
Bladder neck needle suspension for urinary incontinence in women. Glazener CMA & Cooper K (2014) Cochrane Database of Systematic Reviews. 2004; Issue 12: DOI: 10.1002/14651858.CD003636.pub2	To determine the effects of needle suspension on stress or mixed urinary incontinence in comparison with other management options Cochrane Systematic Review	Systematic Review based on evidence ranging from SIGN 1++ (High quality meta-analysis, systematic reviews of Randomised Controlled Trials (RCTs) ,or RCTs with a very low risk of bias) to SIGN 1+.(Well conducted meta-analyses, systematic reviews, or RCTs with	The main comparisons found: ***Needle suspension (NS) v mock procedure*** No studies found. ***NS v conservative Interventions*** No studies found. ***NS v open abdominal retropubic suspension*** **Surgical outcomes** • NS v Burch colposuspension (5 studies), Vagina/obturator shelf repair (1 study);	On reported research outcomes *"The primary outcome of effectiveness used in this review was subjective report of failure to cure incontinence. Objective urodynamic outcome measures, for example change in functional urethral length or maximal urethral pressure… were reported in four of the trials … These are*

Last assessed as up-to-date: November 2014 [NB Superseded Glazener CMA & Cooper K (2004)]		a low risk of bias) Review included 10 RCTs or Quasi-RCTs for UI in which 375 women had undergone a needle suspension procedure. Of the trials, 9 were restricted to women with urodynamic SUI and 1 trial with MUI. Women with prolapse were included in 3 trials and 6 trials included some women with previous, failed incontinence surgery. Long term follow up (>5y) was only recorded in 3 trials. Overall the authors considered that the quality of the evidence was "poor".	and German 1992), and the other used a Marshall-Marchetti Krantz colposuspension (1 study) • NS less effective than colposuspension, based on subjective outcome at both < one year of (RR for failure 1.70, 95% CI: 1.11 to 2.60 and > one (RR for failure 2.00, 95% CI 1.47 to 2.72). NS after one year = 29% failure rate v open abdominal retropubic suspension failure rate = 16% • Data on the effects of previous surgery for incontinence on failure rates suggested it had no effect on the failure rates for NS, though data was only available from four small trials. **Adverse outcomes** • Three studies reported no statistically significant differences in perioperative complications (haematoma, abscess, infection, pain, urinary tract infection, stitch removal for pain, and sheath removal for infection) for NS (RR 1.44, 95% CI 0.73 to 2.83) Though these findings include 1 study with an unusually low rate of complications after colposuspension which may be a source of bias. • Previous surgery for incontinence seemed to have no effect on adverse outcomes. ***NS v suburethral sling operations*** **Surgical outcomes** • One small trial (n=10), each trial arm. Trial	*measurable continuous variables, which allow trials with smaller numbers of participants to obtain relatively precise statistical estimates of any differences. However, they are of limited help in determining optimal treatment because they have no proven correlation with clinical outcome." (Pg 8)* *"Morbidity outcomes relevant to surgical complications (such as pain, voiding dysfunction, detrusor overactivity, entero-rectocoele, wound and urinary infections, length of stay and time to return to normal function) were not consistently reported." (Pg 8)* *"Data describing treatment failure in terms of need for alternative interventions, or for repeat surgery for incontinence and prolapse, would be particularly useful." (Pg 8)*

			was too small to address differences in cure rates, **Adverse outcomes** • Sling operations were associated with higher complication rates (90% v 20%) • Complications included: pyrexia; blood loss; wound infection; and pulmonary embolus, • Also associated with need for a permanent suprapubic catheter, more adjuvant therapy, and resulted in longer hospital stays. ***NS v anterior vaginal repair (AVR)*** **Surgical outcomes** • Compared in 3 trials, with small numbers (pooled n = NR 156, AVR = 181) • Subjective cure rates for NR and AVR after 12 months were similar (RR = 0.86, 95%95% CI 0.64 to 1.16,) • Also comparable on voiding dysfunction post-surgery, irrespective of whether patients had prolapse as well as SUI. • No difference reported for the sole objective clinical outcome – no women had long-term problems with voiding dysfunction after NS or AVR. **Adverse outcomes** • No differences in surgical failure rate: AVR 39% failed compared with 36% after NS.	On clinical practice implications *"The limited evidence indicates that bladder neck needle suspension operations are worse than the open abdominal approach (retropubic suspension) for the treatment of primary or secondary urodynamic stress incontinence. However, data were inadequate for comparing morbidity. Although cure rates appeared to be similar after needle suspension when compared with anterior vaginal repair, the data were insufficient to be reliable." (Pg 8)* On research implications *"Surgical trials related to stress incontinence should systematically address surgical morbidity outcomes such as adverse peri-operative events, length of hospital stay, time to return to normal activities, de novo*

			NS v laparoscopic colposuspension No studies found. ***NS v peri-urethral injections*** No studies found. ***NS v drug treatment (e.g adrenergic agonists)*** No studies found. ***Comparisons between types of NS*** While there were no significant differences in outcomes, the number of patients was very small (n – 46 v 44), ***Different types of suture materials used in NS*** One small trial (n= 9 treatment v 10 controls) found that postoperative pain was significantly less at three months in women whose NS used polytetrafluoroethylene sutures compared with polypropylene (Diff. in pain score -0.92, 95% CI -1.77 to -0.07,) However the numbers are very small to determine effectiveness.	*development of urge symptoms or detrusor overactivity, and especially the need for repeat surgery or alternative interventions. Long-term follow-up (at least one year, preferably five years or more) is essential for the proper evaluation of incontinence treatments." (Pg 9).*
Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women. Ford et a (2015) Cochrane Database of	To assess the clinical effects of mid-urethral sling (MUS) operations for the treatment of stress urinary incontinence (SUI), urodynamic stress incontinence (USI) or	Systematic Review based on evidence ranging from SIGN 1++ (High quality meta-analysis, systematic reviews of Randomised Controlled Trials	The main reported findings are: ***Transobturator (TOR) versus retropubic Route (RPR)*** Fifty-five trials identified **Surgical outcomes** • Patient reported subjective cure	*"Overall mid-urethral slings are a highly effective treatment for SUI. In the short term there is equivalence in the efficacy between the two routes, and this persists into the medium and*

Systematic Reviews 2015, Issue 7. DOI:10.1002/14651858.CD006375.pub3 Last assessed as up-to-date: June 2014 ***[NB Update of: Ogah J (2009). Cochrane Database of Systematic Reviews. 2009 Issue 4: DOI:10.1002/14651858.CD006375.pub2]***	mixed urinary incontinence (MUI) in women. Cochrane systematic review	(RCTs) ,or RCTs with a very low risk of bias) to SIGN 1+.(Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias) In total 81 completed and 2 ongoing trials were included, all were randomised or quasi-randomised controlled trials amongst women with SUI, USI or MUI, in which both trial arms involved a MUS operation. All trials were formally assessed for the quality of evidence they could provide in relation to trial using the GRADE assessment tool. The reviewers assessed the quality of most outcomes as "moderate" mainly due to risk of bias. In assessing bias, only 1 trial was considered to be rated at "high" risk of bias overall. The	○ < 1 year the rate was found to be not significantly different between TOR or RPR approaches (RR 0.98 95% CI 0.96 to 1.00) (36 trials). There was also no statistically significant difference between the two groups in terms of symptomatic improvement and cure rate ○ 1 to 5 years the cure rate also showed no significant difference in subjective cure between the two groups (RR 0.97, 95% CI 0.87 to 1.09) (5 trials) ○ > 5 years cure rates were also not significantly different between the two routes (RR 0.95, 95% CI 0.80 to 1.12) • Objective (clinical) cure rate ○ < 1 year the cure rate with TOR (85.7%) versus RPR (87.2%) was not significantly different (RR = 0.98, 95% CI 0.96 to 1.00). (40 trials). This is unlikely to represent a clinically significant difference in outcome between the two methods in the short term. ○ 1 to 5 years no significant difference observed (RR = 1.00, 95%CI 0.95 to 1.06) (5 trials) ○ > 5 years no significant difference observed in cure rates (RR = 0.97 95%CI 0.90 to 1.06) (3 trials) • TOR was found to provide significantly shorter operating times (MD = -7.54 minutes 95% CI -9.31 to -5.77) (31 trials); and Intraoperative blood loss (MD = -6.49 ml 95% CI -12.33 to -0.65) (3 trials).	*longer term, though the data for this is somewhat limited by small numbers. There is some evidence that suggests women are more likely to require repeat incontinence surgery in the longer term with the TOR, but this requires cautious interpretation, as there are extremely small numbers." (Pg 44)* *"Five trials… [that] compared the retropubic bottom-to-top with the retropubic top-to-bottom approach. These showed that passage of the tape through the retropubic route in a bottom to-top path (e.g. TVTTM) was more effective than passage in a top-to-bottom path (e.g. SPARCTM), and resulted in fewer intra and post-operative adverse events." (Pg 44)* *"Ten trials… [that] compared the obturator medial-to-lateral approach with the obturator lateral-*

		majority of studies were rated as "unclear", with only 1 trial being considered at "low" risk of bias in all five sources of bias.	Heterogeneity on the pooled data was high. • Length of hospital stay and mean time taken to return to normal activities were not found to be significant. **Adverse outcomes** • In the 25 trials where only overall perioperative complication rates were reported, there were no statistically significant differences in the rate of perioperative complications between the TOR and RPR groups • In trials reported individual differences for specific adverse outcomes the following were found to be significant • TOR was associated with significantly fewer: major vascular injury (RR = 0.33 95% CI 0.19 to 0.55) (28 trials); bladder / urethral perforation (RR = 0.13 95% CI 0.08 to 0.20) (40 trials); and postoperative voiding dysfunction (POVD) was assessed (RR = 0.53 95% CI 0.43 to 0.65) (37 trials) • Pain rates were found to vary between groups as to which approach was associated with greater pain. TOR was found to give rise to significantly higher rates of groin pain (RR = 4.12 95% CI 2.71 to 6.27) (18 trials) but significantly lower suprapubic pain (RR = 0.29 95% CI 0.11 to 0.78) (4 trials). In most cases, pain resolved within 6 months of the procedure • Need for repeat incontinence surgery was found to be not significantly different	*to-medial approach. Evidence from the ten trials, two of which reported medium-term data, showed no difference between the two approaches with respect to most outcomes measured. The only exceptions were voiding dysfunction, where higher rates were reported in the medial-to-lateral group, and vaginal perforation, which had higher rates in the lateral-to-medial group. Despite this, there was no resultant increase in the rate of tape erosion." (Pg 44)* *"Ten trials compared one method of mid-urethral tape insertion with another using the same route… there was no difference in the efficacy, surgical outcomes or occurrence of adverse events." (Pg 44)* *"Four trials compared monofilament tapes with multifilament tapes. There was no statistical*

			between groups under 12 months (9 trials); higher need in the TOR group between 1 to 5 years (RR = 21.89 95% CI 4.36 to 109.77) (2 trials); and for over 5 year (RR = 8.79 95%CI 3.36 to 23.00) (three trials) **QoL** • General measures of QoL using validated instruments found that women's QoL improved significantly post-operatively within each group, but no statistically significant differences were found between randomised procedure groups (11 trials). One trail reported a statistically significantly higher QoL after surgery for RPR. • Sexual function was assessed using validated instruments and direct questions. Significant improvement in sexual function from baseline scores were reported for follow-up periods between six to 24 months. There were no significant differences between the two groups (11 trials) ***Retropubic bottom-to-top (RPR-b) approach versus retropubic top-to-bottom (RPR-t) approach*** Five small trials identified **Surgical outcomes** • Patient reported subjective cure rate o < 1 year women were significantly more often dry with the RPR-b	*difference in physician-observed cure rates or patient-reported cure between the groups. There was no significant difference in the rate of vaginal tape erosion." (Pg 44)* *"There is low to moderate quality evidence that retropubic tapes and transobturator tapes have comparable effects on cure of incontinence between one and five years, and limited evidence for the same in the long term. With the exception of a two-fold increase in the incidence of groin pain, transobturator tapes have fewer adverse events. Retropubic tapes have an eight-fold increase in the incidence of bladder perforation and a two-fold increase in the incidence of post -operative voiding difficulties." (Pg 47)* *"There was moderate quality evidence that when a retropubic route is*

			(87.34%) compared to RPR-t (79.58%) (RR = 1.10, 95% CI 1.01 to 1.19) (3 trials)
			• Objective (clinical) cure was assessed using a variety of measures show no statistical differences between approaches (5 trials)
			• No statistically significant differences were reported for duration of operation or length of hospital stay (2 small trials)
			
			Adverse outcomes
			• No statistically significant difference was seen in overall perioperative complications
			• Significantly fewer women experienced certain complications with RPR-b
			  ○ bladder perforation (RR = 0.55 95% CI 0.31 to 0.98) (5 trials)
			  ○ voiding dysfunction (RR = 0.40 95% CI 0.18 to 0.90) (5 trials)
			  ○ vaginal tape erosions (RR = 0.27 95% CI 0.08 to 0.95) (4 trials)
			• There were no statistically significant between procedures in respect of de novo urgency symptoms (4 trials) or detrusor overactivity (1 trial)
			
			Obturator medial-to-lateral (TOR-m) approach versus obturator lateral-to-medial (TOR-l) approach
			Ten trials identified
			
			Surgical outcomes
			• Patient reported Subjective cure rate
				employed a bottom-to-top approach is more effective in terms of subjective cure than a top-to-bottom approach. When traversing the transobturator route, there was moderate quality evidence showing that medial-to-lateral ('inside-out') and lateral-to-medial ('outside-in') approaches have similar effects." (Pg 47)
				
				"Many trials have evaluated the use of mid-urethral tapes in the short term. However, the long-term effects of surgery, and how the different insertion routes affect long-term outcome, have not been established." (Pg 47)
				
				"More of the trials included in this review should publish the results of their longer term follow-up to increase the robustness of evidence supporting the use of mid-urethral sling (MUS) in the long term, to provide

			○ < 1 year reported to be no statistically significant differences in either subjective cure or subjective cure and improvement (5 trials) ○ 1 to 5 years also reported no difference in subjective cure (2 trials) or subjective cure and improvement (2 trials) ○ > 5 years was not included as an outcome in any trial • Objective (clinical) cure rate for < 1 year was reported to be not statistically significant between groups for either objective cure or objective cure and improvement (6 trials) **Adverse outcomes** • TOR-m was found to be associated with fewer vaginal wall perforations (RR = 0.25 95% CI 0.12 to 0.53) (3 trials with high heterogeneity I^2 = 43%) but also higher levels of voiding dysfunction (RR = 1.74 95%CI 1.06 to 2.88) (8 trials) • There were no statistically significant differences between the two groups for: overall perioperative complication rate (2 trials); major vascular / visceral injury(4 trials); bladder perforation (6 trials); de novo urgency symptoms (3 trials); detrusor overactivity (1 trial); vaginal tape erosions (7 trials); and groin/thigh pain • Two large trials showed no significant difference in the rates of repeat incontinence surgery in the medium term (1 to 5 years)	*answers about the long-term adverse events of these operations, including whether there is a significant decline in the effectiveness of these procedures over time, and to identify the point at which decline becomes significant enough to require women to need repeat procedures." (Pg 47)* *"More research is required into trials assessing the clinical effectiveness of different [surgical] routes." (Pg 47)*

			QoL Five trials used condition-specific validated instruments • Significant improvement post-operatively was found in four trials for both routes, but no differences between groups • There was significant improvement in post-surgery sexual function compared to baseline, but no significant difference between the two groups at follow-up. Rates of dyspareunia following surgery were extremely low, with evidence of resolution by 24 months ***One method of mid-urethral tape insertion versus another method, same route*** Ten trials identified which compared different methods of carrying out TOR and RPR operations using the same route. The comparison analysed were: i. Transobturator lateral-to-medial; ii. Transobturator medial-to-lateral; and iii. Retropubic Each comparison group included only a small single trial, which did not provide suitable data for pooled statistical analysis save one comparion with two trials. ***Transobturator lateral-to-medial, synthetic versus biological TOT*** (2 small trials)	

			Surgical outcomes • Objective (clinical) cure rate < 1 year for synthetic versus biological TOT showed no significant difference (RR = 1.03 95% CI 0.94 to 1.14) (2 trials) No other outcomes were significantly different between groups. ***One type of tape material versus another*** Four trials compared specific procedures using different types of tapes used to create the mid-urethral sling. The comparison were: i. monofilament (TVT SPARC) v multifilament (IVS) (1 trial); ii. monofilament (TVT) v multifilament (IVS) (1 trials) iii. synthetic monofilament (prolene light mesh) v combined synthetic and biological (Ultrapro mesh) v multifilament mesh (Vypro) (1 trial); and iv. monofilament (TVT) v multifilament (IVS) (1 trial) **Surgical outcomes** • Patient reported subjective cure rate was found to be not significantly different at either the short (< 1 year) or medium-terms (1 to 5 years) • Objective (clinical) cure rates for monofilament tape and multifilament tapes were shown to be not significantly different • No statistically significant differences in	

			the duration of operation or length of hospital stay were reported **Adverse outcomes** • No significant differences were reported for any adverse outcome in any of the comparisons between tapes types. The number of perioperative events was low. **QoL** • Only on trial assessed Qol. This showed improvement from baseline scores, but no significant difference between the comparison groups.	

Table 2b: Systematic Reviews of POP Procedures

Title & Author(s)	**Purpose of Review & Review type,**	**Level of evidence included & Quality of evidence**	**Findings** • **Surgical Outcomes** • **Adverse Outcomes** • **Quality of Life (QoL)**	**Conclusions**
Surgical management of pelvic organ prolapse in women Maher C, Feiner B, Baessler K, Schmid C (2013) Cochrane Database of Systematic Reviews 2013, Issue 4 DOI:10.1002/14651858.CD004014.pub5. Last assessed as up-to-date: August 2012	To determine the effects of the many different surgeries used in the management of pelvic organ prolapse Cochrane systematic review	Systematic Review based on evidence ranging from SIGN 1++ (High quality meta-analysis, systematic reviews of Randomised Controlled Trials (RCTs) ,or RCTs with a very low risk of bias) to SIGN 1+.(Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias) In all 56 completed randomised or quasi-randomised trials were included in the review. Four ongoing studies were also included. The quality of the trials was described as “”variable”. In almost all cases, the trials	The results of the procedure comparisons were: • **One type of upper vaginal prolapse (uterine and vaginal vault) repair versus another** Nineteen studies evaluated surgeries for upper vaginal prolapse (uterine or vault) ***Abdominal sacral colpopexy versus vaginal sacrospinous colpopexy*** Three trials included. **Surgical outcomes** • Patient reported subjective outcomes ○ No statistically significant difference reported between the abdominal and vaginal approach in the number of women reporting prolapse symptoms and although there were more reports of subjective failure in the vaginal group, this was also not significant ○ There was insufficient data to detect any statistically significant difference between approaches for patient satisfaction	*“The data from randomised trials are currently insufficient to guide practice.” (Pg 29)* *“Abdominal sacral colpopexy was associated with a lower rate of recurrent vault prolapse and less dyspareunia than vaginal sacrospinous colpopexy. “ (Pg 29)* *“The use of absorbable polyglactin mesh overlay, absorbable porcine dermis or polypropylene mesh at the time of anterior vaginal wall repair reduces the risk of recurrent cystocele on examination, however improved outcomes including patient satisfaction, quality of life and reduced operations for recurrences have not*

		were assessed by the reviewers as being at an “unclear” level of risk for bias. Two trials were assessed as being at the “low” level for risk of bias across all sources of bias.	• The abdominal approach was reported to be better than the vaginal in terms of:
			  ○ number of women failing to improve to Stage 2 or better (RR = 0.29 95% CI 0.09 to 0.97) (1 trial);
			  ○ a lower rate of recurrent vault prolapse (RR = 0.23 95% CI 0.07 to 0.77) (2 trials);
			  ○ less post-operative SUI (RR = 0.5, 95% CI 0.32 to 0.95) (2 trials);
			  ○ less post-operative dyspareunia (RR = 0.39, 95% CI 0.18 to 0.86) (3 trials)
			• Objective (clinical) outcomes
			  ○ No statistically significant differences in objective failure at any site, for any pelvic organ prolapse (1 trials) or for reoperation rates for SUI (3 trials).
			
			Adverse outcomes
			• Data on adverse outcomes were too few to provide sufficiently precise estimates from pooled analysis to identify or rule out clinically important differences.
			
			Sacral colpopexy and abdominal hysterectomy versus vaginal Mayo McCall culdoplasty and vaginal hysterectomy
			One small trial identified – no statistical analysis was included.
			
			Abdominal sacral colpopexy versus high vaginal uterosacral colpopexy
			One trial identified
				yet been demonstrated.” (Pg 29)
				
				“Posterior vaginal wall repair may have a better anatomical success rate than transanal repair in the management of posterior vaginal wall prolapse but the clinical effects are uncertain. There was no evidence to support the use of graft materials in the posterior compartment.” (Pg 29)
				
				“The evidence at this stage does not support the use of transvaginal combined total, anterior or posterior mesh kits for multi-compartment prolapse… three studies demonstrated an improved anatomical outcome after the transvaginal permanent mesh as compared to native tissue repair, no difference was found in symptoms or quality of life outcomes. The mesh exposure rate was 18%, with one half of these (9%) requiring surgical

			Surgical outcomes • Intervention with sacral colpopexy compared with high uterosacral vault suspension (HUSLS). At one year the objective success rate 100% for sacral colpopexy compared to HUSLS (82%) • Recurrence in the anterior or posterior compartment was significantly less after the sacral colpopexy (5.5%) v HUSLS (33.9%) • Reoperation rate for prolapse was significantly lower after sacral colpopexy: (5%) compared with HUSLS (17.8%) • The operating time in minutes (102 versus 80) and hospital stay in days (3.7 versus 2.1) were significantly less (P < 0.01) after sacral colpopexy as compared to HUSLS **Adverse outcomes** • Both intra-operative and post-complications were higher for sacral colpopexy, but only that for post-operative was significant with sacral colpopexy (20.4%) v HUSLS (3.7%) (P = 0.047) ***Uterine suspension (preservation) versus vaginal hysterectomy – Abdominal uterine preservation versus vaginal hysterectomy and repair*** One trial identified **Surgical outcomes** • Patient reported subjective cure o < 1 year more women had subjective prolapse symptoms	*intervention. The total reoperation rate was significantly higher after the transvaginal permanent mesh at 11%." (Pg 29).* *"Performing continence surgery at the time of prolapse surgery in women with stress urinary incontinence is likely to be beneficial. This benefit is also considerable in continent women undergoing prolapse who have demonstrated occult stress incontinence pre-operatively." (Pg 29)* *"The challenge in prolapse surgery is that while the prolapse itself may cause difficulties with bladder, bowel and sexual function, surgical correction may also affect these functions in unpredictable ways. Therefore, all trials need to include patient-reported and clinician-observed outcomes; and direct interaction with bladder, bowel and sexual function must be measured." (Pg*

			after abdominal surgery (RR = 3.2 95% CI 1.29 to 7.92) ○ No statistically significant difference in the prolapse domain of the urinary distress inventory (UDI) or for urinary incontinence was observed ○ At 8 year follow up 87% in the vaginal group versus 68% in the abdominal group reported that prolapse symptoms had improved compared to before primary surgery (RR = 2.60 95% CI 1.02 to 6.65) • Objective (clinical) cure ○ < 1 year more women in the abdominal group required repeat prolapse repair (RR =9.00 95% CI 1.19 to 67.85) ○ At 8 year follow up there was no statistically significant difference in the prolapse reoperation rate for abdominal patients (26%) compared to the vaginal group (14%) (RR = 1.83, 95% CI 0.75 to 4.50) **Adverse outcomes** • < 1 year after surgery the vaginal group reported significantly better (lower) scores on the (UDI) compared to the abdominal group for ○ discomfort/pain (7.1, 95% CI 1.1 to 13.2); ○ overactive bladder domain (8.7,	*30)* *"Ideally long-term outcomes should be reported, at least at two and five years after surgery." (Pg 30)*

			95% CI 0.5 to 16.9); and the ○ obstructive micturition domain (10.3, 95% CI 0.6 to 20.1) • At 8 year follow up there was a significant the difference in the constipation obstruction domain of the Defecation Distress Inventory, vaginal group (19%, 8/42) v the abdominal group (43%, 18/42) (P = 0.03) ***Uterine suspension (preservation) versus vaginal hysterectomy – vaginal sacrospinous uterine suspension versus vaginal hysterectomy*** Two trials identified. In one vaginal hysterectomy was compared to vaginal sacrospinous uterine hysteropexy (suspension) with uterine preservation, whilst in the second it was compared without uterine preservation **Surgical outcomes** • In the trial without uterine preservation showed no significant differences for either apical compartment recurrence or for rates of cystocele and rectocele recurrence **Adverse outcomes** • In the trial with uterine preservation the only significant difference between treatment groups was the observation of more adverse symptoms in the sacrospinous suspension arm, mostly due to buttock pain (RR = 4.23, 97% 1.25 to	

			14.25) • In the trial without uterine preservation no differences were reported for quality of life scores and for urogenital symptoms between the two procedures at < 1 year post-surgery. ***Hysterectomy with high levator myorrhaphy (HLM) versus hysterectomy with uterosacral vaginal vault suspension (UVVS)*** One trial compared two vaginal vault procedures (HLM or UVVS), in patients with Stage 2 or more uterine prolapse. All women underwent vaginal hysterectomy and anterior repair, 90% of which used concomitant mono-filament polypropylene mesh **Surgical outcomes** • There were no data on the patient reported subjective prolapse symptoms by participants • At follow up: o Apical, anterior, and posterior compartment recurrence rates were similar in both groups. o Mean total vaginal length was significantly shorter after HLM (7.9 cm) than after UVVS (8.91 cm) P = 0.04). **Adverse outcomes** • No significant differences were seen between groups for either urinary symptoms, bowel symptoms, sexual	

			function, or any urodynamic parameters post-operatively • Post-operative unilateral ureteric angulation leading to hydronephrosis was identified in 9% (10/113) of UVVS patients. • Mesh erosion rates were comparable between the two groups. ***Open abdominal sacral colpopexy versus laparoscopic sacral colpopexy (LSC)*** One multi-centre equivalence trial was identified. This compared open surgery and LSC in the treatment of prolapse in the vault of the uterus assessed as having reached a stage 2 (no more than 1cm prolapse), based on the POP-Q-prolapse staging system. (This is a clinical description of where and by how much the pelvic organs have prolapsed, the scale runs from 0 to 4, with 4 being the most complete prolapse.) **Surgical outcomes** • No difference was found in the number of patients who were 'very satisfied' post-surgery using the validated Patient Generated – Index • There was no difference in operating time between the procedures but the number of inpatient days was less in the laparoscopic group (Mean Difference.0.9 days, 95% CI 0.1 to 1.7) • At one year objective (clinical) outcomes were similar in the two groups with the elevation of the vaginal vault above the	

			hymen (point C) for open (6.6 cm) v laparoscopic (6.7 cm) (P = 0.71 MD = 0.00 95%CI -0.74 to 0.74) **Adverse outcomes** • There were no differences in serious adverse events between the groups. • Mean blood loss during surgery was significantly greater in the open arm (MD = 184 ml, 95% CI 96 to 272) ***Laparoscopic sacral colpopexy (LSC) versus total vaginal polypropylene mesh kit (TVM)*** A single centre randomised controlled trial compared LSC with a total vaginal polypropylene mesh kit (TVM) in women with grade 2 post-hysterectomy vaginal vault prolapse at mean two year review **Surgical outcomes** • Patient reported subjective outcomes ○ Mean patient satisfaction on a visual analogue was significantly higher following LSC as compared to TVM (MD = 8.1 VAS points 95% CI 0.2 to 16.0) ○ Two validated pelvic floor questionnaires were used to assess improvement. Both showed significant improvement following the interventions; however, there was not enough data to detect a difference in outcomes between the groups after the intervention.	

			• Objective (clinical) outcomes
			  ○ Objective recurrence rate (Stage 2 POP at any vaginal site) was significantly lower in the LSC group (23%) compared to the TVM group (58%) (RR = 0.39 95% CI 0.23 to 0.67)
			  ○ Following LSC the vaginal vault was significantly higher (MD =1.39 cm 95% CI 0.39 to 2.39) as it was for the middle anterior vaginal wall (MD = 0.7 cm 95% CI 0.36 to 1.04) and the mid-point posterior vaginal wall (MD = 0.7 cm 95% CI 0.37 to 1.03). Total vaginal length was significantly longer with LSC (MD = 1.0 cm 95% CI 0.6 to 1.4). All in comparison to TVM.
			• Surgical parameters indicated that LSC took significantly longer to perform (MD = 52 min 95% CI 41.2 to 62.6, gave rise to a lower level of blood loss (MD = 32 ml 95% CI 5 to 59), reduced inpatient stays (MD = 0.5 days 95% CI 0.1 to 0.9), and resulted in quicker return to activities of daily living (MD = 5.3 days, 95% CI 2.3 to 8.4) as compared to TVM.
			
			Adverse outcomes
			• Mesh exposure risk was not significantly different after the LSC (2%) as compared to TVM (13%) (RR = 0.13 95% CI 0.02 to 1.11)
			• The reoperation rate was significantly less likely after the LSC (6%) v TVM (22%) (RR 0.26, 95% CI 0.08 to 0.87)	

			Total vaginal polypropylene mesh (TVM) versus sacrospinous colpopexy A single multi-centre randomised trial compared sacrospinous colpopexy and native tissue repairs with TVM for grade 2 or greater post-hysterectomy prolapse **Surgical outcomes** • At one year review the sacrospinous colpopexy group had a higher objective recurrence rate (39%, 28/72) compared to the TVM group (17%, 13/79) **Adverse outcomes** • Mesh exposure was identified in 20% of the TVM group undergoing surgical correction • Reoperation for prolapse was not significantly different between the two groups • No differences were identified between the groups in terms of de novo SUI, bladder overactivity, dyspareunia, pelvic pain • No differences were identified between the groups as measures in four validated instruments of functional outcomes ***Laparoscopic versus robotic sacral colpopexy*** One trial identified. • At one year both groups reported significant and similar improvements in objective assessment and functional	

			outcomes
			
			Vaginal sacrospinous colpopexy versus posterior intravaginal slingplasty (PIVS)
			Two trials identified. These compared vaginal sacrospinous colpopexy with PIVS using multi-filament polypropylene tape in women having uterine or vault suspension.
			
			• Pooled data from the trials was insufficient to identify differences in most of the clinically important outcomes.
			
			Apical prolapse repair without continence surgery versus prolapse repair with any continence surgery
			Two trials (Brubaker 2008;Costantini 2008) evaluated the efficacy of adding continence surgery to sacral colpopexy
			
			• After additional colposuspension women were found:
			  ○ to be more satisfied with their surgery (trial only),
			  ○ have a higher vaginal vault and a longer vaginal length
			  ○ have a higher anterior wall of the vagina higher
			  ○ have a higher posterior wall (in one trial only). In the second trial, the posterior was found to be higher the sacral colpopexy only group.
			• there were too few women having repeat prolapse surgery to draw conclusions	

			One type of graft versus another type of graft in sacral colpopexy One trial compared abdominal sacral colpopexy using either absorbable cadaveric fascia lata graft or non-absorbable (permanent) monofilament polypropylene mesh **Surgical outcomes** • There were no recurrences of vaginal vault prolapse in either group, but the objective failure rate for recurrence at any other vaginal site was significantly worse in the fascial graft group (32%, 14/44) versus the mesh group (9%, 4/45) (RR = 3.58 95% CI 1.28 to 10.03) • At five years recurrence for prolapse (POP-Q stage > 1) was higher if cadaveric fascia had been used (31%, 9/29) rather than mesh (7%, 2/29) (P = 0.02) **Adverse outcomes** • There were no vaginal erosions in the fascial graft group (0/46),but 7% (2/54) in the mesh group had erosion • No data on bladder, bowel or sexual function were provided. **2. One type of anterior vaginal wall prolapse repair versus another** Twenty-one trials included various surgical procedures for treating anterior vaginal wall prolapse with or without SUI	

			Anterior vaginal wall repair versus abdominal paravaginal repair No trials were identified. ***Anterior vaginal wall repair versus anterior vaginal wall repair with biological graft reinforcement (for midline cystocele defects)*** Six trials were identified, each using different biologic materials or combination of materials for grafts. Meta-analysis was only possible in subsets of these trials, for selected comparisons. • In two trials anterior colporrhaphy (AC) was compared to a porcine dermis graft. The objective failure rate at 1 year with for AC was significantly greater as compared to the biologic graft (RR = 2.09 95% CI 1.14 to 3.84) • Three trials compared AC to porcine dermis graft and found the objective failure rate in the anterior compartment was significantly higher in the AC group (RR = 1.7 95% CI 1.1 to 2.6) • In five trials where AC was compared to any biological graft, the objective failure rate in the anterior compartment was significantly higher for the AC group (RR = 1.64 95% CI 1.18 to 2.27 • Results from two trials demonstrated no difference in awareness of prolapse when native tissue repair was compared to biological graft repair (RR = 1.2 95% CI 0.6 to 2.3)	

			Anterior vaginal wall repair alone versus anterior vaginal wall repair with synthetic mesh reinforcement (for cystocele or anterior compartment prolapse) – absorbable synthetic mesh Three trials evaluated the effects of using absorbable polyglactin mesh inlay to augment prolapse repairs **Surgical outcome** • Standard colporrhaphy was associated with a significantly higher recurrence rate of cystocele compared with augmentation with absorbable synthetic mesh (RR = 1.39 95% CI 1.02 to 1.90) (2 trials) **Adverse outcome** • Vaginal mesh erosion was reported for 1 woman (2 trials) • Two women were reported as needing removal of some mesh (1 trial) • Rectocele recurrence appeared to be equally common with and without mesh augmentation (1 trial) • Other outcomes were inconclusive due to small numbers ***Anterior vaginal wall repair alone versus anterior vaginal wall repair with synthetic mesh reinforcement (for cystocele or anterior compartment prolapse) – Non-absorbable synthetic mesh*** Ten trials identified.	

			Surgical outcomes • In the management of anterior compartment prolapse, AC was associated with a higher recurrence rate on examination (46%, 220/478) compared to any transvaginal polypropylene mesh (14%, 69/498) (RR = 3.3 95% CI 2.6 to 4.2) (8 trials) • Native tissue AC was found to have a higher recurrence rate on examination (29%, 25/87, 29%) compared to polypropylene mesh (10%, 9/94) (RR = 3.08, 95% CI 1.56 to 6.11) (3 trials) • Transobturator armed polypropylene meshes had a lower rate of anterior compartment prolapse on examination • (14%, 59/424) compared to AC alone (49%, 200/410) (RR = 3.50, 95% CI 2.71 to 4.52) (5 trials) • Transobturator polypropylene mesh, whether self-styled (2 trials) or as a commercial kit (3 trials) had a lower rate of anterior compartment prolapse as compared to AC alone. (RR self-styled = 3.41 95%CI 2.04 to 5.67 and RR commercial = 3.53 95%CI 2.62 to 4.74) • Polypropylene mesh repair without a concomitant AC was superior AC alone in reducing anterior compartment prolapse (RR = 3.49 95% CI 2.59 to 4.7) (4 trials). Polypropylene mesh repair with a concomitant AC was also better than AC alone (RR = 3.38 95%CI 2.15 to 5.33) (3 trials) • Women receiving AC (26%, 98/349) had a	

			higher awareness of prolapse (subjective failure) than with the anterior transvaginal mesh repair (17%, 62/363) (RR = 1.6 95% CI 1.2 to 2.2) (4 trials) • Further prolapse surgery was not significantly more common after AC compared to after transobturator polypropylene mesh (RR = 2.18, 95% CI 0.93 to 5.10) (6 trials). • Two trials reported on the impact of anterior compartment surgery on other vaginal compartments. Women undergoing polypropylene mesh kits repair were more likely to develop apical or posterior compartment prolapse (18%, 27/153) than those undergoing AC (10%, 14/147) (RR = 1.8 95% CI 1.0 to 3.4) • When surgical parameters were compared ○ Blood loss was significantly less likely in transobturator mesh group compared with the AC group (MD = -56 ml 95% CI -72 to -42) (4 trials). Change in haemoglobin was also better with the transobturator mesh group (1 trial). ○ Operating time was significantly reduced in the AC group compared to polypropylene mesh repair (Weighted Mean Difference = -16 min 95% CI -18 to -13; Analysis 2.24.6) (3 trials) **Adverse outcomes** • Intra-operative cystotomy rate found to be lower with AC than after a transobturator mesh procedure (RR = 0.19 95%CI 0.0 to	

			1.1 (4 trials) • Mesh erosions were reported in 11.4% (64/563) of women who had an anterior compartment polypropylene mesh. Surgical intervention to correct mesh erosion occurred in 6.8% (32/470) patients (6 trials) • The risk of subsequent surgery (arising from prolapse, stress incontinence, mesh exposure or pain) was significantly reduced after native tissue anterior repair (10%, 31/626) compared to anterior transvaginal permanent polypropylene mesh (10%, 65/647) (RR = 0.5 95% CI 0.4 to 0.8) (8 trials). • Post-surgery incontinence was evaluated in a number of trials ○ there was a lower rate of de novo SUI after anterior repair as compared to transvaginal polypropylene mesh (RR = 0.6, 95% CI 0.4 to 0.9;(4 trials) ○ further continence surgery was performed in 4% (15/368) women following AC and 3% (12/380) after the polypropylene mesh procedure (RR 1.29, 95%CI 0.63 to 2.63) (4 trials) • There were no significant differences in the reported rates of de novo dyspareunia (5 trials) or sexual function (2 trials) **QoL** Eight trials were identified, each using a different array of validated instruments. No meta-analysis was possible	

			• No significant differences were observed between the two treatment groups ***Anterior colporrhaphy versus any permanent mesh or biological graft*** ***No mesh versus all types of grafts*** **See below** ***One type of graft (synthetic mesh or biological graft inlays) versus another type of graft (for midline cystocele defects)*** • One trial compared two types of absorbable mesh, polyglactin inlay versus porcine dermis. The objective failure rate at 25months follow-up was significantly worse in the polyglactin inlay group (RR = 3.22 95% CI 1.38 to 7.52). Further prolapse surgery had to be performed in 12 women, 3 in the polyglactin inlay group and 9 in the porcine dermis group (RR = 3.05, 95%CI 0.87 to 10.73) • The second trial compared polypropylene mesh with porcine dermis. At two years, significantly fewer women had anterior vaginal wall recurrence with the mesh procedure (28%, 27/96) compared to the porcine graft procedure (44%, 41/94) (RR = 0.64 95% CI 0.43 to 0.96) *Other comparisons for anterior vaginal wall prolapse*	

			• One trial comparing AC with Burch colposuspension showed statistically significant lower rates of cystocele recurrence with AC (RR = 0.09 95% CI 0.01 to 0.64), but higher rates of persisting urinary incontinence (RR = 3.39 95%CI 1.40 to 8.22) **3. One type of posterior vaginal wall prolapse repair versus another** ***Posterior vaginal wall repair versus a transanal repair*** Seven trials identified. Many of the important outcome parameters were not reported limiting the data available and the ability to perform meta-analyses. **Surgical outcomes** • The results for posterior vaginal wall repair were better than for transanal repair for both awareness of prolapse (subjective failure) (RR = 0.36, 95% CI 0.13 to 1) and recurrence on examination (objective failure) (RR 0.24, 95% CI 0.09 to 0.64 (both 2 trials) • Post-operative enterocele was significantly lower vaginal surgery (RR = 0.23 95% CI 0.07 to 0.83 (2 trials) • The vaginal approach was associated with a significantly higher blood loss (MD = 79ml, 95%CI 40 to 119) (1 trial) **Adverse outcomes**	

			• Post-surgery bowel evacuation problems were seen in 9 out of 31 in the vaginal group as compared to 14 out of 34 in the transanal group. The difference was not statistically significant • Other post-surgery outcomes which were not significantly different between groups were: the rate of incontinence to flatus or faeces and dyspareunia, but the trials were too small for these data to be reliable • There were differences between the trials for post-operative complications involving individual patients. These were in the vaginal group: haematoma (4 patients); blood transfusion (1 patient); and in the transanal group one patient has woman a wound infection (1 trial) ***Fascial plication posterior repair versus levator ani plication repair*** • A single small trial reported at six months that superior support of the posterior vaginal wall was attained after the fascial plication as compared to levator ani repair (MD = -0.68 cm, 95% CI -1.08 to -0.28) ***Posterior vaginal wall repair versus an abdominal posterior repai***r No trials identified. ***Posterior vaginal wall prolapse: a traditional posterior repair versus posterior repair with graft reinforcement***	

			• One trial compared posterior repair with and without mesh reinforcement. Rectocele recurrence appeared equally with and without mesh augmentation (RR = 1.13, 95% CI 0.40 to 3.19). The trial did not report any mesh erosion.
			• Another single trial compared posterior colporrhaphy, site-specific repair and site-specific repair augmented with porcine small intestine submucosa graft inlay for repairing rectocele
			  ○ There was no statistical difference in recurrence rate on examination (objective failure) between posterior colporrhaphy and site-specific repair
			  ○ There was a lower objective failure rate at one year following the posterior colporrhaphy as compared to porcine graft inlay (RR = 0.31 95% CI 0.11 to 0.84;)
			  ○ No statistical differences in patient reported subjective prolapse symptoms were reported between groups
			  ○ There were no significant differences between the groups in operating time or change in haematocrit, or duration of hospital stay
			  ○ There were no differences between groups in relation to reoperation rate for prolapse recurrence
			  ○ No significant differences were observed in adverse outcomes relating to: post-operative	

			complications, rates of post-operative dyspareunia, post-operative bowel function, or sexual function
			• Two trials compared native tissue repair (site-specific or fascial repair) as compared to native tissue repair with porcine small intestine submocosa (SIS) overlay
			  ○ the objective failure rate was significantly lower in the native tissue group (10%, 10/98) v the SIS group (21%, 20/93) (RR = 0.4 95% CI 0.24 to 0.94);
			  ○ the subjective failure rate was similar between the groups (RR = 1.09, 95% CI 0.45 to 2.62)
			  ○ There was no difference in the rate of post-operative dyspareunia between the groups (RR = 1.26 95% CI 0.59 to 2.68)
			
			Posterior vaginal wall prolapse: one type of graft (synthetic mesh or biological graft inlays) versus another type of graft
			No trials were identified.
			
			4. Any type of surgical prolapse repair versus conservative treatment
			No trials addressed this comparison.
			
			5. Any type of surgical prolapse repair versus mechanical devices
			No trials addressed this comparison.
			
			6. No graft versus use of graft (synthetic	

			mesh or biological graft) in any prolapse surgery
			Twenty-one trials compared standard (no graft or mesh) vaginal prolapse repairs with those which included mesh or graft material
			
			No mesh versus biological graft
			Seven trials used biological graft inlays for anterior or posterior repairs
			
			• There were no statistically significant differences in prolapse symptoms in any of these seven trials
			• In trials that compared anterior vaginal wall repair without and with biologic graft (either porcine dermis graft or cadaveric fascia lata), AC has a higher recurrence rate on examination compared to porcine dermis graft (RR = 1.7, 95% CI 1.1 to 2.6). Objective recurrence of prolapse for the cadaveric fascia lata group was not significantly different (4 trials)
			• In trials that compared native tissue repair with SIS graft on the posterior vaginal wall
			  ○ the recurrence rate on examination was significantly less after native tissue repair (18%, 10/55) compared with SIS (46% 12/26) (RR = 0.39 95% CI 0.20 to 0.79) (1 trial)
			  ○ the recurrence rate in the anterior compartment was significantly higher after anterior repair compared to SIS graft (RR = 2.95 95% CI 1.07 to 8.17) (1 trial)
			• The objective failure rate was not	

			significantly different after native tissue repair in anterior or posterior compartments (24% 66/277) as compared to any biological graft ((RR = 1.3 95% CI 0.6 to 2.7)) (6 trials) ***No mesh versus permanent synthetic mesh reinforcement*** *Absorbable polyglactin mesh inlay to augment prolapse repairs* See above section – Anterior vaginal wall repair alone versus anterior vaginal wall repair with synthetic mesh reinforcement (for midline cystocele defects). *Permanent mesh reinforcement (inlay, armed inlay or mesh kit)* 13 trials evaluated native tissue repair at any site versus any transvaginal polypropylene mesh • 10 trials compared anterior repair to a variety of permanent transvaginal mesh repair techniques and subject to meta-analyses – See above section – Anterior vaginal wall repair alone versus anterior vaginal wall repair with synthetic mesh reinforcement (for midline cystocele defects). • The remaining compared native tissue repairs with a variety of total, anterior or posterior polypropylene kit meshes ○ No difference in awareness of prolapse (subjective failure) was able to be	

			identified between the groups. (3 trials) ○ Objective recurrence rate on examination was higher in the native tissue repair group (55%,103/189) compared with transvaginal polypropylene mesh (38%, 74/194) (RR = 1.39, 95% CI 0.97 to 2.0) (2 trials) ○ Mesh erosion rate was 18% (35/194), of which 9% (18/194) required surgical correction for mesh erosion. (3 trials) ○ The reoperation rate after native tissue repair was higher after all polypropylene mesh kits combined (11%, 22/194) compared with native tissue procedures (3.7%, 7/189, 3.7%) (RR = 1.1, 95% CI 1.0 to 1.2) (3 trials) ***No mesh (native tissue) versus any graft (synthetic mesh or biological graft)*** Meta-analysis of no mesh versus all types of grafts showed: • In trials comparing native tissue repair with any graft demonstrated that symptoms of awareness of prolapse (subjective failure) are significantly greater after native tissue repair (24% 162/682) than a graft repair (18%, 117/649) (RR = 1.4 95% CI 1.1 to 1.7) (8 trials) • No difference in awareness of prolapse subjective failure was noted when native tissue repair was compared to biologic graft repair (RR = 1.03 95% CI 0.61 to 1.75) (3 trials) • More women had objective failure with no	

			mesh (38%, 346/905) as compared to any graft (22%, 180/856) (RR = 1.8 95% CI 1.4 to 2.5) (17 trials) • No significant difference in prolapse recurrence (objective failure) on examination when comparing native tissue repair to biologic graft repair (6 trials). However, this may be the result of including the one trial which masks the effect of evaluate posterior compartment prolapse. If this trial is excluded the benefits of utilising biologic grafts as compared to native tissue anterior repair were significant on objective examination (RR = 1.7 95% CI 1.2 to 2.50 (5 trials). **7. One type of graft (synthetic mesh or biological graft) versus another type of graft** Three trials identified. • One trial compared women having anterior repair compared non-absorbable polypropylene mesh versus absorbable porcine dermis graft. This was the only trial to measure subjective reported prolapse symptoms but did not find any statistically significant differences between the groups. • One small trial compared absorbable porcine dermis graft versus absorbable polyglactin mesh. This found that fewer women had objective recurrence of prolapse with porcine dermis rather than polyglactin to reinforce an anterior repair	

			(RR = 3.22 95%CI 1.38 to 7.52) • Finally, one trial compared armed polypropylene mesh proved better than armed inlay regarding objective success (RR = 0.64 95% CI 0.43 to 0.96) though women had more daytime urinary frequency (RR = 4.24 95% CI 1.83 to 9.84) • The trials were too small to demonstrate other statistically significant differences and the CIs were wide **8. One type of suture versus another type of suture** One trial identified. This compared polyglactin sutures with polydioxanone sutures. • The study was too small to draw reliable conclusions **9. Pelvic organ prolapse (POP) surgery and bladder function** ***All POP*** • After all types of prolapse surgery 20.4% (434/2125) women reported new subjective SUI after prolapse surgery (16 trials) • New overactive bladder symptoms were noted in 12% (119/1005) undergoing prolapse surgery (11 trials) • New voiding dysfunction was reported in 9% (109 /1209) (12 trials)	

			One type of pelvic organ prolapse (POP) surgery alone versus another type of POP surgery • Six trials compared anterior native tissue repair with anterior transobturator mesh repair included only symptomatically continent women or provided separate data on pre-operatively continent women showed a reduced risk of developing SUI post-operatively in the anterior native tissue groups (11%, 50/449) compared to polypropylene mesh repair (17%, 74/449) (RR = 0.7 95% CI 0.5 to 0.9) • Two trials found that women with pre-operative prolapse and stress urinary incontinence, who underwent prolapse surgery without concomitant continence surgery, had significantly higher rates of persisting SUI (65%, 76/117), than those that had continence surgery performed at the time of prolapse surgery (15, 17/111) (RR = 4.4, 95% CI 2.7 to 7.1) ***Pelvic organ prolapse (POP) surgery alone versus POP surgery with an additional continence procedure*** *Needle suspension* • One trial demonstrated no difference in objective rate of new SUI after pubo-urethral ligament plication or Pereyra needle suspension (RR = 1.2 95% CI 0.8 to 1.9) • Two trials found no difference in	

			subjective reduction in post-operative SUI in including a needle suspension as compared to bladder neck plication at vaginal prolapse surgery *Colposuspension* • Two trials evaluated the impact of adding a colposuspension to sacral colposuspension in women who had prolapse and were continent pre-operatively. While more women (who were continent at baseline) had become incontinent in the group who did not have Burch colposuspension in addition to abdominal sacral colpopexy in one trial, in the second a reduction was observed. A random-effects model meta-analysis did not reveal significant a difference • Sacral colpopexy alone, as compared to sacral colpopexy and colposuspension, resulted in lower blood loss (MD = -73 g, 95% CI -115 to -31) and a shorter operating time (MD = -20 min, 95% CI -33 to -7). At two years, symptoms of SUI were not significantly different between the groups (2 trials) • One trial demonstrated no benefit in adding colposuspension to sacral colpopexy in those with prolapse and SUI. Persisting SUI post-operatively was similar whether without (39%,9/23) or with colposuspension (54%, 13/24) (RR = 0.54, 95% CI 0.2 to 1.7) *Suburethral tape*	

			• Three trials evaluated vaginal prolapse surgery with and without suburethral tape (TVT) in women with hidden SUI.
			  ○ There was no difference in rates on post-operative assessment after prolapse repair without a tape as compared to prolapse repair with TVT in respect to both subjective SUI (43% versus 25%, RR = 2.4 95% CI 0.7 to 8.0) (2 trials) and objective SUI (41% versus 22%, RR = 3.7 95% CI 0.9 to15.2) (3 trials)
			  ○ Subsequent continence surgery was required more frequently in those that underwent prolapse surgery without TVT as compared to prolapse surgery with TVT (5.7% versus 0.5%, RR = 6.8 95% CI 1.5 to 30.5) (2 trials)
			• One trial showed a higher rate of persisting SUI in women with prolapse and SUI undergoing prolapse surgery without TVT (17%, 67/94) compared to prolapse surgery with TVT (5%,4/87) (RR = 51, 96% CI 17 to 154) (1 trial).
			• Eight trials described the rate of objective SUI in all women undergoing prolapse surgery with and without continence surgery (procedures varied). The trials showed that not performing continence surgery at the time of prolapse surgery significantly increased the risk of SUI post-operatively (RR = 1.6 95% CI 1.3 to 2.1)
			• Six trials described the rate of de novo SUI after prolapse surgery without	

			continence surgery and prolapse surgery with continence surgery. It was found that including continence surgery at the time of prolapse surgery reduced the risk of de novo SUI (RR = 2.0 95% CI 1.4 to 2.3) • Five trials described the rate of de novo SUI after prolapse surgery without continence surgery and prolapse surgery with continence surgery in a subgroup of women with hidden SUI preoperatively. The meta-analysis demonstrated a significantly higher rate of post-operative SUI in women who did not receive continence surgery (43%, 53/124) with those who had a continence procedure at the time of prolapse surgery (19%, 23/118) (RR = 2.0 95% CI 1.4 to 2.8). • Two trials described the benefit of adding continence surgery to prolapse surgery in women who pre-operatively had no SUI and no hidden stress incontinence (SUI with prolapse reduced). Women undergoing prolapse surgery, who were without symptoms of SUI, and had no SUI with the prolapse reduced, and did not have continence surgery performed were more likely to develop post-operative SUI (40%, 94/235) than if continence surgery was performed (25%, 52/220) (RR = 2.2 95% CI 1.4 to 3.3). • Two trials demonstrated that in those with prolapse and SUI pre-operatively, who underwent prolapse surgery without continence surgery, had non-significantly higher rates of persisting SUI (65%,	

			76/117) ,than those that had continence surgery performed at the time of prolapse surgery (15%, 17/111) (RR = 4.36 95% CI 2.68 to 7.10)	
Bugge C, Adams EJ, Gopinath D, Reid F.(2013) Pessaries (mechanical devices) for pelvic organ prolapse in women Cochrane Database of Systematic Reviews 2013, Issue 2. DOI:10.1002/14651858.CD004010.pub3. Last assessed as up-to-date: March 2012	To determine the effectiveness of pessaries (mechanical devices) for pelvic organ prolapse Cochrane systematic review	Systematic Review based on evidence ranging from SIGN 1++ (High quality meta-analysis, systematic reviews of Randomised Controlled Trials (RCTs) ,or RCTs with a very low risk of bias) to SIGN 1+.(Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias) One trial met the inclusion criteria – that in a randomised or quasi-randomised controlled trial at least one arm of the study included a pessary for pelvic organ prolapse.	Formal comparison between the use of a mechanical device and the use of any surgery, with or without any form of mesh, were not considered in this review.	No comment.
Hagen S, Stark D.(2011) Conservative prevention and management of	To determine the effects of conservative management (physical and lifestyle	Systematic Review based on evidence ranging from SIGN 1++ (High quality meta-	The trial considered four comparisons in which physical and/or lifestyle interventions were compared with surgery for POP.	*"There is still relatively little evidence from large, well-conducted trials to inform this review, and a*

pelvic organ prolapse in women. Cochrane Database of Systematic Reviews 2011, Issue 12. DOI:10.1002/14651858.CD003882.pub4. Last assessed as up-to-date: May 2010.	interventions) for the prevention or treatment of pelvic organ prolapse in comparison with no treatment or other treatment options (such as mechanical devices or surgery). Cochrane systematic review	analysis, systematic reviews of Randomised Controlled Trials (RCTs) ,or RCTs with a very low risk of bias) to SIGN 1+.(Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias) Six randomised and quasi-randomised trials in women with pelvic organ prolapse that included a physical or lifestyle intervention in at least one arm of the trial were included. Risk of bias was assessed as being "low" in 4 trials and either "uncertain" or "high" in the remaining two.	No trials were identified in which the following were compared: • Physical intervention versus surgery; • Lifestyle intervention versus surgery; and • Combined physical and lifestyle intervention against surgery **Physical and/or lifestyle interventions supplementing surgery versus surgery alone**. Two trials identified that compared surgery plus pelvic floor muscle training (PFMT) with surgery alone • Neither trial specifically measured the primary outcome of the review; prolapse symptoms and severity • Amongst the secondary outcomes, prolapse severity was not measured in either trial. • Both trials included blinded measurement of pelvic floor muscle function, using both digital assessment (modified Oxford score) and manometry ○ One trial reported that despite the tendency towards improvement in the PFMT group over time, there were no significant differences in manometry scores between the controls and those in the PFMT arm. Observed change in the muscle strength (measured digitally) did significantly differ between the two groups with PMFT (D = 0.69 +/- 0.64) being favoured over Controls (D = 0.21 +/- 0.66) (MD = -0.48 95% CI -0.84 to -	*lack of data on long-term outcomes." (Pg 16)* *"There was no prolapse-specific data available from either trial [that considered surgery]. Both trials reported on pelvic floor muscle strength and urinary outcomes but findings were contradictory." (Pg 16)* *"There are now some rigorous trial findings to support the use of PFMT as a treatment for women with prolapse, however the evidence remains limited. There was insufficient evidence about other interventions or combinations of interventions to inform practice.""" (Pg 16)*

			0.122). Change from baseline in the other objective measures (vaginal resting pressure, peak maximum vaginal squeeze pressure, and area maximum vaginal squeeze pressure) did not differ between groups ○ The second trial, however, reported that improvement in mean maximum pelvic floor muscle squeeze was significantly greater in the PFMT group than the control group • Both trials reported on urinary function ○ One trial reported that there were no significant differences between the intervention and control groups in reported incontinence using validated instruments. Nor were there any significant difference between groups on bladder diary reports or (objective) pad test weights. ○ The second trial reported a significant improvement in urine leakage (measured via an objective pad volume test) for both the intervention and control groups, but no significant difference in improvement between the groups. Both groups had an improvement in urinary symptoms but the improvement for the intervention group was reported to be significantly greater than for the control group (Between group difference in mean reduction = 3.8; P = 0.017; 95% CI 0.7 to 6.9). ○ The second trial also reported a	

			significant reduction in diurnal frequency with a greater mean reduction observed for the intervention group (mean reduction 1.5) compared with the control group (mean reduction 0.4) (P = 0.024) • One trial reported on a further subjective, symptom outcomes finding that there were no differences between PFMT and Control groups for the bowel symptoms or QoL scores. There was a difference in favour of the intervention group in terms of increased frequency of general physical activity (mean sessions per week = 1.8 +/- 2.97) over the Control group (mean sessions per week = 0.27 +/- 1.99).	

Note regarding:

Chughtai B, Mao J, Buck J, Kaplan S, & Sedrakyan A.(2015) *Use and risks of surgical mesh for pelvic organ prolapse surgery in women in New York state: population based cohort study.* BMJ 2015;350:h2685 doi: 10.1136/bmj.h2685

At present data from this recent paper published in the British Medical Journal has not been included in this analysis. As a population based, cohort study this would be classified by SIGN as a Grade 3 study ("Non analytic").as it describes the clinical (safety) outcomes post mesh and non-mesh surgery for POP at 3 months (90 days) for clinical (safety) outcomes and a 1 year re-intervention rate. It is notable that no subjective measures were included. Potential sources of bias due to covariance were managed by the used of propensity score matching (though in practice it had little impact on potential bias). No account is taken of types of mesh or site-specific POP factors.
The main findings from this study of note are:

- Any form of mesh was associated with an increased risk of re-intervention within one year following the initial procedure, Re-intervention risk was significantly higher in the younger age group (<65y) with no increased risk observed among older patients;
- In relation to 90 day post-operative complicate rates, only increased urinary retention was found to be significantly greater amongst mesh patients after propensity score matching. This too was age sensitive with urinary retention complications associated with mesh use were among people aged 65 years and older;
- No other 90 day post-operative complicate rates were found to be significantly different between patients with or without mesh during POP surgery.

However, as no patient reported symptoms were available to the researchers, and the maximum follow up was only to 1 year, the types of adverse outcome more commonly reported by patients, (e.g. mesh erosion, chronic pain, recurrent SUI, mobility problems, etc.) cannot be considered.

The main value in this study is to emphasise the potential for particular sub-groups of patients being more susceptible to longer term mesh related problems.