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Horizon Scanning Technology Prioritising Summary

Transvaginal pelvic reconstruction using mesh for genitourinary prolapse

August 2004

(Updated December 2005, February 2007, December 2007 and February 2008)



ASERNIPs

**Australian
Safety
and Efficacy
Register
of New
Interventional
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**Royal Australasian
College of Surgeons**



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The production of this Horizon scanning prioritising summary was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

This Horizon scanning prioritising summary was prepared by staff from the Australian safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).



Name of Technology:

Transvaginal pelvic reconstruction using mesh

Purpose and Target Group:

Transvaginal pelvic reconstruction using mesh is designed to rectify genitourinary prolapse. This procedure may therefore be applicable for women with pelvic floor defects, with or without stress urinary incontinence (Shah *et al.* 2004).

Stage of Development (in Australia): Yet to emerge in Australia.

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use

International Utilisation:

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely Diffused
USA	✓		
Italy	✓		

Impact Summary:

Background

Genitourinary prolapse is caused by many different factors, such as advancing age, multiparity, prolonged or difficult labour, and hysterectomy, which impair the integrity of the pelvic floor. Other factors that may increase the risk of developing genitourinary prolapse include obesity, straining to pass stool as a child or young adult, heavy manual labour, chronic obstructive pulmonary disease, abnormal collagen diseases such as Marfan disease, and smoking (Jackson *et al.* 1997, <http://www.emedicine.com>).

Treatment for genitourinary prolapse generally depends on the severity of the condition; a mild condition usually responds well to conservative treatment such as pelvic exercise, pessaries and vaginal support devices. Surgical therapy is recommended when conservative treatment fails (Jackson *et al.* 1997, <http://www.emedicine.com>).

Surgical therapy can take an abdominal, vaginal or laparoscopic approach. Long term results for surgery are uncertain with little published work comparing alternate procedures and techniques (Jackson *et al.* 1997). Transvaginal pelvic reconstruction using synthetic mesh is a procedure that



gains access via the vagina, which involves reinforcing the pelvic floor with a non-absorbable synthetic mesh.

Clinical Need and Burden of Disease

An Australian study conducted by MacLennan *et al.* (2000) has reported that 8.8% of women over the age of 15 had symptoms of pelvic organ prolapse. Treatment of prolapse comprises of approximately 20% of the gynaecological surgical workload (Jackson *et al.* 1997).

Pelvic organ prolapse depending on the stage is associated with a variety of symptoms. These include urinary stress incontinence, urinary retention, urinary tract infections, back ache, difficulty in tampon usage, ulceration and constipation (Jackson *et al.* 1997). The condition impacts heavily on not only the physical well-being of the patient but also the mental and social well-being of the patient.

Estimated Speed, Geographic and Practitioner Use Patterns of Diffusion in the Health System

This procedure was commenced in January 1989 by Julian (1996) in the United States. Published data by Nicita (1998) indicate that the procedure was utilised on 44 patients in Italy from January 1996. Choe *et al.* (1999) published data on 40 women in the United States who had undergone the procedure and Shah *et al.* (2004) have used the procedure on a total of 29 patients in the United States since March 1999.

Existing Comparators

- Colpopexy

Estimated Cost Impact

The costs associated with this new procedure are not available. The cost of surgery involving abdominal or vaginal repair of suspension of the vaginal vault in Australia is also not available. However, reimbursement fees for traditional abdominal repair of suspension of the vaginal vault, colpopexy (item number 35590) as stated in the Medicare Benefits Schedule is estimated to be approximately \$445 (<http://www.health.gov.au>). According to HIC, 1064 claims to Medicare were processed between July 2002 to June 2003 for item number 35590 (<http://www.hic.gov.au>).

Efficacy and Safety Issues

Safety and efficacy findings are based on one randomised controlled trial (RCT) (Choe *et al.* 1999), one non-randomised comparative study (Julian 1996) and two case series (Nicita 1998, Shah *et al.* 2004).

Choe *et al.* (1999) used an antimicrobial Mycromesh and compared this with a vaginal wall sling. Patients allocated to receive the Mycromesh had a significantly shorter operative time and lower blood loss ($p < 0.05$), while preoperative pad usage was less in patients who had the vaginal wall sling. Stress incontinence was cured in 95% (19/20) of Mycromesh patients and 70% (14/20) of



patients who had the vaginal wall sling. Postoperative satisfaction was higher in Mycromesh patients (20/20, 100%) compared with 16/20 (80%) patients who had the vaginal wall sling and reported dissatisfaction due to recurrent stress incontinence and recurrent cystocele formation. Mycromesh patients reported more complications (clogged suprapubic tube, abdominal wound infection and urinary tract infection) than patients who had the vaginal wall sling. However, one patient who had the vaginal wall sling required an intraoperative blood transfusion. There were no late complications in either group.

In the non-randomised comparative study (Julian 1996), 24 patients underwent transvaginal repair; 12 had the anterior vaginal segment reinforced with a non-absorbable Marlex mesh and the other 12 had no additional reinforcement. All patients had at least two previous occurrences of severe anterior wall prolapse. There were no significant differences in blood loss or operative time between groups. There were no significant intraoperative complications; however, 3/12 (25%) patients who received Marlex mesh had mesh-related complications within six months of surgery. At 2-year follow-up, recurrent prolapse of the anterior vaginal segment was reported in 4/12 (33.3%) patients who had no additional reinforcement. None of the Marlex mesh patients reported recurrent prolapse.

Two case series used non-absorbable mesh in 44 patients (Nicita 1998) and 29 patients (Shah *et al.* 2004). Patients in the study by Nicita (1998) had varying degrees of incontinence and combinations of cystocele, uterine or vaginal vault prolapse, rectocele and/or enterocele. One patient had erosion of the vaginal wall. There were no cases of urinary retention requiring catheterisation, blood transfusions, vaginal suppuration or recurrent cystoceles. There were reports of reduced urgency and frequency after two months. Ten patients with vaginal vault prolapse and 14 with first and second degree uterine prolapse were cured. Partial success occurred in 3/6 (50%) of patients with third degree uterine prolapse, where cystocele was cured but first degree prolapse recurred after three months. Shah *et al.* (2004) reported a range of complications including perineal pain, frequency, urgency, sacral pain and constipation, at 1, 12 and 24 weeks' follow-up with the numbers of each complication decreasing up to 24 weeks. Six of the ten patients who were sexually active reported dyspareunia at six-month follow-up. The mean score for subjective satisfaction of surgical outcomes was 8.04 (where 0 is very disappointed and 10 is very satisfied).

A few studies have reported on the safety and efficacy of transvaginal pelvic reconstruction using mesh as an alternative to standard colpopexy. They indicate that transvaginal pelvic reconstruction may enable effective realignment of genitourinary organs by providing reinforcement of the pelvic floor whilst resulting in a decreased operative time, blood loss and recurrence of stress incontinence.



2005 update

A search of relevant databases, online journals and the Internet was conducted in December 2005, following recommendation in August 2004 that transvaginal pelvic reconstruction using mesh be monitored for assessment in 12 months time. One new source of evidence on the safety and efficacy of this intervention has been located in the literature. Rutman et al. (2005) conducted a case series study to evaluate the safety and efficacy of transvaginal pelvic reconstruction using mesh in fifty patients. This study examines a new transvaginal technique that recreates the sacrouterine ligament/ cardinal complex with the use of a prolene mesh. The procedure is the first to reconstruct the entire pelvic floor repairing vault prolapse/enterocele, as well as widening of the levator hiatus and levator/perineal body descent.

This study reported results after a mean follow-up of six months. Seventy-three percent of patients underwent concomitant sling, 63% Grade 4 cystocele repair, and 39% underwent vaginal hysterectomy. The study authors recorded no intraoperative complications. Patients were discharged from hospital approximately two hours after surgery with oral antibiotics. Five patients (10%) required post procedural intervention. Two patients (4%) had recurrent Grade 2 enteroceles without vault prolapse – one of these patients required a second surgery. One additional patient (2%) had an asymptomatic Grade 2 rectocele. One patient had small mesh erosion at the posterior vaginal wall cured with an office excision. An additional patient had unilateral ureteral obstruction requiring ureteroneocystostomy.

The authors reported that 49/50 (98%) patients were delighted, pleased, or mostly satisfied with the results of their procedure.

Reference:

1) Rutman MP, Deng DY, Rodríguez LV, Raz S. Repair of Vaginal Vault Prolapse and Pelvic Floor Relaxation Using Polypropylene Mesh. *Neurology and Urodynamics* 2005; **24**: 654-658.

2007 update

A search of relevant databases, online journals and the Internet was conducted in January 2007, following the recommendation in December 2005 that transvaginal pelvic reconstruction using mesh for prolapse be monitored for an additional 12 months. A total of 3 studies on the safety and effectiveness of this procedure were identified and retrieved.

A retrospective analysis on 76 patients (mean follow-up: 30.7 ± 1.7 months) treated for total pelvic organ prolapse with a specially fashioned 'H' shaped polypropylene mesh using a tension-free 4-point fixation technique was conducted by Amrute et al. (2007). Prolapse recurrence was reported in 4 patients (5.2%). A total of 68 patients (89%) were completely dry or had an occasional leak. Stress incontinence symptoms recurred in two patients (2.1%) while 12 patients (15.7%) indicated symptoms of new onset urgency (6 were incontinent [7.8%]). In patients who had preoperative incontinence ($n = 36$), the average pad use per day was shown to have decreased significantly from 2.1 ± 0.4 to 0.8 ± 0.2 postoperatively ($p < 0.005$). A total of 4 complications were reported, 2 patients (2.1%) experienced vaginal erosions, one patient (1.1%) had obstruction, and another patient (1.1%) had palpable retained vaginal suture. Within the subgroup of 21 sexually active patients, 19 (90.4%) denied any dyspareunia. Overall patient satisfaction was good, with a mean value of 7.9 ± 0.3 (on scale of 1 [least satisfied] to 10 [most satisfied]). However, the lack of objective criteria to determine success and the potential patient bias (due to the reliance on a questionnaire) limits the conclusiveness of this study (Amrute et al. 2007).

An earlier study conducted by Milani et al. (2005) was identified and was retrieved for inclusion in this update. Sixty three women suffering from prolapse were recruited and treated with anterior or posterior repair with a prolene mesh (mean follow-up: 17 months). The overall anatomical success rate was 94% in this cohort. In the subgroup of 32 patients who underwent repair of an *anterior* vaginal prolapse, the investigators reported that sexual activity rate remained similar to preoperative rates, however dyspareunia increased by 20%. No significant improvement was noted for urge and stress incontinence postoperatively, while 10% of patients experienced improved urgency. Vaginal erosion was observed in 13% of patients in this subgroup. Investigators reported that 20% of patients within this subgroup experienced recurrent urinary tract infection after surgery (Milani et al. 2005). Meanwhile, the subgroup of women who underwent *posterior* repair ($n = 31$) reported a significant 12% decrease in sexual activity and a significant increase (63%) in dyspareunia ($p < 0.05$). Constipation improved in 5 patients (15%) while anal incontinence improved in one patient (4%). Mesh erosion through the vaginal wall was observed in 6.5% of cases at a mean of 14 months post-treatment, one patient required mesh removal due to the development of a pelvic abscess (Milani et al. 2005).

Overall, despite the encouraging anatomical results achieved with the prolene mesh, a substantial amount of patients experienced vaginal erosion and *de novo* dyspareunia. As a result of the relatively high rate of morbidity, the investigators concluded that the use of a prolene mesh for the treatment of prolapse should be abandoned (Milani et al. 2005).



In an attempt to identify the risk factors that are associated to the occurrence of mesh erosion, Actari et al. (2005) retrospectively reviewed the use of the Atrium and Vypro II mesh in patients (n = 198) requiring repair of pelvic organ prolapse. No association was observed between mesh type and mesh erosion following surgery. However, in patients treated with the Vypro II mesh, the investigators noted that experienced surgeons had significantly less erosions compared to their less experienced colleagues (p = 0.02). In addition to this, the investigators reported that for each 5-year increase in patient age, the risk of mesh erosion decreased by 0.8 times (p = 0.05) for both mesh types. Overall, this study concluded that patient age and surgeon experience were the only factors associated with mesh erosion for the Atrium and Vypro II meshes.

2007 Recommendation

The evidence currently available on the use of mesh for the treatment of vaginal prolapse remains limited. More comparative studies are required to determine which meshes are suitable and safe for the treatment of vaginal prolapse. Based on the available studies and the potential risks of increased morbidity with the use of unsuitable meshes, HealthPACT recommends that the technology be monitored.

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References

Achtari C, Hiscock R, O'Reilly BA, Schierlitz L, Dwyer PL. Risk factors for mesh erosion after transvaginal surgery using polypropylene (Atrium) or composite polypropylene/polyglactin 910 (Vypro II) mesh. *Int Urogyn Journal* 2005; 16(5): 389-394.

Amrute KV, Eisenberg ER, Rastinehad AR, Kushner L, Badlani GH. Analysis of outcomes of single polypropylene mesh in total pelvic floor reconstruction. *Neurourology and Urodynamics* 2007; 26(1): 53-58.

Milani R, Salvator S, Soligo M, Pifarotti P, Meschia M, Cortese M. Functional and anatomical outcome of anterior and posterior vaginal prolapse repair with prolene mesh. *British Journal of Obstetrics and Gynaecology* 2005; 112(1): 107-111.

2008 Update

A search of relevant databases, online journals and the Internet was conducted in January 2008, following the recommendation in January 2007 that transvaginal pelvic reconstruction using mesh for prolapse be monitored for an additional 12 months. A total of three case series regarding the safety and effectiveness of this procedure were identified and retrieved.

Jo et al. (2007) reported on 38 patients (mean age 58.2 years) with symptomatic anterior vaginal wall prolapse who underwent anterior colporrhaphy using tension-free polypropylene mesh. Twenty-nine patients underwent prolapse repair concurrently with either vaginal hysterectomy (n=18), tension-free vaginal tapes (TVT) (n=22) or posterior colporrhaphy (n=25). Five patients with stage II vault prolapse underwent TVT and posterior colporrhaphy instead of vaginal vault suspension because the main reason for surgery was to correct urinary incontinence.

Perioperative prolapse severity was determined using the pelvic organ prolapse quantification system (POPQ) and stress urinary incontinence was diagnosed during gynecological examination. At baseline, stage II prolapse was observed in 12 patients (31.6%), stage III in 23 patients (60.5%) and stage IV in three patients (7.9%), and 22 patients (57.9%) were considered incontinent. Patient outcomes at follow up were considered as subjective (if patient no longer experienced prolapse sensation) or objective (if prolapse was \leq stage I). Follow-up included gynecological examination and occurred postoperatively at three weeks, three months, six months and every six months thereafter (mean follow up duration 23.4 months, range 13-62 months).

At the three week follow up (n = 38) stage 0 prolapse was observed in 21 patients (55.3%), stage I in 17 patients (44.7%) and none in stage II-IV. At six months (n=38) 18 patients (47.7%) had stage 0 prolapse, 19 (50.0%) had stage I and one (2.6%) had stage II (none in stage III-IV). At 12 months (n = 37) 17 patients (45.9%) had stage 0 prolapse, 18 (48.6%) had stage I and two (5.4%) had stage II (none in stage III-IV). And, at 18 months follow up (n = 35) 14 patients (40.0%) had stage 0 prolapse, 19 (54.3%) had stage I and two (5.7%) had stage II (none in stage III-IV).

The 12 month postoperative subjective and objective cure rates were 94% and 94.5%, respectively. Of the 30 symptomatic patients enrolled 28 (93.3%) were relieved of prolapse symptoms for the entirety of the follow-up period. Vaginal examination of the two remaining patients, with marginal symptoms, did not provide findings of recurrent prolapse therefore their symptoms were seen as subjective. Urinary incontinence cure rate was 100% for the entirety of the follow up period. Preoperatively 2/14 sexually active patients reported dyspareunia, this was postoperatively resolved.

The mean operation time was 67 minutes and the mean hospital stay was 4.8 days (range 2 - 7 days). There were no complications associated with the use of the synthetic mesh in reconstruction (i.e. no mesh erosion or mesh related infection during the follow-up). No intraoperative complications were reported. Postoperative complications included six patients with urinary retention; treated with catheterization (no further problems) and one patient suffering hematoma at the vaginal cuff site (no



transfusion was required). Prolapse repair did not cause de novo stress urinary incontinence or urgency in any patient during the follow up period (Jo et al. 2007).

Gabriel et al. (2007) reported 73 patients (mean age 66 years) with severe symptomatic posterior compartment defects who underwent transvaginal pelvic reconstruction using a posterior four-armed polypropylene mesh implant, suspended by pararectal and infracoccygeal technique. Patients were assessed perioperatively using a simplified version of the POPQ staging system, only patients considered to have clinically significant prolapse (> stage II) were included in the study with some stage I patients being circumstantially enrolled. Concomitant procedures were performed in 53 patients (72.6%), and included hysterectomy, anterior colporrhaphy, sacrospinous ligament fixations and transobturator tape. Postvoid residual volume (PVR) and urinary incontinence (stress, urge and mixed) was also considered before and after surgery as symptomatic characteristics of prolapse.

Fifty women (68.5%) had previously undergone pelvic floor reconstruction, 13 of which with posterior colporrhaphy. At baseline, patient rectocele characteristic (POPQ) were as follows; 11 patients (15%) in stage I, 36 patients (49%) in stage II, 23 patients (32%) in stage III and three patients (4%) in stage IV. Preoperatively, 12 women had a PVR > 100 ml and 38 women suffered urinary incontinence (stress n=19, urge n=10, mixed n=9).

Mean operative time (posterior four-armed mesh implant only) was 56.5 minutes. Intraoperative complications occurred in 3/73 (4.2%) patients, including two cases of blood loss > 500ml (not requiring transfusion) and one case of bladder injury. Fifteen (20%) patients incurred minor complications immediately after surgery, including moderate or severe pelvic pain which resolved after their hospital stay (n = 5). Nine patients had a PVR > 100 ml. One patient had a postoperative hemorrhage requiring surgical revision and as a result incurred mesh erosion necessitating secondary vaginal wall suture. One patient with a preoperative inept anal sphincter experienced a worsening of this condition postoperatively. There were no cases of wound or urinary infection.

Follow up gynecological examination occurred at 2 to 6 months (mean follow up period 3.8 months) postoperatively, 66/73 patients (82.2%) attended, 48 (72.7%) of which reported normal findings. The stages of rectocele (POPQ) observed at the end of follow up (n = 60) was as follows; 53 patients (88%) in stage 0, seven (12%) in stage I and none in stages II-IV. No recurrence of posterior compartment prolapse > stage I was observed, as well as no incidence of infection or rectovaginal fistula. There was one additional case of mesh erosion during the follow up period bringing the total mesh erosion rate to 3.1%. At the end of the follow up period 3/60 patients (5%) displayed a PVR > 100ml, one of which was a de novo condition, and 10 women with high PVR before surgery were relieved of this condition. Of the 19 patients with either urge incontinence or mixed stress and urge incontinence 18 (94.7%) were relieved of their symptoms. De novo urinary incontinence developed in three women (5%) (one urge and two stress) and dyspareunia occurred in 2/60 patients (3.3%) (Gabriel et al. 2007).



de Tayrac et al. (2007) reported 26 patients (mean age 63.7 ± 13.4 years) with symptomatic stage II ($n = 11$), III ($n = 7$) and IV ($n = 8$) posterior vaginal wall prolapse who underwent rectocele repair by vaginal route using polypropylene mesh. There were 39 cases of concomitant procedures carried out, including anterior colporrhaphy with mesh ($n=13$), hysterectomy ($n=16$) and TVT ($n=10$). Perioperative assessment included the use of the POPQ staging system at six weeks post-operation and every six months thereafter, follow up period ranged from 10 to 44 months (mean followed time 22.7 ± 9.2 months). The objective cure rate was defined by the number of surgical outcomes $<$ stage I and subjective outcomes were defined by impact questionnaire scores (scores $<$ 100/300 were considered unsuccessful). Ten women (38.5%) had associated genuine stress urinary incontinence.

Mean operative time (all procedures) was 73 ± 29 minutes and mean hospital stay was 4.1 days (range 3-7). There were no major intraoperative complications and blood loss was estimated to be $<$ 300ml, no transfusions were required. Postoperative complications shortly after surgery included two urinary tract infections, one unilateral supra-pubic abscess and one case of urinary retention. Of the 26 participants 25 attended follow up.

Surgical outcomes were as follows; 23 (92%) patients had stage 0 prolapse, one (4%) had stage I prolapse and one (4%) had stage II prolapse (this was the only case of recurrence however the patient did not experience mesh shrinkage, pain or impaired quality of life). The objective cure rate was calculated as 24/26 patients (92.3%) and the subjective cure rate was calculated as 22/25 (88%). All patients followed up expressed high or very high satisfaction with the surgical outcome, with the exception of one who had stage 0 postoperative prolapse and experienced no pain at rest however encountered de novo dyspareunia (this was the only sexually active patients ($n=13$) with de novo dyspareunia), 20 months later this patient removed the mesh and alleviated the condition.

There were no further reports of postoperative recurrence, infection of the mesh or rectovaginal fistula during the follow up period. One patient (4%) complained of regular moderate coccygeal pain. There were a total of three vaginal mesh erosions (all occurring on the midline in front of the vaginal scar) occurring at six weeks, 11 months and 13 months, two of these women were symptomatic and treated accordingly. No further erosions occurred in the patients reviewed after this time (up to 44 months). Defecation disorders improved in 3/5 (60%) patients and de novo defecation disorders occurred in 2/20 (10%), fecal incontinence was cured in 1/1 patients and de novo fecal incontinence occurred in 1/24 (4.2%) patients. One patient suffered from de novo stress urinary incontinence and three patients had de novo urinary urgencies (de Tayrac et al. 2007).

2008 HealthPACT Action

The evidence currently available on the use of mesh for the treatment of vaginal prolapse remains limited. High level evidence studies are required to fully assess the worth of this surgical procedure. Based on the lack of high quality studies undertaken between the time the technology first emerged to present this technology will be archived.



Number of Studies Included

Total number of studies included	3
Level IV intervention evidence	3

References

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Gabriel B, Farthmann J, Brintrup B, Fünfgeld C, Jezek P, Kraus A, Lenz F, Kumbier E, Niesel A, Stickeler E and Watermann D. Surgical repair of posterior compartment prolapse: Preliminary results of a novel transvaginal procedure using a four-armed polypropylene mesh with infracoccygeal and pararectal suspension. *Acta Obstetrica et Gynecologica Scandinavica* 2007; 86 **(10)**: 1236-1242

Jo H, Kim JW, Park NH, Kang SB, Lee HP and Song YS. Efficacy and outcome of anterior vaginal wall repair using polypropylene mesh (Gynemesh). *Journal of Obstetrics and Gynaecology Research* 2007; 33 **(5)**: 700-704.



Ethical Issues

Ethical issues may arise depending on the necessity for a hysterectomy for the procedure. Shah *et al.* (2004) recommend when performing repair of uterine prolapse, a simultaneous transvaginal hysterectomy should occur to prevent recurrence.

Cultural or Religious Considerations

No issues were identified from the retrieved material.

Other Issues

No issues were identified from the retrieved material.

Recommendation:

Some evidence exists on the safety and efficacy of transvaginal pelvic reconstruction using mesh. Additional long-term safety and efficacy data from randomised controlled trials may be required before this procedure can be widely accepted

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Sources of Further Information:

What are the surgical procedures for treating stress incontinence?

<http://www.ucdmc.ucdavis.edu/ucdhs/health/a-z/50urinaryincontinence/doc50surgical...>

Accessed March 2004.

Pubovaginal sling. Emedicine

<http://www.emedicine.com/med/topic3057.htm> Accessed March 2004.

Search Criteria:

A search of MEDLINE, PubMed and Cochrane Library, Current Controlled Trials metaRegister, UK National Research Register, International Network for Agencies for Health Technology Assessments, relevant online journals and the Internet was conducted in March 2004.

Search terms used were: 'transvaginal pelvic reconstruction', 'genitourinary prolapse', 'pelvic reconstruction with mesh', 'genitourinary prolapse and mesh repair', 'shah DK', 'transvaginal and pelvic prolapse and mesh' and 'transvaginal and vaginal vault and mesh'.