



Australia and New Zealand Horizon Scanning Network
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Australian Government
Department of Health and Ageing



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Horizon Scanning Technology Prioritising Summary

Transvaginal pelvic reconstruction using mesh for genitourinary prolapse

August 2004

(Updated December 2005 and February 2007)



ASERNIP(S)

**Australian
Safety
and Efficacy
Register
of New
Interventional
Procedures -
Surgical**



**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, backache, 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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| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input checked="" type="checkbox"/> Monitor | <input type="checkbox"/> Archive |

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.

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

2005 Update: This procedure will be monitored for a further 12 months.

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| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input checked="" type="checkbox"/> Monitor | <input type="checkbox"/> Archive |

References:

Choe JM, Ogan K, Battino BS. Antimicrobial mesh versus vaginal wall sling:: A comparative outcomes analysis. *The Journal of Urology* 1999; **163**(6): 1829-34.

Jackson S, Smith P. Diagnosing and managing genitourinary prolapse. *British Medical Journal* 1997; **314**(7084): 875-880.

Julian T. The efficacy of Marlex mesh in the repair of severe, recurrent vaginal prolapse of the anterior midvaginal wall. *American Journal of Obstetrics and Gynecology* 1996; **175**(6): 1472-75.

Shah DK, Paul EM, Rastinehad AR, Eisenberg Er, Badlani GH. Short-term outcome analysis of total pelvic reconstruction with mesh:: The vaginal approach. *The Journal of Urology* 2004; **171**(1): 261-63.

MacLennan A, Taylor A, Wilson DH, Wilson D. The prevalence of pelvic floor disorders and their relationship to age, gender, parity and mode of delivery. *British Journal of Obstetrics and Gynaecology* 2000; **107**: 1460-1470.

Nicita G. A new operation for genitourinary prolapse. *The Journal of Urology* 1998; **160**(3 Pt 1): 741-745.

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'.