Horizon Scanning Technology
Prioritising Summary

Transvaginal pelvic reconstruction using mesh for genitourinary prolapse

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

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

International Utilisation:

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>LEVEL OF USE</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Trials underway</td>
</tr>
<tr>
<td>USA</td>
<td>✓</td>
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<tr>
<td>Italy</td>
<td>✓</td>
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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.
**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.

- Horizon Scanning Report
- Full Health Technology Assessment
- Monitor
- Archive

**References:**


**Sources of Further Information:**
What are the surgical procedures for treating stress incontinence?
Pubovaginal sling. Emedicine

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’.