TITLE: Pelvic Floor Repair Systems: A Review of the Clinical-Effectiveness, Cost-Effectiveness, and Guidelines

DATE: 22 July 2009

CONTEXT AND POLICY ISSUES:

Pelvic organ prolapse (POP), also known as genital prolapse, refers to uterine, uterovaginal, or vaginal prolapse.\(^1\) It is a common disorder, especially for women of older age.\(^1\) POP can greatly impact the patient’s quality of life by its local physical symptoms (pressure, bulging, heaviness, or discomfort) as well as urinary and bowel symptoms (e.g., urinary incontinence, incomplete urinary emptying, and difficult defecation).\(^1-3\) POP has several causes but occurs primarily from loss of muscle support in the pelvic region.\(^1\)

Treatment options for POP include surgical methods (e.g., anterior or posterior colporrhaphy and site specific defect repair), and non-surgical methods.\(^2\) The major non-surgical treatments are vaginal pessaries, pelvic floor muscle exercises, and vaginal estrogen.\(^3,4\) A woman’s lifetime risk for undergoing a surgical intervention for symptomatic pelvic floor disorders is 11%, and approximately one-third of them need reoperation as the disorder has recurred.\(^5,6\) Augmenting surgery with pelvic floor repair systems, which is the implantation of mesh or graft materials, may reduce the risk of recurrence, particularly for women with recurrent prolapse or with congenital connective tissue disorders.\(^3,7\) The mesh or graft materials provide a broader support base which eliminates the need for the prolapsed organs to depend on the existing weakened fascia and other musculature. The mesh or graft materials are classified into absorbable synthetic mesh (e.g., polyglactin), biological graft (e.g., porcine dermis), combined absorbable and nonabsorbable mesh or graft (e.g., polypropylene mesh coated with absorbable porcine collagen), and nonabsorbable synthetic mesh (e.g., polypropylene).\(^2\) While nonabsorbable synthetic mesh has the lowest rates of recurrence of prolapse or prolapse-related symptoms, it is associated with the highest rate of mesh erosion, which results in defective healing and requires further surgery.\(^4,8\)
This HTIS report examines the evidence on clinical-effectiveness, cost-effectiveness, and clinical practice guidelines of three pelvic floor repair systems: the Prolift Pelvic Floor Repair System, the Pinnacle Pelvic Floor Repair Kit, and the Elevate Prolapse Repair System. They are all made of polypropylene and are the most commonly used permanent, synthetic graft material in anterior vaginal wall repair. The Prolift Pelvic Floor Repair System (Ethicon, Gynecare Division, Sommerville, NJ, USA) includes a precut mesh, an anatomical guide, and corresponding cannula, and a retrieval device for manipulating the mesh. The Pinnacle Pelvic Floor Repair Kit (Boston Scientific Corporation, Urology and Gynecology Division, Marlborough, MA, USA) consists of a Pinnacle synthetic mesh assembly and one Capio suture capture device. It is designed for anterior or apical prolapse repair. Elevate Prolapse Repair System is a soft synthetic mesh that is designed to correct concomitant posterior and apical vaginal defects via a single posterior vaginal incision. All three pelvic floor repair systems have obtained approval for use in Canada.

RESEARCH QUESTIONS:

1. What is the clinical-effectiveness of the Prolift Pelvic Floor Repair System, the Pinnacle Pelvic Floor Repair Kit, and the Elevate Prolapse Repair System?

2. What is the cost-effectiveness of the Prolift Pelvic Floor Repair System, the Pinnacle Pelvic Floor Repair Kit, and the Elevate Prolapse Repair System?

3. What are the guidelines for using the Prolift Pelvic Floor Repair System, the Pinnacle Pelvic Floor Repair Kit, and the Elevate Prolapse Repair System?

METHODS:

A limited literature search was conducted on key health technology assessment (HTA) resources, including PubMed, The Cochrane Library (Issue 2, 2009), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international health technology agencies, and a focused Internet search. The search was limited to English language articles published between 2004 and July 2009. Filters were applied to limit the retrieval to health technology assessments, systematic reviews and meta analyses, randomized controlled trials (RCTs), controlled clinical trials, observational studies, economic evaluations, and guidelines.

HTIS reports are organized so that the higher quality evidence is presented first. Therefore, HTAs, and systematic reviews and meta-analyses are presented first. These are followed by RCTs, controlled clinical trials, observational studies, economic evaluations, and evidence-based guidelines.

SUMMARY OF FINDINGS:

From the literature search, one systematic review and two observational studies were identified that assessed the clinical effectiveness of the Prolift Pelvic Floor Repair System in repairing POP. One study had two publications that reported different outcomes. No relevant HTAs, RCTs, economic evaluations, or guidelines were identified for the Prolift pelvic floor repair system. No literature was identified for the Pinnacle Pelvic Floor Repair Kit or Elevate Prolapse Repair System.
Health technology assessments
No HTAs were identified.

Systematic reviews and meta-analyses
Feiner et al. conducted a systematic review to assess the efficacy and safety of transvaginal mesh kits in the treatment of apical vaginal prolapse. The authors searched literature (cross-sectional studies, case series, case-control studies, any design with historical controls, cohort studies, RCTs or non-randomized controlled trials) published between 1950 and 2007. Outcomes included objective success, which was defined as any description of symptomatic or asymptomatic prolapse less than stage 2 of the Pelvic Organ Prolapse Quantification (POP-Q) system or grade 2 of the Baden-Walker Halfway System, and perioperative surgical complications. In total, 2653 patients in 30 studies, who underwent vaginal surgery for uterine or post-hysterectomy vaginal vault prolapse and had graft material vaginally placed to surgically reinforce the apical portion of the repair, were eligible to be included in the systematic review. Among them, eight studies with 1295 women were treated with the Prolift system (either anterior, posterior, or total meshes). Five of the eight studies were full articles and three of them were conference abstracts. None of them were RCTs. There was no information about the settings and countries of the included studies. The average follow-up period was 30 weeks. Due to the paucity of published manuscript data and the large proportion presented in abstract form, the authors did not formally assess the quality of each individual study. The authors reported that the mean objective success rate was 87% ± 7.3 standard deviation (SD) and the mean complication rate was 16% ± 11.2 SD. The most common complications with using Prolift were mesh erosion (5.7% ± 4.8 SD) and dyspareunia (2.1% ± 2.1 SD). Serious adverse events occurred: one woman had rectal injury, three women had fistula formation, and 10 women received blood transfusions. One woman had necrotizing fasciitis which was considered a life-threatening complication. She was treated by complete removal of the mesh, extensive perineal debridement, laparotomy and colostomy followed by prolonged stay in the intensive care unit. The authors concluded that transvaginal mesh kits appeared to be effective in restoring apical vaginal prolapse; however, data on functional outcomes and long-term follow up are unknown. The authors declared no conflict of interest and no funding was involved in this review.

Randomized controlled trials
No randomized controlled trials were identified.

Controlled clinical trials
No controlled trials were identified.

Observational studies
Two case series were identified; one of them was presented in two publications that reported different outcomes.

Altman et al. (2009) conducted a prospective multicenter study to assess the sexual dysfunction in women who underwent the POP surgery augmented with the Prolift system. Patients were recruited at 26 centers in Sweden, Denmark, Finland, and Norway during June 2006 through March 2007. Two-hundred and sixty-one women were enrolled in this study, 232 of whom participated in the one-year assessment. One-hundred and five of the 261 women (40%) acknowledged being sexually active initially, while 84 of the 232 women (36%) reported sexual activity at the one-year follow-up. Women who were not sexually active were older, but other
baseline characteristics between sexually active patients and non-sexually active patients were similar, such as parity, body mass index, menopausal status, and previous pelvic surgery.

Before the surgery, the stage of disease was assessed by gynecologists using POP-Q. Patients whose disease was assessed to be at stage 2 or higher were eligible to participate in the study. When assessed postoperatively, a prolapse stage of 0 or 1 was considered an anatomical cure. The surgeons who performed the operation had pretrial, supervised, hands-on training in using a standardized trocar-guided transvaginal mesh technique with the Prolift system. Before and one year after the surgery, patients completed a Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12), which is a condition-specific, 12-item questionnaire on sexual function. The maximum PISQ-12 score is 48, with higher scores indicating better sexual function. In this study, a score lower than 12 was considered poor sexual function.

The number of patients who achieved or failed anatomical cure was not reported, nor the adverse events related to the surgical treatment. The authors reported an overall significant decrease in average PISQ scores when comparing preoperative with one-year postoperative values (15.5 ± 8.0 SD versus 11.7 ± 6.9 SD, p < 0.001), especially among women younger than 65 years of age (16.0 ± 8.4 SD versus 11.8 ± 6.9 SD, p < 0.001), those who were not postmenopausal during the study (17.4 ± 8.8 SD versus 10.6 ± 8.3 SD, p < 0.001), those with body mass index >25 (16.7 ± 8.9 SD versus 11.9 ± 7.2 SD, p = 0.006) and those with more than three childbirths (16.2 ± 7.5 SD versus 10.8 ± 6.0 SD, p = 0.01). At follow-up, there was no noticeable difference in PISQ scores between patients who achieved anatomical cure of POP and those who did not achieve an anatomical cure (13.0 ± 8.9 SD versus 12.8 ± 8.7 SD for anterior Prolift system repair; 12.3 ± 5.3 SD versus 12.5 ± 5.5 SD for posterior Prolift system repair). In a multiple regression analysis, failing to achieve anatomical cure was not a predictor for worsening sexual function at one year post surgery. The authors concluded that sexual function scores deteriorate one year after transvaginal mesh surgery, and that anatomical cure after surgery was not associated with improved PISQ scores.

Using data from the same case series,

Altman et al. (2008) evaluated the short-term outcome after the application of the Prolift system in a subset of patients. One-hundred and twenty-three symptomatic patients who completed their two-month follow-up were enrolled. The mean age of these patients was 67.5 ± 8.7 SD years. The urogenital distress inventory (UDI) and the incontinence impact questionnaire (IIQ-7), were used to evaluate subjective outcomes such as quality of life and POP symptoms. Two months after the surgery, there was a significant improvement of anatomical support in all vaginal compartments as measured by POP-Q. Table 1 presents the changes in disease stages assessed using POP-Q before and after surgical intervention. The number of patients with adverse effects on quality of life, pelvic floor function, and lower urinary tract symptoms attributed to POP decreased significantly when compared to the baseline. There were also significant improvements of the UDI and IIQ-7 severity scores. Two examples from the UDI tool are: for the question, “Do you experience frequent urination?”, the postoperative median score of 1 (range: 0 to 3) significantly decreased from the baseline median score of 2 (range: 0 to 3), p < 0.001; for the question, “Do you experience a feeling of bulging or protrusion in the vaginal area?” the postoperative median score of 0 (range: 0 to 3) significantly decreased from the baseline score of 3 (range: 0 to 3), p < 0.001. From the IIQ-7 tool, two examples are: after surgery, 17% of the patients responded that prolapse affected their participation in social activities outside of the home compared to 32% before the surgery, p = 0.01; and, 15% of the patients had feelings of frustration two months after the surgery compared to 43% before the surgery, p < 0.001.
Pelvic organ perforation occurred, including three bladder injuries detected during the surgery and one rectal perforation one week postoperatively. There were five cases of postoperative urinary tract infections and three cases of postoperative urinary retention. The authors concluded that transvaginal mesh surgery with the Prolift system was associated with satisfactory outcomes two months after surgery.

### Table 1. Pelvic Organ Prolapse Quantification at Baseline and at Two-month Postoperatively

<table>
<thead>
<tr>
<th>Disease stage (by pelvic compartment)</th>
<th>Preoperative POP-Q (median*)</th>
<th>Postoperative POP-Q (median*)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior</td>
<td>2</td>
<td>1</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Middle</td>
<td>2</td>
<td>1</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Posterior</td>
<td>2</td>
<td>0</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

POP-Q = Pelvic Organ Prolapse Quantification system
* range or standard deviation of the median was not reported

Song et al. (2009) conducted a case series to assess the changes in anatomic features of the levator ani, in patients who underwent surgical treatment for POP in a single center in China. Twenty women aged from 44 years to 80 years were included in the study. The stage of prolapse ranged from 2 to 4, which was determined by gynecologic examination and the use of POP-Q. All patients underwent vaginal hysterectomy followed by prolapse repair using the Gynecare Prolift Total Pelvic Floor Repair System. Before and three months after the surgery, the patients underwent magnetic resonance imaging (MRI) scan for the evaluation on changes in the levator plate angle (LPA), anteroposterior length of the levator hiatus (H-line), and pelvic floor descent (M-line) after the surgery. The LPA was smaller (46.92° versus 55.39°, p < 0.05), the H-line was shorter [53.70 cm versus 60.46 cm, p < 0.05], and the M-line was shorter (19.58 cm versus 25.27 cm, p < 0.05). Three months after the surgery, the stage of disease showed a statistically significant improvement for patients who underwent anterior vaginal wall repair, middle vaginal wall repair, and posterior vaginal wall repair, as measured by the POP-Q. Table 2 presents more details on the changes in disease stages assessed using POP-Q before and after surgical intervention. Adverse events were not reported in this study. Results of this small trial suggest an efficient reconstruction and reinforcement of the pelvic floor from surgery augmented with the Prolift system.

### Table 2. Pelvic Organ Prolapse Quantification at Baseline and at Three-month Postoperatively

<table>
<thead>
<tr>
<th>Disease stage (by pelvic compartment)</th>
<th>Preoperative POP-Q</th>
<th>Postoperative POP-Q</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior</td>
<td>3</td>
<td>1</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Middle</td>
<td>3</td>
<td>0</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Posterior</td>
<td>2</td>
<td>0</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

POP-Q = Pelvic Organ Prolapse Quantification system

**Economic evaluations**

No economic evaluations were identified.
Guidelines and recommendations

No guidelines or recommendations were identified that provided guidance towards the use of Prolift Pelvic Floor Repair System, the Pinnacle Pelvic Floor Repair Kit, or the Elevate Prolapse Repair System.

Limitations

- There were no HTAs, RCTs, controlled trials, or economic evaluations evaluating the clinical- and cost-effectiveness of the three pelvic floor repair systems in the target population identified from 2004 to date. In addition, no clinical guidelines provided direction on their use.
- No comparison was made between surgery with mesh and surgery without mesh, or between various types of mesh.
- There were a limited number of systematic reviews and observational studies available.
- There were no long-term health outcomes reported in the included studies; in addition, important clinical outcomes such as disease recurrence, reoperation for recurrence and or adverse events were not assessed.
- The studies had important methodological flaws, such as:
  - the systematic review did not have a quality assessment component for the included individual studies (the authors justified that this was due to the paucity of published manuscript data and the large proportion presented in abstract form),
  - the observational studies had small sample sizes,
  - the observational studies had different response rates to the questionnaires before and after the surgery, and
  - the risk of bias inherent to observational studies.

- No studies were identified to evaluating the clinical- or cost-effectiveness of the Pinnacle Pelvic Floor Repair Kit, or the Elevate Prolapse Repair System.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:

Published evidence for answering the research questions is very limited. One systematic review assessed the efficacy and safety of the Prolift system in patients with apical vaginal prolapse who required surgical repair. The authors suggested that the Prolift system was clinically effective in restoring apical vaginal prolapse; however, they admitted that the peer-reviewed data to support their conclusion was limited. The authors of one observational study indicated that the worsening sexual function in women with POP was not associated with the degree of success experienced with surgery using Prolift. The authors of the same observational study concluded that two months after the surgery, patients reported better quality of life and less severe symptoms. Another observational study suggests that surgery augmented with the Prolift system could reinforce the function of pelvic fascia. Adverse events were reported in some of the included studies, such as mesh erosion and infections; serious adverse events (e.g., pelvic organ perforation and necrotizing fasciitis) were rare but did occur.

There was no compelling evidence in the past five years regarding the clinical-effectiveness and safety of the pelvic floor repair systems of interest for this HTIS report. The reason may be that these are relatively new products, with the Pinnacle system being approved for use in Canada in the summer of 2009.
In the future, well-designed clinical studies with longer follow-up periods and patient-reported outcomes are required in order to provide more rigorous and clinically relevant evidence on the effectiveness of the Prolift, Pinnacle, and Elevate pelvic floor repair systems. The benefits and risks of these pelvic floor repair systems will also have to be established in comparison to surgery without the use of these products as well as in comparison to other pelvic floor repair systems, such as absorbable synthetic mesh or biological graft.

PREPARED BY:
Stella Chen, Research Officer, MD, MSc
Charlene Argáez, Information Specialist, MLIS
Health Technology Inquiry Service
Email: htis@cadth.ca
Tel: 1-866-898-8439
REFERENCES


