Title:  Prolift™ for Pelvic Floor Repair: A Review of Clinical and Cost Effectiveness

Date:  15 November 2007

Context and policy issues:

Pelvic organ prolapse (POP) occurs when the ligaments and muscles that hold the vagina within the pelvis are weakened or break. This causes the vagina to sag and slide through the vaginal opening (called apical prolapse). In turn, the organs within the pelvis lose vaginal support and may descend into the vaginal opening. Various medical terms are used to describe POP depending on the organ protruding. Cystocele (anterior defect), rectocele (posterior defect) and enterocele occur when the bladder, rectum or intestine descends into the vagina respectively. These may occur in combination. The extent of the prolapse in relation to the hymen is classified using the Pelvic Organ Prolapse Quantification (POP-Q) system. For example, stage 0 is defined as no prolapse. At stage 4 there is complete eversion.¹

POP affects half of the women over the age of 50 and has a lifetime prevalence of 30 to 50%.² Risk factors for POP include vaginal delivery, advanced age and increased body-mass index. Patients’ main complaints are vagina bulging, and bladder, bowel and pelvic symptoms.³

Choice of treatment depends on the patient’s health status, symptoms, quality of life and prolapse stage.⁴ Treatment options include observation (for women with mild prolapse that does not extend beyond the hymen), the use of a vaginal pessary for support and surgery. The incidence of surgery for POP is 1.5 to 4.9 cases per 1,000 women-years.³ The main goal of surgery is to restore the anatomy of the pelvis,⁴ but recurrent prolapse and re-operations are common. Thirty percent of women that undergo surgery will be re-operated within 4 years.⁵

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A variety of abdominal and vaginal surgical techniques are used to treat POP. Some include the use of biological grafts or absorbable and non-absorbable synthetic meshes. Synthetic meshes are used to improve surgical success and increase the longevity of repairs. Their roles are to substitute or augment supportive tissue or to complement insufficient surgical technique. The mesh most likely to be used is a Type I monofilament polypropylene mesh with a large pore size.

Increasingly, surgeons are adopting procedural kits. Three comparable kits licensed in Canada include Prolift™ with Gynemesh™ PS Non-absorbable Prolene™ Soft Mesh Implant by Gynecare (a division of Ethicon Inc., a subsidiary of Johnson & Johnson) and Perigee™ and Apogee™ systems with Intepro™ by American Medical Systems Inc. They include insertion needles, retrieval devices and a pre-shaped polypropylene mesh for cystocele, rectocele or total repairs.

Prolift™ was granted approval in Canada in May 2005. It is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect. To use the Prolift™ kit, surgeons must apply a surgical technique called Tension free vaginal mesh technique (or TVM) invented by a group in France.

Obstetrical surgeons in one regional health authority are considering trialing the Prolift™ system in their patients. Toward this end, a request was made to review the literature on Prolift™, specifically the short and long term patient outcomes, its safety and risks (intra and post operative complications), the patient group most likely to benefit, and whether it reduces operating time and length of hospital stay.

Research question:

What is the evidence on the efficacy, harm and cost effectiveness of Prolift™ in women requiring pelvic floor repair?

Methods:

A limited literature search was conducted on key health technology assessment resources, including Medline, Embase, Biosis, CINAHL, PubMed, The Cochrane Library (Issue 4, 2007), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international HTA agencies, and a focused Internet search. Results include articles published between 2002 and the present, and are limited to English and French language publications only. Filters were applied to limit the retrieval to systematic reviews/HTA, guidelines, economic, randomized controlled trial studies, and observational studies.

Summary of findings:

One published report and 23 conference proceedings reporting on 22 studies were found. Of these, four were non-randomized trials and 18 were case series. Details of each study are available in tables 1 and 2.

One author reported different outcomes of the same study in two conference proceedings. The results are presented together. One author did a sub-group analysis of a larger study. Two studies by Fatton et al. and two studies by Groenen et al. appear to report outcomes at different follow-up times but this could not be confirmed.
Non-randomized Trials
One study compared 15 kits, five of which were Prolift™, to simple mesh (n=6). There was no difference in the length of stay, blood loss or complications between the two groups. It showed a decrease of 10 minutes in the operating room (OR) for cystocele repair in favour of the kits (significance not reported).\textsuperscript{11}

One study compared Prolift™ (n=23) to Gynemesh™ (n=33).\textsuperscript{12} The follow-up time was different for each group (8 months for Prolift™ versus 21 months for Gynemesh™) which makes the interpretation of the results difficult. Success rates were similar between the two groups (96% and 90% for Prolift™ and Gynecare™ respectively) albeit at different follow-up times.

One study compared anterior repairs using Prolift™ (n=19) with Perigee™ (n=79). Only aggregated results were provided.\textsuperscript{13} The authors state that there was no difference between groups for clinical prolapse grading or ultrasound quantification of anterior descent.

Finally, another study comparing Prolift™ (n=29) to simple mesh (Pelvichol®, n=39) showed a higher success rate (78.6%) and less relapse (14.3%) with Prolift™ compared to Pelvichol® (42.5% success rate and 42.4% relapse) at 3 months (significance not reported). A third comparator group was included in the study (colporaphy) but results are only provided at 12 months for this group.\textsuperscript{14}

Case-series
Eighteen case series reports were identified on this topic. The outcomes measures reported in the studies were not consistent making comparisons between studies difficult. The results of the case series reports are summarized below according to outcome measures reported.

\textit{Operating room time, hospital length of stay and duration of catheterization}
Mean OR time ranged from 30 to 113 minutes in five studies that included all types of repairs.\textsuperscript{24-26,28,32} The mean hospital LOS ranged from 3.1 to 5.9 days in 4 studies.\textsuperscript{16,21,26,28} Two studies reported that most patients were discharged one day post-operatively.\textsuperscript{20,32} One study reported a short hospitalization but did not specify the duration.\textsuperscript{22} Mean duration of catheterization was 2.4 and 3 days in two studies.\textsuperscript{19,32}

\textit{Complications during surgery}
Intra-operative complications included bladder injuries (e.g., lesions and perforations) with an incidence ranging from 0.6% to 5.0%;\textsuperscript{15,18,19,21-24,26,27,30,32} rectal injuries (e.g., erosion and perforation) with an incidence ranging from 0.2% to 1.7%;\textsuperscript{15,26,27} a 4.0% rate of hematoma;\textsuperscript{19} 0.4% to 4% cases of hemorrhage\textsuperscript{15,19,26} or in need of blood concentrate\textsuperscript{23} and 1.3% and 3.4% of patients with blood loss greater than 300mL.\textsuperscript{21,30}

\textit{Complications immediately following surgery}
Various complications developed shortly after surgery. Hematoma was reported in 0.8% to 2.7% of patients.\textsuperscript{15,16,18,24,27} Urinary retention was present in 11.8% and 19.2% of patients,\textsuperscript{16,28} and 11.8% of patients developed a urinary tract infection.\textsuperscript{16} Perineal cellulitis and abscess was present in 0.2% to 0.3% of patients.\textsuperscript{15} Twenty-seven percent and 35% of patients experienced buttock pain and thigh discomfort respectively.\textsuperscript{19} A fistula was present in 0.4% of patients.\textsuperscript{15} One patient (3.8%) suffered a pulmonary embolism in one study\textsuperscript{28} and two patients (1.8%) developed a fever in another study.\textsuperscript{16} At week 1, one patient (3.4%) had to have drainage of a hematoma.\textsuperscript{30} A grade 1 cystocele was reported in 3.4% of patients.\textsuperscript{30} One study reported a complication rate of 6.3%.\textsuperscript{25}
One study reported more complications (13.9%) and higher transfusion rates (25%) with total repair procedures than with anterior (1.7% and 0%) or posterior (0% and 0%) repair procedures.\(^{19}\)

**Outcomes at 1 to 4 months post-operatively**
More than 77% of patients went from a POP stage 2 or greater to a POP stage 0 or 1 in two studies.\(^{27,28}\) One of the studies further reported improvement in all quality of life aspects and in urogenital complaints, and a significant decrease in symptoms of vaginal bulging, pelvic heaviness and the need for manually assisted defecation (p<0.001).\(^{27}\) A recurrence rate of 5.2%\(^{15}\) and a failure rate of 4.7%\(^{16}\) were reported in two other studies. One study that reported an anatomical success rate of 100% also reported an incidence of 1.8% rectocele after anterior repairs.\(^{18}\)

Additional complications such as mesh shrinkage or erosion (range=1.6% to 17%);\(^{15,16,23,28,30}\) de novo urinary incontinence (5.4%);\(^{15}\) granuloma formation or vaginal erosion (6.7%);\(^{15}\) granuloma without exposure (2.8%);\(^{15}\) 1 patient (0.9%) with vaginal adhesion;\(^{16}\) 2 patients (4.0%) with a hematoma\(^{23}\) and 5 patients (4.5%) with groin pain\(^{16}\) were also reported.

**Outcomes at 5 to 11 months post-operatively**
Objective cure rates were 96.1%, 100% and 82.2% for anterior, posterior and total repairs respectively in one study.\(^{19}\) Recurrences of POP ranged from 2.0% to 37.5%.\(^{19,21,24,31}\) One study reported a failure rate of 5.6%.\(^{32}\) One study reported significant improvement in QoL (p<0.001).\(^{31}\) Seventy four percent of patients reported global improvement of improvement (much better to very much better) but no difference in sexual functioning in one study.\(^{26}\)

Complications included de novo urinary incontinence (3.5% and 11.0%)\(^{19,21}\) or recurrent bladder symptoms;\(^{24}\) de novo urge (2% and 6.6%);\(^{19,21}\) wound dehiscence (8.8%)\(^{19}\) and mesh exposure or erosion (2.5% to 8.3%).\(^{19,21,24,26}\) One study reported that one patient (1.1%) had a vesico-vaginal fistula with mesh erosion.\(^{32}\) Another study reported a rate of 14.3% recurrent constipation and a 10% rate of pain or dyspaneuria.\(^{24}\) Vaginal erosions occurred after 6 months in 5.6% of patients and 2.8% had vaginal cyst after 7 months.\(^{29}\)

**Outcomes at ≥12 months post-operatively**
Objective success rate was 80% in one study, with a 20% failure rate.\(^{17}\) In the same study 14.9% of patients had recurrences compared to 8.3% in another study.\(^{29}\) Ninety percent of patients had global impression of improvement (much better to very much better)\(^{26}\) and 7.5% of patient reported improved intercourse.\(^{17}\)

Complications included mesh exposure and erosion (4.5% and 6.5%);\(^{17,26}\) urinary retention (1.5%); persistent vaginal pain (1.5%) and de novo dyspareunia (3.0%).\(^{17}\)

**Conclusions and implications for decision or policy making:**

There were no randomized controlled trials or economic evaluations of Prolift™ identified. Evidence of efficacy and harm was derived from non-randomized trials and case-series which are considered lower quality studies. Except in one case, the studies were available as conference proceedings and limited information could be extracted from these. Furthermore, the studies had different follow-up times, patient populations and outcomes of interest. As such, reliable conclusions on which patients are most likely to benefit in the short and long-term and conclusion on the possible harm cannot be drawn. The cost implications of adopting this technology cannot be determined due to the lack of economic analysis.
Before adopting this technology, well designed comparative trials will be required to determine the benefits, cost effectiveness and harm of this system relative to standard surgical interventions.

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Table 1: Non-Randomized Trials Including Prolift™

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<tr>
<td>Georgiopoulos, 2007</td>
<td>n=21</td>
<td>15 kits (11 cystocele + 4 cystourethrocele), 10 using Perigee™ ± Apogee™, 5 using Prolift™</td>
<td>6 simple mesh (6 cystocele), 4 using Pelvichol® and 2 using Pelvisoft®</td>
<td>OR time, LOS, blood loss, complications, recurrences</td>
<td>Simple mesh: cystocele repair OR time = 30 minutes; 2 recurrent cystocele at 3 months. Kits: cystocele repair OR time = 20 minutes; cystourethrocele repair OR time = 45 minutes. No difference in LOS (2 days), blood loss and complications.</td>
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<td>Paplomata, 2007</td>
<td>n=56</td>
<td>23 Prolift™ (3 anterior, 4 posterior and 16 total repairs)</td>
<td>33 Gynemesh™ (12 anterior, 2 posterior, 19 anterior and posterior repairs)</td>
<td>Cure rate, QoL, complications</td>
<td>Gynemesh™: 30 (90%) cure rate with 3 (9.1%) stage 2 prolapse; 4 (12%) erosion rate. Prolift™: 21 (96%) cure rate with 2 de novo dyspareunia; 1 (4%) erosion rate; excellent subjective patient satisfaction.</td>
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<tr>
<td>Shek, 2007</td>
<td>n=98, 60 analysed†</td>
<td>Prolift™ (19 anterior repairs)</td>
<td>Perigee™ (79 anterior repairs)</td>
<td>Symptoms of urinary stress incontinence</td>
<td>Results not reported separately. 23/ 26 (88%) of women incontinent before surgery reported cure or improvement after surgery; 1 (3.7%) reported worse stress leakage; 7/ 34 (20.6%) de novo incontinence after surgery (p=0.002). No difference between groups for clinical prolapse grading or ultrasound quantification of anterior descent.</td>
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† mean age=65 years

| mean age=61 years (range 31-84)

| vaginal parity=3 (range 0-9)
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<th>Author, year*</th>
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<tr>
<td>Valentin-Lourenço, 2006†</td>
<td>n=120</td>
<td>Prolift™ (29 pelvic prolapse) F/U= 3 months</td>
<td>Pelvichol® (39 anterior repairs) F/U= 3 months Classical colporaphy + hysterectomy (52 anterior ± posterior) F/U= 12 months</td>
<td>Relapse, de novo prolapse, cure</td>
<td>Prolift™: 4 (14.3%) relapse; 2 (7.1%) de novo prolapse; 23 (78.6%) cure. Pelvichol®: 16 (42.2%) relapse; 6 (15.6%) de novo prolapse; 16 (42.2%) cure. Colporaphy: 34 (65.4%) relapse; 13 (25.0%) de novo prolapse; 5 (9.6%) cure.</td>
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* all study data reported only in conference proceedings †38 patients excluded due to concomitant suburethral sling insertion; break down by group not reported F/U=follow-up; LOS=length of stay; OR= operating room; QoL=quality of life
Table 2: Case Series Reports Including Prolift™

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<tr>
<td>Altman, 2007</td>
<td>n=123, POP stage≥2</td>
<td>Prolift™ (61 anterior, 32 posterior, 17 anterior and posterior, and 13 total repairs)</td>
<td>Complications, cure, QoL, symptom improvement</td>
<td>Complications during surgery: 3 (2.4%) bladder injuries; 1 (0.8%) rectal perforation. Complications immediately post surgery: 1 (0.8%) vaginal hematoma. At 2 months: significant improvement of anatomical support (p&lt;0.001); POP stage 0-1= 49 (87%) for anterior, 32 (91%) for posterior, 11 (88%) for total repairs; improvement in all QoL aspects and in urogenital complaints; significant decrease in symptoms of vaginal bulging, pelvic heaviness and need for manually assisted defecation (p&lt;0.001)</td>
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Prospective, multicentre

mean age=67.5 years ±8.7 (sd)
mean BMI =31.0±10.1 (sd)
median parity=2 (range 1-5)
postmenopausal=110 (89.4%)

F/U= 2 months
<table>
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<tr>
<th>Author, year</th>
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| Cosson, 2005 | Retrospective, multicentre | n=687, data from 3 patients missing from the analysis  
mean age=63.8 years  
postmenopausal=579 (84.3%)  
previous prolapse surgery=115 (16.7%) | Prolift™ using TVM technique  
F/U=3.6 months | Complications, recurrences | Complications during surgery:  
4 (0.6%) vesical injuries; 1 (0.2%) rectal injury; 1 (0.2%) rectal erosion; 3 (0.4%) hemorrhages.  
Complications immediately post-surgery:  
1 (0.2%) perineal cellulitis; 2 (0.3%) perineal abscesses; 12 (1.8%) pelvic haematoma; 1 (0.2%) recto-vaginal fistula; 1 (0.2%) vesico-vaginal fistula.  
At 3.6 months:  
46 (6.7%) granuloma formation or vaginal erosion; 19 (2.8%) mesh shrinkages; 36 (5.2%) recurrences; 37 (5.4%) de novo urinary incontinence. |
| Cosson, 2005 | Subgroup analysis of Cosson | n=96  
mean age=44.9 years  
previous prolapse surgery=12 (12.5%) | Prolift™ using TVM technique  
F/U=3.6 months | Complications, recurrences | Complications during surgery:  
1 (1%) vesical injury; 1 (1%) hemorrhage.  
Complications immediately post-surgery:  
1 (1%) perineal abscess; 4 (4.2%) haematoma.  
At 3.6 months:  
6 (6.3%) granuloma formation or vaginal erosion; 4 (1.6%) mesh shrinkages; 8 (8.3%) recurrences; 3 (3.1%) de novo urinary incontinence. |
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<tr>
<td>Fatton, 2007&lt;sup&gt;16&lt;/sup&gt;</td>
<td>Retrospective, multicentre</td>
<td>n=110, 106 at F/U</td>
<td>Prolift™ using TVM technique (22 anterior, 29 posterior and 59 total repairs)</td>
<td>Hospital LOS; complications, recurrences</td>
<td>Mean LOS=3.75 days (range 2-11). Complications immediately post-surgery: 2 (1.8%) hematoma; 2 (1.8%) fever; 13 (11.8%) UTIs; 13 (11.8%) urinary retention. At 3 months: 5/106 (4.7%) failures†; 3 (2.8%) granuloma without exposure; 5 (4.7%) mesh exposure; 18 (17.0%) mesh shrinkages; 1 (0.9%) vaginal adhesion.</td>
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<td>mean age=63.2 years (range 29-90)</td>
<td>median F/U= 25 weeks (range 12-42)</td>
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<td></td>
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<td>mean BMI=26.7 (range19-43)</td>
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<td>parity=3.13 (range 1-11)</td>
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<td>postmenopausal=93 (85.3%)</td>
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<td>previous prolapse repair= 22 (20.0%)</td>
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<td>Fatton, 2007&lt;sup&gt;17&lt;/sup&gt;</td>
<td>Multicentre (Possibly a F/U to Fatton&lt;sup&gt;16&lt;/sup&gt;)</td>
<td>n=67 (n=62 at 12 months)</td>
<td>Prolift™ (24 anterior, 15 posterior, 16 anterior and posterior, and 12 total repairs)</td>
<td>Hospital LOS; complications, recurrences</td>
<td>Mean OR time=89 minutes. Mean LOS=3.6 days. Complications during surgery: 1 (1.5%) bladder injury; 1 (1.5%) urethral injury. Complications immediately post-surgery: 1 (1.5%) hematoma. At F/U: 54 (80.1%) objective success rate; 14 (20.9%) failures§; 10 (14.9%) recurrences; 1 urinary retention; 1 persistent vaginal pain; 3 (4.5%) mesh exposure; 2 (3.0%) de novo dyspareunia; 5 (7.5%) improved intercourse.</td>
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<td></td>
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<td>mean age=65.5 years (range 40-89)</td>
<td>Mean F/U=14 months (range 12-21)</td>
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<td>postmenopausal=61 (91.0%)</td>
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<td>POP stage ≥2</td>
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<td>previous prolapse repair= 12 (17.9%)</td>
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| Futyma, 2007 | Prospective  | n=112, 80 at F/U  
mean age=59 years  
POP stage 2, n=20  
(17.9%)  
POP stage 3, n=69  
(61.6%)  
POP stage 4, n=23  
(20.5%) | Prolift™ (43 anterior, 18 posterior, 37 anterior and posterior, and 14 total repairs)  
F/U=3 months | Objective and subjective clinical outcomes | Complications during surgery: 1 (0.9%) bladder perforation.  
Complications immediately post-surgery: 3 (2.7%) haematoma.  
At 82 days (median): 100% anatomical success rate with POP stage 0-1; 5 (4.5%) urinary incontinence; 5 (4.5%) complaints of groin pain; 2 (1.8%) rectocele after anterior repair; no mesh erosion; no sexual dysfunction and no dyspareunia reported. |
| Groenen, 2006 | Design N/R   | n=26  
median age=61 years (range 40-83)  
multiparous=23 (88%)  
previous prolapse repair=25 (96.1%) | Prolift™ (6 anterior, 10 posterior, and 10 total repairs)  
F/U=2 months | OR time, LOS, complications | Mean length of surgery=67 min±28 (sd)  
Mean LOS=5.9days±2.5 (sd) (range 4-15)  
Complications during surgery: 121mL±96 (sd) mean blood loss; no other complications.  
Complications immediately post-surgery: 5 (19.2%) temporary urinary retention; 1 (3.8%) pulmonary embolism.  
At 2 months: 1 (3.8%) erosion; 20 (76.9%) POP stage 1. |
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| Groenen, 2007 (Possibly a F/U to Groenen) | n=36  
mean age=61.2 years±11.4 (sd)  
multiparous=34 (94.4%)  
no previous surgery=3 (8.3%) | Prolift™ (9 anterior, 13 posterior, and 14 total repairs)  
F/U=13.9 months (range 6-22) | Intra and post-operative performance | Mean length of surgery=70.3min.±27.8 (sd)  
During surgery: 11 (30.5%) blood loss>100mL; 189mL±255 (sd) mean blood loss.  
Immediately post-surgery: 8 (22.2%) urinary retention; 1 (2.8%) pulmonary embolism.  
At F/U: 3 (8.3%) recurrences; 2 (5.6%) vaginal erosions (after 6 months); 1 (2.8%) vaginal cyst (after 7 months). |
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<td>Han, 2007</td>
<td>Retrospective</td>
<td>n=101, 10 lost to F/U</td>
<td>Prolift™ (59 anterior, 6 posterior, and 36 total repairs) Mean F/U= 5 months (range 1-19)</td>
<td>Complications, cure rates</td>
<td>Complications during surgery: 1 (1.0%) bladder perforation; 4 (4.0%) hematomas; 2 (2.0%) intra-abdominal hemorrhage. Complications immediately post-surgery: more complications with total repair [5 (13.9%) vs. 1 (1.7%) and 0 for anterior and posterior respectively]; higher transfusion rates with total repair [9 (25%) vs. 1 (1.7%) and 0 for anterior and posterior respectively]; 27 (26.7%) buttock pain; 35 (34.7%) thigh discomfort; 3 days (range 1-20) mean duration of catheterization. At 5 months: objective cure rates were 57 (96.1%), 6 (100%) and 30 (82.2%) for anterior, posterior and total respectively; 2 (2.0%) recurrent cystourethrocele (1 with vault prolapse); 2 (2.0%) recurrent uterine descent; 11 (11.0%) de novo urinary incontinence; 7 (6.6%) de novo urge; 9 (8.8%) wound dehiscence; 7 (6.6%) mesh erosion.</td>
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*Prolift™ for Pelvic Floor Repair*
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<tr>
<td>Hinoul, 2006</td>
<td>N/R</td>
<td>n=29</td>
<td>Prolift™ (anterior repairs) F/U=6 weeks and 6 months</td>
<td>Complications, cure rates</td>
<td>During surgery: 1 (3.4%) bladder perforation; 1 (3.4%) 300mL blood loss. Immediately post-surgery: 28 (96.5%) successful anatomical repair; 1 (3.4%) grade 1 cystocele. At 1 week: 1 (3.4%) draining hematoma (this patient required surgery for bilateral phlebitis 2 weeks after surgery). At 6 weeks: 2 (6.9%) mesh erosion. Number of weeks not specified: 1 (3.4%) pelvic pain; 1/19 (5.3%) de novo urinary incontinence.</td>
</tr>
<tr>
<td>Jakimiuk, 2007</td>
<td>N/R</td>
<td>n=40</td>
<td>Prolift™ F/U=6 months</td>
<td>Anatomical and functional outcomes, QoL</td>
<td>Significant improvement in prolapse (p&lt;0.001); 1 (2.5%) urinary retention; 1 (2.5%) lumbar post-operative pain; no mesh erosion. At 6 months: 3 (7.5%) recurrent prolapse stage 1; significant improvement in QoL (p&lt;0.001)</td>
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<tr>
<td>Lucioni, 2006</td>
<td>N/R</td>
<td>n=4</td>
<td>Prolift™ (vaginal vault repairs) F/U=not reported</td>
<td>Complications</td>
<td>Discharge on day 1= 4 (100%) During surgery: no complications. After surgery: no erosion; no recurrence of prolapse.</td>
</tr>
<tr>
<td>Author, year</td>
<td>Study Design</td>
<td>Patients</td>
<td>Intervention</td>
<td>Outcomes</td>
<td>Results</td>
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<tr>
<td>Meschia, 2007&lt;sup&gt;21&lt;/sup&gt;</td>
<td>Retrospective, multicentre</td>
<td>n=236, 228 at F/U POP stage ≥2</td>
<td>Prolift™ (95 anterior, 16 posterior and 125 total repairs) F/U=8 months ±4 (median=6)</td>
<td>LOS, Complications</td>
<td>Mean LOS=3.1days±1.2 (range 2-13) During surgery: 6 (2.5%) bladder perforations; 3 (1.3%) 300mL blood loss. At 8 months: 58 (25.4%) recurrences; 11 (4.8%) mesh exposures; 9 (3.9%) mesh shrinkages; 8 (3.5%) de novo urinary incontinence; 5 (2%) de novo urge incontinence; 5 (2%) symptomatic hysterocèle.</td>
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<tr>
<td>Murphy, 2006&lt;sup&gt;32&lt;/sup&gt;</td>
<td>Prospective, multicentre</td>
<td>n=89 mean age=65 years ±11.2(sd) mean BMI=30.1 ±6.5(sd) parity=3.2±1.6(sd) median POP=stage 3</td>
<td>Prolift™ (48 anterior, 11 posterior, and 30 total repairs) Mean F/U=5 months (range 1-9)</td>
<td>Perioperative data, mesh erosions, repair failures, sexual function.</td>
<td>Mean OR time=113min±40(sd) Discharge on day 1 = 85 (95.5%) Mean catheterization=2.4days±3.3(sd) During surgery: 71mL±46(sd) blood loss; 2 (2.2%) cystotomies. At F/U: 6 (5.6%) failures; 1 (1.1%) vesico-vaginal fistula with mesh erosion; 102.4±12.1(sd) mean PISQ-12 score.</td>
</tr>
<tr>
<td>Neuman, 2007&lt;sup&gt;22&lt;/sup&gt;</td>
<td>Design N/R</td>
<td>n=150</td>
<td>Prolift™ F/U= not reported</td>
<td>Complications</td>
<td>Short hospitalization; 5 (3.3%) dissatisfied patients; 3 (2%) bladder penetration; 3 (2%) tape protusion; 1 (0.7%) therapeutic failure.</td>
</tr>
<tr>
<td>Author, year</td>
<td>Study Design</td>
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<tr>
<td>Perschler, 2006&lt;sup&gt;23&lt;/sup&gt;</td>
<td>Design N/R</td>
<td>n=50</td>
<td>Prolift™ (25 high grade uterine and vaginal wall prolapse and 25 vaginal wall prolapse) F/U=3 months</td>
<td>Complications</td>
<td>Complications during surgery: 1 (2%) bladder lesion; 2 (4%) needed blood concentrate. Complications at 4 to 12 weeks: 6 (12%) mesh erosions of which 4 (8%) had to be closed surgically; 2 (4%) retrovesical hematoma causing pain.</td>
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<td>Roberts, 2007&lt;sup&gt;24&lt;/sup&gt;</td>
<td>Prospective, multicentre</td>
<td>n=40, 2 lost to F/U POP stage ≥3 previous prolapse surgery=19 (47.5%)</td>
<td>Prolfit™ (23 anterior, 29 posterior, and 3 total) F/U=6 weeks and 6 months</td>
<td>Functional and anatomical outcomes</td>
<td>Mean OR time=60 minutes (range 30-100) During surgery: mean blood loss 143mL (range 50-400mL); 2 (5%) bladder perforation. Immediately post-surgery: 1 (2.5%) urinary retention; 1 (2.5%) hematoma. At 6 months: 1 (2.5%) recurrent uterine prolapse; 1 (2.5%) stage 2 recurrent anterior prolapse; 6/16 (37.5%) prolapse of another compartment; 1/7 (14.3%) recurrent constipation; 5/23 (21.7%) recurrent bladder symptoms; 4 (10%) pain or dyspareunia; 1 (2.5%) mesh excision; 2 (5%) mesh erosions.</td>
</tr>
<tr>
<td>Author, year</td>
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<td>Solà, 2007&lt;sup&gt;25&lt;/sup&gt;</td>
<td>Prospective</td>
<td>n=32</td>
<td>Prolfit™ (5 cystocele, 7 rectocele, 16 cystocele and rectocele, and 4 vaginal cuff prolapse)</td>
<td>OR time, complications, recurrences</td>
<td>Surgical time=40 minutes for anterior and 30 minutes for posterior repairs.</td>
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<td>age=37-81 (range)</td>
<td>F/U=not reported</td>
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<td>Complications during surgery: no complications.</td>
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<td>Complications immediately post-surgery: 2 (6.3%) complications.</td>
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<td>Delayed post-operative time: 2 (6.3%) recurrences</td>
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<td>Withagen, 2007&lt;sup&gt;26,33&lt;/sup&gt;</td>
<td>Prospective, multicentre</td>
<td>n=118</td>
<td>Prolfit™ (21 anterior, 52 posterior, 23 anterior and posterior, and 22 total repairs)</td>
<td>OR time, LOS, blood loss, complications, QoL, sexual functioning</td>
<td>median OR time=58 minutes (range 30-150)</td>
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<td>median age=66 years (range 19-86)</td>
<td>F/U=6 months (n=60)</td>
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<td>mean LOS= 4 days (2-11)</td>
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<td>postmenopausal=92 (78.0%)</td>
<td>F/U=12 months (n=31)</td>
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<td>Complications during surgery: median blood loss=100mL (range 50-1200); 3 (2.5%) bladder lesions; 2 (1.7%) rectal lesions; 2 (1.7%) hemorrhage.</td>
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<td>previous prolapse surgery=76 (64.0%)</td>
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<td>At 6 months: 5 (8.3%) mesh erosions (2 requiring excision); 34/ 58 (74.1%) patient global impression of improvement (much better to very much better); no difference in sexual functioning.</td>
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<td>At 12 months: 2 (6.5%) mesh erosions requiring excision; 27/ 30 (90.0%) patient global impression of improvement (much better to very much better).</td>
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<td>No major complications. Overall QoL significantly improved.</td>
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</tbody>
</table>
*all are conference proceedings except for one published report
†failure was defined as any symptomatic prolapse or a grade 3 or 4 prolapse with or without symptoms
§patients who needed further repair for recurrence or symptomatic low grade prolapse and patients with stage 2 prolapse of any compartment at follow-up were considered a failure
BMI=body mass index; F/U=follow-up; LOS=length of stay; N/R=not reported; POP=pelvic organ prolapse; PISQ-12 =Pelvic Organ Prolapse/ Urinary Incontinence Sexual Function Questionnaire; QoL=quality of life; UTI=urinary tract infection
References:


