

Case Series

A single incision monoprosthesis for simultaneous management of apical, anterior prolapses and stress urinary incontinence: initial data of four cases

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Abstract

This study aims to evaluate the safety and feasibility of a new second generation single incision sling and life quality tests after pelvic organ prolapsed (POP) surgery. The procedure was performed in four patients with POP-Q stage 3 and 4 anterior and apical prolapses. The work-up included history, physical examination, stress test, POP-Q staging and validated Pelvic Floor Impact Questionnaire-short form 7 (PFIQ-7) and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12). Follow-up was performed at 1 and 6 months after surgery and scheduled for 1 year. No intraoperative complications or postoperative significant adverse events were observed. Mean follow-up was 7.5 months (6 to 10 months). All patients were considered cured (POP-Q stage 0 or 1). Mean PISQ-12 total score improved from 32.12 ± 7.15 to 36.96 ± 6.46 and mean PFIQ-7 score improved from 57.3 to 8.6 at postoperative 6 month follow-up. Our initial results confirm that this procedure is efficient and supports fully level I correction.

Key words:

Transvaginal mesh, pelvic organ prolapse, monoprosthesis

Introduction

Pelvic organ prolapsed (POP) is a complex condition resulting from defects in the supporting structures of the vagina. Women are estimated to have a 30-50% risk of pelvic organ prolapse, with 2% having symptoms [1].

Pelvic organ prolapse is a condition that can cause significant symptoms that affect a woman's quality of life. It is the result of defects in the supporting structures of the vagina and, depending on the location and size, can alter the functions of the organs contained within the female pelvis. Approximately 11% of women will undergo surgical intervention for their prolapse or for incontinence in their lifetime. Unfortunately, one third of these will require reoperation for failed procedures [2].

In response to concerns regarding inherent tissue defects in women with prolapse, and high rates of recurrence, interposition grafts and mesh have been used to improve outcomes. In 2008, the FDA issued a Public Health Notification [3] and followed with an update in 2011 [4] regarding concerns for an increased rate of complications associated with the use of vaginal mesh for prolapse. It seems increasingly clear that patient satisfaction is predicated on the relief of symptoms as well as anatomic correction.

A new second generation single incision sling (Calistar A – Promedon, Argentine) was developed to treat concomitantly anterior and apical prolapses. It is made of type I macroporous polypropylene with 6 millimeter diameter orifices in the body to improve tissue in growth and to provide flexibility. The type of mesh that is presently used in the treatment of pelvic organ prolapse is a Type I monofilament, large-pore polypropylene mesh. Theoretically, this promotes a hostgraft response that ultimately results in tissue ingrowth and facilitates immune cells to fight bacterial invasion [5,6]. In this study, we evaluated the safety and feasibility of the afore-mentioned mesh and life quality tests before and after surgery.

Case presentation

From May 2013 to February 2014, this procedure was performed in 4 patients with POP-Q stage 3 and 4 anterior and apical prolapses. The work-up included history, physical examination, stress test, POP-Q staging and validated Pelvic Floor Impact Questionnaire-short form 7 (PFIQ-7) and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12). Follow-up was performed at 1, 6 and 12 months post implant.

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Ages of patients were 46, 53, 61 and 65 years old. Three cases had parity 2 and one case had parity 8. One case had POP-Q stage 3 vaginal cuff prolapse three years after abdominal hysterectomy, two cases had POP-Q stage 3 and one case had stage 4 uterine prolapse. One patient had concomitant stress urinary incontinence preoperatively.

The procedure was carried on with the patient in lithotomy position via the same surgeon under spinal anesthesia. The anterior vaginal wall was incised from midurethra towards the uterine cervix and the pubocervical fascia is dissected. Blunt dissection was performed until identification of the ischial spines and the sacrospinous ligaments. Then, the retractable insertion guide was primed with the tissue anchoring system and was introduced into the sacrospinous ligament 1.5 cm medial from the ischial spine bilaterally. The same retractable guide was connected to the multipoint fixation arm for fixation of the suburethral part of the mesh bilaterally to the internal obturator muscle, one centimeter above the vaginal fornix. Then the polypropylene stitches were attached to the arms of the implant bilaterally. And the other 2 arms of the mesh were fixed to uterine cervix/vaginal cuff (Figure 1, 2 and 3). Finally, the vaginal incision was sutured. Cystoscopy was not mandatory. A vaginal tampon was placed for hemostasis and the foley catheter was removed on the first postoperative day. Antibiotic prophylaxis was given intraoperatively. Patients were advised to avoid heavy exercise and sexual activity for at least 1 month after the procedure.

Figure 1.



Polypropylene mesh and multipoint fixation arms.

Mean operative time was 68.7 minutes. No intraoperative complications or postoperative significant adverse events were observed. During the follow-up period, no mesh erosion was detected. Mean follow-up was 7.5 months (6 to 10 months). All of the patients were considered as cured (POP-Q stage 0 or 1). Only a case bothered pelvic pressure complaint for the first 3 months after the operation and this complaint decreased during the follow-up

period. Mean PISQ-12 total score improved from 32.12 ± 7.15 to 36.96 ± 6.46 and mean PFIQ-7 score improved from 57.3 to 8.6 at postoperative 6 month follow-up. And also one case who had SUI was treated successfully.

Discussion

In recent years, mesh usage is getting more popular and sacrospinous ligament fixation via meshes is being popular in POP surgery. Using surgical mesh is intended to increase the longevity of the repair, restore anatomy and prevent recurrence. Newer anchor-based or suture-based systems have since been developed. These procedures are distinctly different from established procedures using transabdominal mesh, which had been used for support of the vaginal vault with success rates of 80-90% [7,8].

Palma et al. studied 31 patients with POP-Q stage 3 anterior vaginal wall prolapse and performed second generation single incision sling (Calistar A – Promedon, Argentine). Concomitant SUI was diagnosed in 19 (61%) patients. The mean age of patients was 59 ± 8.5 years old. Seven patients (22%) completed 12 months follow up but as soon as 11 patients (35%) who completed 6 months follow up showed successful POP-Q staging improvement. One patient (3%) presented mesh exposure and infection. This patient was treated with excision of the extruded mesh and vaginal suture of the mucosa. Urinary retention was observed in one patient (3%), and one patient maintained urgency in the post-operative period. The Female Sexual Function Index (FSFI) was reported 26 ± 1.4 before surgery, 48 ± 21.5 in six months and 49 ± 12.7 in one year follow up [9].

Figure 2.



Tissue anchoring system and trocar.

In another study, Palma et al. performed second generation single incision sling (Calistar A – Promedon, Argentine) in 12 patients (mean age 57 years-old) with POP-Q stage 3 anterior prolapse. Four of them also presented stage 2 apical prolapse. Six of them had concomitant stress urinary incontinence (mean ICIQ-SF score: 16 ± 4),

and four had recurrence after previous anterior prolapse repair. Mean operative time was 45 min. No intraoperative complications or post-operative significant adverse events were observed. None presented post-operative vaginal mesh exposure, infection or visceral erosion. Mean follow up was 6 months (3 to 9 months). Five patients showed complete cure of the incontinence (ICIQ-SF score: 0) and one was improved (ICIQ-SF score: 6) [10].

Fatton *et al.* reported the preliminary results of a transvaginal mesh repair of genital prolapse using the Prolift™ system. This retrospective multicentric study included 110 patients. All patients had a stage 3 or stage 4 prolapse. Total mesh was used in 59 patients (53.6%), an isolated anterior mesh in 22 patients (20%) and an isolated posterior mesh in 29 patients (26.4%). They reported one bladder injury sutured at surgery and two hematomas requiring secondary surgical management. At 3 months, 106 patients were available for follow-up. Mesh exposure occurred in five patients (4.7%) while granuloma without exposure occurred in three patients (2.8%). Failure rate was 4.7% [11].

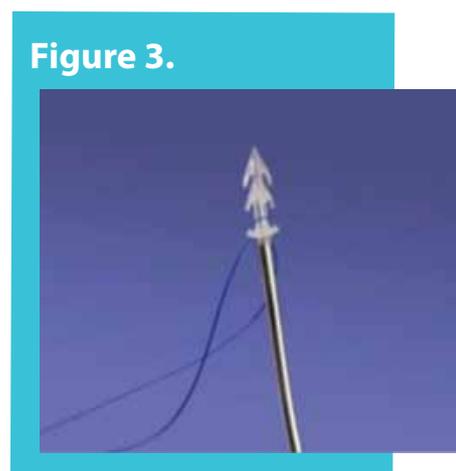


Figure 3.

Surgical set

Long *et al.* sheduled one hundred and eight women with POP stages II to IV for either Perigee/Apogee® (Perigee group; n = 60) or Prolift® device (Prolift group; n = 48). Follow-up periods were 20 months for the Perigee group and 12 months for Prolift group ($P < 0.01$). The success rates for two groups were comparable ($P > 0.05$). Postoperative points Aa and Ba of Prolift group were significantly higher than the other group ($P < 0.01$). The prevalences of detrusor overactivity and urinary symptoms decreased significantly postoperatively in both groups ($P < 0.05$). Comparisons of all operative complications revealed no significant differences between the two groups ($P > 0.05$) [12].

Feiner *et al.* summarised success and complication rates for commonly used vaginal mesh kits in the treatment of apical prolapse in their systematic review. Thirty studies totalling 2653 women met inclusion criteria in the above-mentioned review. Objective success rates (95% CI) were Apogee (American Medical Systems Inc., Minnetonka, MN, USA) 95% (95-96), Prolift (Ethicon Women's Health and Urology, Somerville, NJ, USA) 87% (86-87) and posterior intravaginal slingplasty 88% (87-89). Reoperations not requiring anaesthesia occurred in 0.4-2.3% and requiring anaesthesia in 1.5-6.0%, with a follow up between 26 and 78 weeks. Mesh erosion was the most commonly reported complication occurring in 4.6-10.7% of the patients [13].

Our initial results confirm that this procedure is efficient and supports fully level I correction. It has low morbidity and is well tolerated by the patients. It seems to be a satisfactory procedure for the repair of anterior and apical POP. More randomized and controlled trials and their long term results will allow surgeons and patients more information about the role of meshes and long term success rates in POP surgery.

Conflict of interest statement

The authors declare no conflict of interest.

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