



Full length article

The novel technique of post-hysterectomy vaginal vault prolapse repair: Apical sling and “neocervix” formation



Dmitry Shkarupa^a, Nikita Kubin^a, Ekaterina Shapovalova^{b,*}, Anastasiya Zaytseva^a, Alexey Pisarev^a, Olga Staroseltseva^a

^a Urology Department, Saint-Petersburg State University Clinic, 154, Fontanka Embankment, Saint-Petersburg, 190103, Russia

^b Gynecology Department, Saint-Petersburg State University Clinic, 154, Fontanka Embankment, Saint-Petersburg, 190103, Russia

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ABSTRACT

Objective: We primarily aimed to evaluate the effectiveness of the novel technique: bilateral sacrospinous fixation by monofilament polypropylene apical sling combined with “neocervix” formation in surgical treatment of post – hysterectomy vaginal vault prolapse. The secondary objective was to estimate the impact of the surgery on voiding function and quality of life.

Study design: This prospective study involved 61 women suffering from post-hysterectomy prolapse. We used the following criteria to evaluate the results of surgical treatment: results of vaginal examination (POP-Q system), uroflowmetry, bladder ultrasound, validated questionnaires were used. All listed parameters were determined before the surgery and at control examinations in 1, 6, 12 months after the treatment.

Results: Mean operation time was 35 min. No cases of intraoperative damage to the bladder/rectum, as well as clinically significant bleeding were noted. At 12-month follow-up anatomical cure rate (\leq stage I, POP-Q) was 100%, 94,4% and 100% for vaginal apex, anterior and posterior vaginal walls, respectively. The following long-term complications were noted stress urinary incontinence de novo and urgency de novo were noted in 6,5% and 4,9%, respectively. Statistically significant ($P < 0.05$) improvement in peak flow rate was observed according to uroflowmetry. Comparison of the scores by the questionnaires revealed a significant improvement in the quality of life in the postoperative period.

Conclusion: The novel technique: combination of the apical sling and purse-string “neocervix” formation appears to be effective and safe method for treatment patients with vaginal vault prolapse. The technique improves voiding function and quality of life.

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Introduction

Hysterectomy is one of the most frequent procedures in gynecologic surgery. As an example, 433.621 surgeries were performed in 2010 in USA [1]. Achilles' heel of this procedure is that cardinal and uterosacral ligaments (1 level of support acc. to DeLancey) are separated from the cervix leaving a little fibers attached to the vagina. Defects of supporting structures at this level are primarily responsible for apical vaginal vault prolapse (VVP) [2]. Frequency of VVP requiring surgical repair is up to 8%, and 45% in patients with prior hysterectomy for uterine prolapse [3,4].

Among the techniques for VVP reconstruction the most studied and widespread are the following: McCall culdoplasty, uterosacral

ligament fixation, sacrospinous fixation and sacrocolpopexy. Today there is no consensus on the management of vaginal vault prolapse, however the key role of the apical compartment restoration is established. Nevertheless, coexistent pelvic floor defects which may be a cystocele, rectocele or enterocele are present in 72% [5]. According to DeLancey, enterocele formation often accompanies a simple eversion of the upper vagina and its correction is achieved by an additional cul-de-sac obliteration. By the authors data, a complex vaginal eversion including cystocele or rectocele (defects of the 2nd level of support) represented in 67% of cases of VVP [2]. This condition indicates a need of reconstructive technique aimed at simultaneous correction of the 1st and 2nd levels of support.

The primary objective of this study was to evaluate the effectiveness of the novel technique of post-hysterectomy vaginal vault repair: bilateral sacrospinous fixation with modern monofilament synthetic tape – apical sling combined with the “neocervix”

* Corresponding author.

E-mail address: katerina_andmed@mail.ru (E. Shapovalova).

formation. The secondary objective was to estimate the impact of the surgery on voiding function, quality of life and patient's satisfaction.

Materials and methods

This study started on September 2014 and closed April 2015, was designed to be open and prospective. Women suffering from post-hysterectomy vaginal vault prolapse stage III–IV according to Pelvic Organ Prolapse-Quantification (POP-Q) system were enrolled [6]. Exclusion criteria were: history of gynecological cancer and stress urinary incontinence (SUI). Patients were provided with thorough information and signed a consent. The study was registered and approved by the ethical committee of the University Clinic of Saint-Petersburg State University.

All patients underwent physical and urogynecological examination, uroflowmetry and ultrasound measurement of post-void residual volume (PVR). Prolapse staging was recorded according to the POP-Q system. Patients with positive stress cough test were excluded from the study. Postoperative examination was performed by physicians of Department of urology in 1, 6, 12 months after surgery and then annually. Anatomical success of the surgery was defined as absence of stage 2 prolapse or higher. Voiding function was assessed by comparing pre- and postoperative data. The quality of life (QoL) was estimated at each follow-up appointment by the use of questionnaires translated and validated in Russia: Pelvic Floor Distress Inventory (PFDI-20), Pelvic Floor Impact Questionnaire (PFIQ-7), Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) [7]. Patient's satisfaction was assessed using a separate dichotomous (yes/no) questionnaire item. Also, a satisfaction criterion was the answer to the question: "Would you recommend the procedure to friends?"

Surgical technique

All surgical procedures were performed by two staff urologists experienced in this technique of POP repair. Patients received intravenous antibiotics (amoxicillin clavulanate) within an hour before the operation. Surgery was performed under general anesthesia. After the deep hydrodissection of the vaginal wall (40 cc of sterile saline), a full thickness midline vaginal incision was made. The incision passed through the most prolapsing point of the vagina, that was one of the follows: post-hysterectomy scar, anterior or posterior vaginal walls. The vaginal edges were grasped by the Allis clamps and blunt subfascial dissection was continued bilaterally. When the ischial spines were reached sacrospinous ligaments and rectum were palpated as well. Skin incisions were done in the perianal area about 7 cm laterally and 3 cm downwards from the anus. Then the introducer with the tunneler put on it passed bilaterally through the skin incisions, ischio-rectal space and perforated the sacrospinous ligaments not less than 2 cm medially from the ischial spine (Fig. 1C). The monofilament polypropylene woven unstretchable tape (60 g/m²) with atraumatic edges 1,5 cm x 45 cm (UroSling 1, Lintex LLC, St.-Petersburg, Russia) with the help of its applicators was put through the tunnelers (Figs. 1 and 2). Intactness of the rectum was checked after the sling installation.

The keystone of this procedure was the method of the vaginal vault fixation to the tape (apical sling). When the tape was put in the SSLs two USP 1 non-absorbable fixing ligatures were passed through the central part of the sling bilaterally (Fig. 3A.a). We used Ftorex nonabsorbable polyester braided coated with fluoropolymer pseudo-monofilament suture (Lintex LLC, St.-Petersburg, Russia). The latter has the same biocompatibility as monofilament polypropylene suture, though has no capillarity and micropores; it is soft and needs only three knots to fix the suture. Then the purse

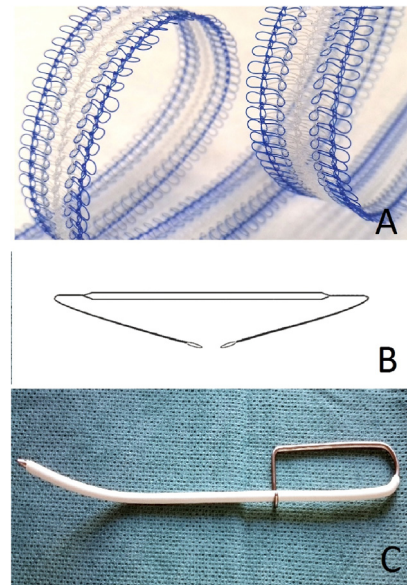


Fig. 1. A, B. Tape UroSling 1; 1C. Urofix PL tool with a tunneler put on.

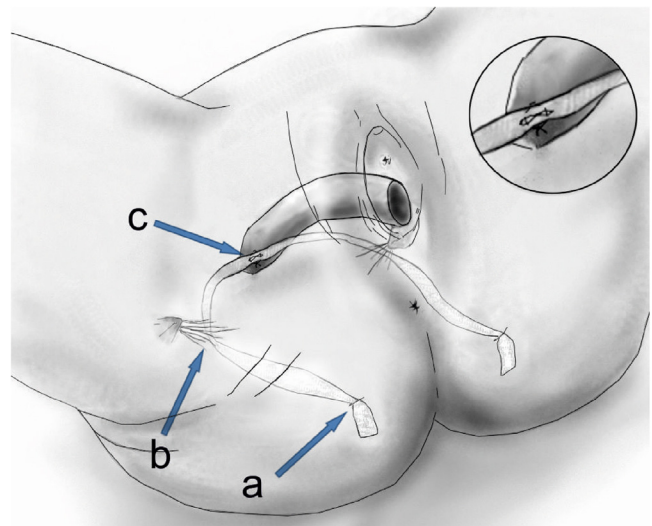


Fig. 2. The position of the apical sling: a. The apical sling, b. Sacrospinous ligament, c. Vaginal cuff.

string suture (USP 1 absorbable braided polyglycolide – PGA) was applied to the internal surface of the endo-pelvic fascia so that the lateral stitches of it passed over the fixing ligatures of the tape. Thereby the ligatures were pinned to the internal surface of the vaginal fascia (Fig. 3A.b). In cases when the thickness of the vaginal wall was enough not to perforate it we used for this step a non-absorbable suture Ftorex USP1, otherwise we used absorbable braided polyglycolic suture – PGA. Then the purse string suture was tied (Fig. 3B.a). After that the apical sling fixing ligatures were tied above the tissue conglomerate on the top of the vaginal cuff (so called "Neocervix") formed by the purse string suture (Fig. 3B.b,c). All this "neocervix" formation steps were repeated in cases, when absorbable suture was applied and durability of the construction was valued as insufficient.

So there was created the single construction of the repaired endo-pelvic fascia and the apical sling fixed to the sacrospinous ligaments bilaterally. Vagina was closed by continuous USP 2/0 PGA suture. When the skin ends of apical sling were pulled out the

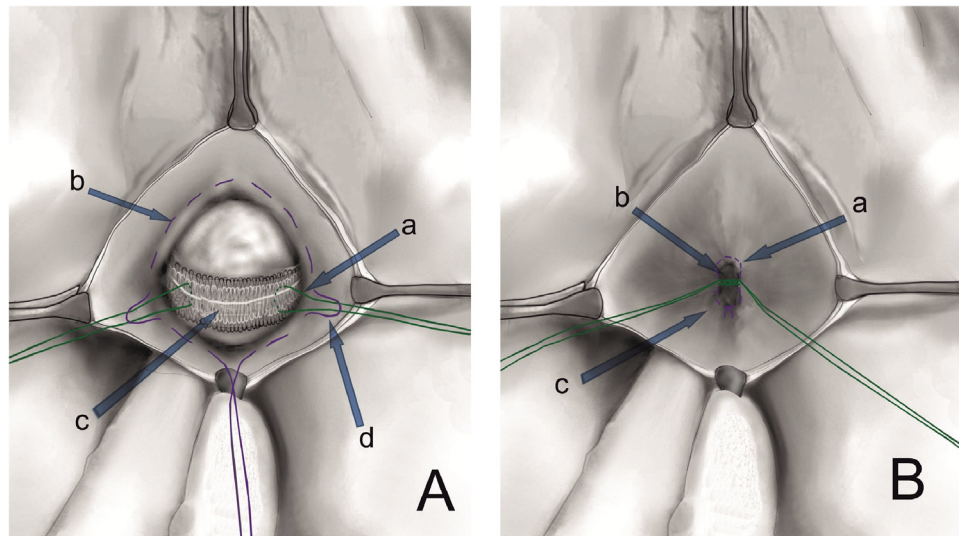


Fig. 3. A. a. Fixing ligatures of the apical sling, b. Purse-string suture on the internal surface of the fascia, c. The apical sling, d. Purse-string suture passes over; B. a. The purse-string suture is tied, b. The ligatures are tied above the tissue conglomerate, c. Neocervix is formed.

whole construction moved upwards to the correct position (Fig. 2. c). Then the rectum lumen was checked not to be obstructed by the apical sling. Cystoscopy was performed routinely to insure that there was no bladder injury. Vaginal packing and a urethral catheter were placed and removed within 24h. Patients were mobilized in the day of the surgery.

These clinical results were analyzed using STATISTICA for Windows software (version 10, Stat Soft Inc., Tulsa, OK, USA). A set of descriptive statistics was used for the quantitative parameters: mean values, standard deviation, minimum and maximum values. QOL scale and POP-Q system were processed by comparing the initial data and values obtained during observation. They were compared using sign and Wilcoxon signed rank tests. Frequency characteristics of qualitative parameters were analyzed using nonparametric Chi-squared and Fisher's tests. We have considered a value of $P < 0.05$ conventional for medical sciences as the criterion for statistical reliability of the conclusions.

Results

The study group consisted of 61 patients with the mean age of $63,49 \pm 8,28$ years. The patients' demographics are tabulated (Table 1). Previous hysterectomy for the uterine prolapse was performed in 68,5% of subjects. Urge incontinence was found preoperatively in 13% (8/61).

Table 1
Patient characteristics.

	N=61
Age, years	$63,49 \pm 8,28$
BMI, kg/m ²	$29,35 \pm 3,82$
The number of childbirths	$2,03 \pm 0,51$
Menopause, n (%)	52 (85%)
Sexually active women, n (%)	16 (26,0%)
Previous surgeries, n (%)	
- Hysterectomy	61 (100%)
Vaginal hysterectomy	29 (47,5%)
Abdominal hysterectomy	32 (52,4%)
Hysterectomy for uterine prolapse	42 (68,5%)
- Suburethral sling	2 (3,3%)
- Anterior/posterior colporrhaphy	9 (14,8%)

* Data are given as mean values \pm standard deviation, s.d.

All patients underwent reconstruction of the pelvic floor in accordance with the proposed method in the Department of Urology of University Clinic of Saint-Petersburg State University. Mean surgery duration from incision to conclusion of entire procedure was 35 ± 13 min (25–60), mean intraoperative blood loss volume – 45 ± 15 ml (30–150). The average duration of bladder drainage was 1.05 ± 0.73 days (max – 4), and duration of hospital stay – 2.1 ± 0.6 days (max – 4). No cases of intraoperative damage of the bladder or rectum were registered, as well as clinically significant bleeding required transfusion. Eight patients complained of the buttock pain after surgery, and these symptoms were completely resolved with nonsteroidal anti-inflammatory drugs during 2 weeks postoperatively. Urinary retention occurred in 3 (4,9%) patients, and was resolved with indwelling transurethral Foley catheter in 3 days. Main postoperative complications are shown in Table 2.

Twelve-month follow-up data was available for 54 (88,5%) patients. Three subjects withdrew consent after 1-month appointment and four failed to appear one-year visit. Anatomical cure rate (\leq stage I, POP-Q) for the vaginal apex was 100% (96,3% stage 0; 3,7% stage I). Regarding the anterior vaginal wall, the surgery was successful in 94,4% (n = 51). Two patients presented asymptomatic recurrent cystocele stage II and another one – stage III. Regarding the posterior wall, anatomical cure rate was found in 100% also (Table 3). The mean C score changed from $3,1 \pm 2,8$ at baseline to $-7,2 \pm 0,3$ at 12-months follow-up ($P < 0.001$). The mean Ba score decreased from $3,0 \pm 2,7$ to $-2,1 \pm 0,9$ ($P < 0.001$). The mean Bp score changed from $2,9 \pm 2,4$ to $-2,8 \pm 0,4$ ($P < 0.001$).

Before the operation, 3 (5,6%) patients had postvoidal residual urine >100 ml (max–250 ml) which significant decreasing (up to 20–30 ml) was observed after surgery ($P < 0.001$). Statistically significant ($P < 0.05$) improvement in peak flow rate (Qmax) also was found. Previous urgent symptoms persisted in 3 (37%) of 8 patients. De novo urgency developed in postoperative period in 3 (5,6%) patients. Urgent symptoms in most of the patients were resolved after anticholinergic drugs administration. Stress urinary incontinence (SUI) de novo was observed in 4 (6,5%) women postoperatively. Suburethral sling was installed in 3 patients within six months about this pathology, and 1 patient refused of the proposed surgical treatment (Table 2). No cases of mesh erosion, defecation dysfunction or chronic pelvic pain were observed at 12-month follow-up.

Table 2
Postoperative complications.

Complications:	1 month (N=61)	6 months (N=58)	12 months (N=54)
Hematoma in the surgical area (< 200 ml)	4 (6,6%)	0	0
Urinary retention ($V_{RU} > 100$ ml)	3 (4,9%)	0	0
De novo SUI	4 (6,6%)	1 (1,7%)	1 (1,9%)
De novo urgency	3 (4,9%)	1 (1,7%)	1(1,9%)

Table 3
Distribution of patients according to preoperative and postoperative Pelvic Organ Prolapse Quantification (POP-Q) stages.

	POP-Q stage	Preoperative n (%)	Postoperative n (%)
Anterior prolapse	Stage 0	0	39 (72,1)
	Stage I	0	12 (22,3)
	Stage II	5 (9,3)	2 (3,7)
	Stage III	37 (68,5)	1 (1,9)
	Stage IV	12 (22,2)	0
Apical prolapse	Stage 0	0	52 (96,3)
	Stage I	0	2 (3,7)
	Stage II	18 (33,3)	0
	Stage III	30 (55,6)	0
	Stage IV	6 (11,1)	0
Posterior prolapse	Stage 0	0	46 (85,1)
	Stage I	0	8 (14,9)
	Stage II	26 (48,2)	0
	Stage III	22 (40,7)	0
	Stage IV	6 (11,1)	0

Comparative analysis of the questionnaires scores revealed significant improvement of postoperative QoL. Table 4 shows that all summary PFDI-20 and PFIQ-7 scores significantly decreased after surgery ($p < 0.001$). Initially sexually active were 16 women, 3 of them (18,6%) complained of dyspareunia, which regressed in the postoperative period in 2 (71,4%) of them. Dyspareunia de novo developed in 1 patient (1,9%). According to PISQ-12, quality of sexual life significantly improved after surgery also.

Assessment of patient satisfaction showed that 98,1% (53/54) were satisfied with the operation and 96,3% (52/54) of the patients would recommend the procedure.

Discussion

The aim of the reconstructive surgery for VVP is to restore normal vaginal support whilst maintaining vaginal capacity and coital function [5]. First reported in 1971, sacrospinous ligament fixation (SLF) was indicated as a method for post-hysterectomy VVP correction [8]. Its success rate is between 75% and 97% [9]. The most common postoperative complications are high rate of cystocele approaches 20–33%, and dyspareunia caused by vaginal narrowing in up to 10–17,6% [8,10]. In comparison, in our study the rate of cystocele in 12-months after surgery was 5,6% (2 patients-stage II and 1-stage III) and dyspareunia de novo was found in 1 patient (1,9%). Sacrocolpopexy (abdominal and laparoscopic) is considered the gold standard procedure for vaginal vault correction with a high long-term cure rate [11]. Nevertheless, it is associated with a long operation time (up to 90–382 min) and risk of life-threatening hemorrhage [11–13]. Reported rate of erosions

is about 2,7–3,4% after this procedure [5,14]. Specific complications of this surgery are postoperative ileus (3,6–9,3), small bowel obstruction (1,1–8,6%) and defecation dysfunction (4,7–50%) [14–16]. Our technique required 35 min (max-60) and was accompanied by insignificant blood loss. During 12 months postoperatively no cases of mesh erosion and defecation dysfunction were found. Next two methods (McCall culdoplasty and uterosacral ligament fixation) are more frequently performed at the time of hysterectomy, than as VVP correction procedures. These techniques require adequate visualization and retraction as a key to a successful operation, that maintain operative time and blood loss. The most common complication with both methods is ureteral obstruction reported in 3,7–9% [17,18].

The first technique of the VVP correction through the vaginal approach with the use of synthetic material was described by P. Petros in 1997–infracoccygeal sacropexy [19]. This method is more popularly known as “posterior intravaginal slingplasty” (PIVS). There is published data about 93,18% success rate of the PIVS at 9-years’ follow-up with the only case of mesh exposure [20]. And this study is controversial to the others reporting higher rate of mesh erosions – about 8,5–9,8% [21,22]. The cause of the latter is thought to be imperfect polyfilament (microporous) structure of originally proposed tape (IVS, Tyco Healthcare).

An article describing the results of the VVP repair with the apical sling was published recently [23]. As well as in our study, authors used monofilament polypropylene tape (I-STOP sling, CL Medical, Winchester, MA). Reported 6-month’ objective (POP-Q apical prolapse stage ≤ 1) and subjective cure rates were 100% and 78,7%, respectively. However, one case of significant blood loss and two cases (4,3%) of suture exposure were noted in the paper. Also, there were 2 subjects (4,8%) with prolapse de novo stage II (POP-Q).

In the contrary to the techniques mentioned above, we had no cases of mesh exposure both due to the type of the mesh used, and the unique method of vaginal cuff fixation to it. The main advantage of our technique is the absence of the direct contact of synthetic sling fixing ligatures with the vaginal wall. The “neo-cervix” (reconstructed vaginal fascia) was used as the anchor point on the apex. According to the evidence of coexisting endo-pelvic fascia defects in patients with VVP, the majority of surgeons perform additional anterior/posterior repair at the time of reconstructive surgery. However traditionally performed colporrhaphy has high recurrence rate, reported up to 70% for the cystocele repair [24]. Castro E.B. et al., showed that anterior colporrhaphy was not effective in preventing SLF-induced cystocele [25]. Original colporrhaphy technique implies interrupted absorbable sutures laid on the external surface of the fascia. In our proposed method one-thread continuous suture is performed on the internal surface of the fascia. Due to this technique the ligature

Table 4
Quality of life data.

	Baseline mean \pm SD score	12-Month mean \pm SD score	P value
PFDI-20 (N=52)	101,5 \pm 27,2	25,1 \pm 9,6	<0.001
PFIQ-7 (N=51)	82,7 \pm 31,7	20,2 \pm 8,1	<0.001
PISQ-12 (N=16)	24,7 \pm 1,4	35,1 \pm 0,5	<0.001

is isolated from vaginal mucosa, that allows using of non-absorbable suture in cases of adequate thickness of the fascia, providing higher durability. Furthermore, high anatomical cure rate in all three compartments in our study was achieved by single construction created with the repaired endo-pelvic fascia (“neo-cervix”) fixed to the apical sling.

In general, our technique incorporates the advantages of native tissue repair and durability of mesh-based reconstruction. It has short operation time and hospital stay duration, low rate of postoperative morbidity. There are some limitations of this study. First, short follow-up period – 12 months. Second, this study is non-randomized. Strengths include a prospective study design, homogeneous cohort and using of validated questionnaires for measurement of subjective outcomes. Longer-term studies are planned to draw firm conclusions.

Conclusion

The novel technique: combination of the bilateral sacrospinous fixation with modern monofilament tape (apical sling) and purse-string “neocervix” formation appears to be effective and safe method for treatment patients with post-hysterectomy vaginal vault prolapse. This technique also provides high functional results and improves quality of life.

Authorship contributions

D.D. Shkarupa: Project development, manuscript writing and editing.

N.D. Kubin: Data collection, data analysis.

E.A. Shapovalova: Data collection, data analysis, manuscript writing.

A.O. Zaytseva: Data collection, data analysis, manuscript writing.

A.V. Pisarev: Data collection, data analysis.

O.U. Staroselseva: Data collection, data analysis.

Conflicts of interest and source of funding

None.

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