

Transvaginal six-arm mesh OPUR in women with apical pelvic organ prolapse — analysis of short-term results, pelvic floor ultrasound evaluation

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ABSTRACT

Objectives: Analysis of feasibility, efficacy and short-term results after six-arm transvaginal mesh OPUR implantation in women with apical prolapse.

Material and methods: The same surgeon operated all of 39 women using mesh OPUR. Preoperatively patients had a standardized interview and clinical examination. Intraoperative and postoperative complications were analyzed. Postoperative evaluation included standardized interview, clinical examination and standardized pelvic floor ultrasound performed with 2D transvaginal probe and 4D abdominal probe.

Results: There was no complication that needed operative intervention. Hematomas in 3 patients resolved spontaneously. Transient voiding difficulties which lasted less than 7 days were observed in 5 patients. No erosion was observed. Comparison of pre- and postoperative results in 34 women revealed that in all 3 compartments improvement in POP-Q scale was statistically significant ($p < 0.0000$). One patient with malposition and rolled up mesh needed re-operation. During PFS-TV in 94.1% of patients urethra was normobile or hypermobile. In all of the patients urethral end of the mesh was positioned far enough from the middle part of the urethra (ultrasound) to implant suburethral sling without risk of collision. Sexually active women did not inform of any important discomfort or pain during intercourse.

Conclusions: It seems that six-arm OPUR mesh, if implanted under strict surgical rules, gives low risk of complications and high chance to successfully reduce POP symptoms in short term after the operation. It seems that OPUR mesh should not have negative influence on the results after anti-incontinence suburethral sling.

Key words: pelvic organ prolapse, apical prolapse, six-arms transvaginal mesh, pelvic floor ultrasound, PFS-TV, transvaginal probe

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INTRODUCTION

In ageing population pelvic organ prolapse (POP) has become an important issue. This is the reason for many operations in women [1]. Apical vaginal prolapse is a descent of the uterus or vaginal vault, if post-hysterectomy. Nowadays apical prolapse is an important clinical and scientific issue, because it is the probable reason for many failures after POP repair operations [2]. Various surgical treatments are available to treat this condition and there are no strict recommendation when to use them [3]. There are data sug-

gesting that sacral colpopexy is operation of choice for apical vaginal prolapse, especially in younger, sexually active women. Supporters of transvaginal meshes (TVM) remind that although complications are more often in TVM meshes, but they are less serious in comparison with abdominal or laparoscopic route. This is one of the reasons why specialists often choose vaginal route [4, 5]. There is limited evidence of transvaginal meshes and most of those evaluated so far are no longer available [3]. There are data suggesting that new lighter meshes with 6 arms are effective to treat both

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anterior and apical prolapse, also in sexually active women, but still more data are needed [5]. Some specialists suggest that such meshes with both anteroposterior and lateral suspension might support the whole base of the bladder [5].

Ultrasound allows visualizing implants used in urogynecological patients, that is why pelvic floor ultrasound is now an imaging of choice in evaluating patients after mesh implantation [6, 7]. It is also often used to evaluate women with stress urinary incontinence before and after suburethral sling implantation [7–11].

OBJECTIVES

Analysis of feasibility, efficacy and short-term results after six-arm transvaginal mesh OPUR implantation in women with apical prolapse.

MATERIAL AND METHODS

This is the analysis of the first 39 operations performed by the same surgeon (T.K.). OPUR mesh (Abiss, Saint Etienne, France) was used in patients with both anterior and apical prolapse minimum 2nd grade in agreement with Pelvic Organ Prolapse Quantification (POP-Q) system [12]. 22 g/m² mesh with six straps was placed after one anterior vaginal incision. This was a retrospective analysis of the patient's data.

Before the operation patients had standardized interview and examination including transvaginal gynecologic ultrasound. Pelvic organ prolapse (POP) was classified according to POP-Q system [12].

The technique of implantation of OPUR mesh described by Guyomard and Delorme was used [5]. The stabilizing tapes were placed in three positions: apical trans-sacrospinous, anterior transobturator, and posterior transobturator. The apical trans-sacrospinous straps were placed by an in-out method which enables precise transfixion of the centre of the sacrospinous ligament, thereby limiting risk of injury to the pudendal neurovascular structures and the sacral plexus. The anterior transobturator straps were placed by an out-in method, around the ischiopubic ramus and over the arch of the levator ani muscle. The posterior transobturator straps were placed by an out-in method in the sagittal plane parallel to the lateral surface of the iliac bone.

Intra- and postoperative data were analyzed with the focus on complications and patient's complaints.

Postoperative evaluation included: standardized interview and examination including POP evaluation using POP-Q scale, standardized pelvic floor ultrasound using GE Voluson Expert: 2D introitally with transvaginal probe — PFS-TV, and 4D translabially with abdominal probe — PFU-4D.

PFS-TV was performed under standardized conditions [13, 14] in patients with full bladder (250–350 mL of urine).

Mobility of the urethra and urethral funneling with urine flow were evaluated [9, 15–17]. Urethral mobility was evaluated as vector calculated from measurements obtained during PFS-TV according to the method specified by Vireck. This parameter is called linear dorsocaudal movement (LDM) [16, 17]. Lately hypomobile urethra was defined as value of the LDM ≤ 5 mm, normobile: 5–15 mm, hypermobile: ≥ 15 mm [9, 16]. Hypomobility of the urethra is one of the risk factors for failure after suburethral sling implantation [9, 16]. Urethral funneling with urine flow, observed during PFS-TV, is regarded as confirmation of stress urinary incontinence [15]. No stress urinary continence was defined as the absence of SUI symptoms or SUI observed by the patient periodically with a negative sitting and standing cough test and no signs of SUI during PFS-TV. First degree of SUI was diagnosed if women observed SUI symptoms occurring from time to time - not every day, cough test was positive and signs of SUI during PFS-TV were visible. 2+ degree of SUI was defined when patients had symptoms every day, cough test was positive which was confirmed during PFS-TV.

Location of urethral end of mesh OPUR was measured during PFS-TV on sagittal view similarly to measurements proposed by Kociszewski et al. for the suburethral tape (Figs. 1, 2) [13, 14]. We measured in mm the shortest distance between mesh and hypoechoic urethra. It was called mesh-urethra distance. We calculated mesh position relative to urethral length in% according to formula (1):

$$\text{relative mesh position} = \frac{\text{distance of the distal end of the mesh from bladder neck} \times 100\%}{\text{sonographic urethral length}}$$

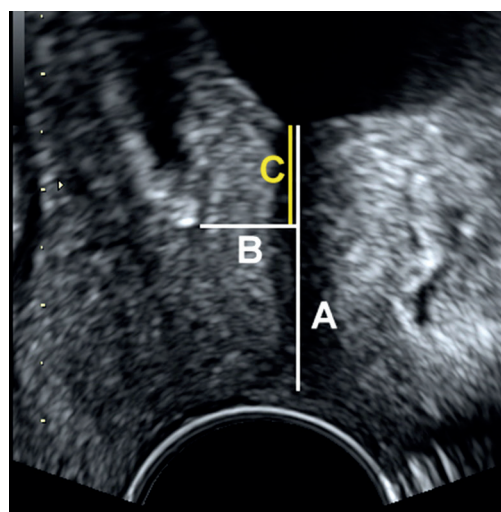


Figure 1. Evaluation of relative mesh position (PFS-TV). A — urethral length, B — projection of distal end of the mesh on urethral axis, C — distance between distal end of the mesh and bladder neck (internal urethral orifice)

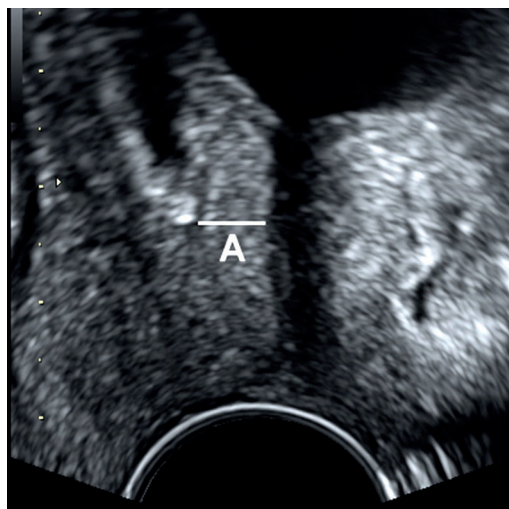


Figure 2. Measuring the mesh-urethra distance (PFS-TV).
A — mesh-urethra distance

PFU-4D was performed under standardized conditions. Hiatal dimensions at rest and on Valsalva were measured in the plane of minimal hiatal dimensions, as previously described. Levator trauma was identified by tomographic ultrasound (TUI) as previously described [7, 18, 19].

Statistical analyzes were carried out using STATISTICA 7.0 StatSoft. The calculations of median, arithmetic mean, standard deviations were done. Student's t-test was applied for testing the significance of differences for dependent variables.

RESULTS

One experienced surgeon (T.K.) performed all of the operations. During the analyzed period 39 patients were operated, 34 came for the control visit between 6 and 12 months after the operation and their data were analyzed in this study. All patients had successfully OPUR mesh implanted. Perineoplasty was additionally performed in 2 patients. No other additional operations were performed in analyzed women. The mean age was 66 years (48–77). The mean BMI was 26.5 (22.7–31.6). Two women were premenopausal, the rest were 1–27 years post menopause. One was taking insulin because of diabetes, 5 were smoking > 10 cigarettes daily. One patient had forceps delivery and 2 times cesarean section. The rest delivered vaginally from 2 to 5 times (mean 3). First baby was delivered between 18 and 27 years (mean 23). Two women had abdominal hysterectomy in the past (leiomyomas), three had urogynecological operations earlier: one had suburethral sling TVT implanted, 2 had vaginal repair. Three months after OPUR mesh implantation, one woman had successfully implanted suburethral sling TVT, because of de novo stress urinary incontinence. All women had at least stage 2 enterocele, 32 (94.1%) had cystocele at least 2nd degree,

and 7 (20.6%) had rectocele at least 2nd degree. None of the women had 4th degree of POP. They were operated because of high negative influence of POP on their quality of life (QoL); seven noted problems to start voiding; two had preoperatively hydronephrosis, which was resolved postoperatively.

On the control visit nine patients (26.5%) informed about de novo SUI: five — 2nd degree, 4 — 1st degree. In 3 patients stress urinary incontinence (SUI) was before and after the operation: 2 had 2nd degree, one observed improvement: from 2nd to 1st degree. Four women (11.8%) noted cure from SUI, one of them had de novo overactive bladder symptoms (OAB) improved after pharmacotherapy introduced before control visit. One more patient informed about de novo OAB — pharmacotherapy was prescribed on the control visit. OAB preoperatively was observed in 8 patients — postoperatively 5 did not notice significant improvement, 3 noticed improvement. All of the patients with 2nd degree of SUI on the control visit asked for the next operation.

There was no complication that needed operative intervention. Hematomas in 3 patients (8.8%) resolved spontaneously. One of them occurred in a woman after previous vaginal repair. Transient voiding difficulties lasted less than 7 days in 5 patients (14.7%). No erosion was observed. Six patients (17.6%) noted transient lower urinary tract infection, but none of them needed long treatment.

On the control visit patients were examined clinically and using pelvic floor ultrasound (PFS-TV and PFU-4D). In 1 patient (2.9%) the mesh was rolled up and malpositioned to the urethra. In this patient we noted cystocele 2nd degree, enterocele 2nd degree and rectocele 1st degree. Urethra was hypomobile probably because of malposition of the mesh. Patient asked for re-operation because of negative influence of POP on the QoL — she noticed only slight improvement after the operation. In the rest of 33 women the mesh was optimally placed without signs of rolling up in PFU-4D. Four patients (11.8%) had cystocele 2nd degree, in 2 cases together with enterocele 2. In twelve cases (35.3%) we noticed cystocele 1st degree, in 3 cases together with enterocele 1st degree. In 6 women (17.6%) we found rectocele 1st degree — in 2 of them ultrasound showed that these were enterocele not rectocele. In 1 case we noticed small cystocele between the mesh and urethra. In both patients after perineoplasty the result in the posterior compartment was not clinically satisfactory. In all 3 compartments improvement was statistically significant ($p < 0.0000$). With the exception of one patient who needed operation, all of the patients noted significant reduction of POP symptoms and significant improvement of QoL — this was analyzed separately from SUI symptoms. None of those patients with clinical and sonographic symptoms of POP wanted pessary treatment or re-operation for POP.

In 9 patients (26.5%), PFU-4D examination revealed area of hiatus $> 25 \text{ cm}^2$ during rest and in 26 patients (76.5%) $> 25 \text{ cm}^2$ during Valsalva. Mean area value at rest was 24 cm^2 (14.3–32.3), at maximal Valsalva — 28.7 cm^2 (16.2–40.8). Mean increase of hiatal area during Valsalva was 4.6 cm^2 (–1.6–10.1). Seven patients (20.6%) had unilateral or bilateral levator avulsion.

During PFS-TV in 32 patients (94.1%) urethra was normobile ($n = 11$) or hypermobile ($n = 21$). Hypomobility was probably caused by malposition of the mesh in one case. One patient was unable to cough and perform properly Valsalva maneuver and this could be the reason for hypomobility of the urethra under PFS-TV. Mean LDM value was 13.7 mm (2.4–23.5). Mean mesh-urethra distance was 7.1 mm (2.0–13.4). In 3 patients mesh urethra-distance was $< 3 \text{ mm}$, but these patients did not have any complaints such as voiding problems or urge de novo.

Mean relative mesh position value was 27.2% (8.9–46.5%). In 4 cases value was between 40% and 47%. This position should allow implanting suburethral tape without risk of collision in all analyzed women — optimal relative tape position for TVT and TOT should be between 50% and 70% [13, 14, 20, 21].

Twenty-one women (62%) were sexually active. They did not inform of any important discomfort or pain during intercourse. In four women clinically vagina was too narrow — diameter less than 2 fingers, which could be the reason for painful intercourse, but these women were sexually inactive.

In 5 women, who were lost to follow up, only OPUR mesh was implanted. Operation and postoperative period during stay in the hospital was without complications.

DISCUSSION

Our study confirms that six-arm OPUR mesh can be attractive option for the patients with anterior and apical POP. Transgluteal fixation through the sacrospinous ligament enables good apical fastening. The posterior trans-sacrospinous straps can be helpful to treat cystocele. The transobturator straps reproduce the lateral suspension of the pubocervical fascia [5].

The incidence of perioperative complications in studied women was low. None of the complications needed operative treatment. Only one patient needed another operation in short term after the first procedure because of malposition and rolling up of the mesh. The anatomical effect was significantly better in all three compartments although most of the patients were at higher risk of failure (hiatal area $> 25 \text{ cm}^2$, levator avulsion) [6].

Guyomard and DeLorme reported the results from 74 women after OPUR implantation. In 4% of cases they had hematomas. One of them had to be drained, 2 others drained spontaneously through vaginal incision [5]. We

observed hematomas in 9% of cases, but all of the resolved spontaneously. In most of our patients OPUR was the first urogynecological operation, in none of them we found 4th degree of POP. These could be the reasons that hematomas were so small that needed no intervention. Similarly to Guyomard and DeLorme we had no case of injuries to the bladder, urethra and rectum. We suspect that rigorous using of their technique helped us to avoid these intraoperative complications.

We did not notice negative influence of the OPUR mesh on urethral mobility. After the operation most of the women had normobile and hypermobile urethra. It is important because hypomobile urethra is a risk factor for failure after operative treatment of stress urinary incontinence after suburethral sling [9, 16]. Thus, in our opinion, we should avoid procedures that have negative influence on urethral mobility.

It was suggested that tape-urethra distance $< 3 \text{ mm}$ is a risk factor for urge de novo and for post-void residual [13, 14, 20, 21]. In most of our patients mesh-urethra distance was $> 3 \text{ mm}$. In 3 patients mesh urethra-distance was $< 3 \text{ mm}$, but these patients did not have any complaints such as voiding problems or urge de novo.

To optimize the results of anti-incontinence operation suburethral sling should be located near the mid-urethra [9, 13, 16]. Because of the risk of collision between tape and mesh (collision phenomenon) it is important that mesh should not be located near the mid urethra [20, 21]. In all of the analyzed patients mesh was located far enough from mid-urethra so there should not be the risk of collision between sling and mesh in them. One patient had anti-incontinence TVT tape implanted 3 months after OPUR operation — tape was optimally positioned, patients had no SUI symptoms.

18% of our patients asked for anti-incontinence operation because of SUI 2nd degree. This is similar to other authors [5, 22]. There is discussion whether suburethral tape should be placed during one operation together with mesh because the results from the studies are controversial [23, 24]. We prefer inserting suburethral tape implantation separately to POP repair operation. We suspect that 6–8 weeks is needed to finish the process of healing, which theoretically may have influence on urethra length and mobility. Studies suggest that urethral mobility and urethral length may have the influence on the success rate after suburethral tape implantation, which may be optimized using individually planned tape implantation [9, 13, 16].

Erosions after transvaginal meshes are usually observed in a few percent of cases [25]. Insertion of the mesh in the optimal layer during first urogynecological procedure (only in 2 patients OPUR was second POP repair procedure) and good quality of light mesh could be the reasons that there was no case of erosion observed among our patients.

After vaginal mesh implantations de novo dyspareunia in 2–17% of cases was observed [26, 27]. In one study after OPUR mesh de novo dyspareunia was not observed [5]. Our patient did not report de novo dyspareunia but this problem was not evaluated in details during our study.

Our study has a few limitations. It is retrospective, number of patients is not high, and time of observation is short. We did not use special questionnaires, also for sexual activity, but we used standardized interview. However one experienced surgeon performed all mesh implantations, which allowed achieving maximal operative standardization of the procedure. This was the first time when OPUR mesh was postoperatively evaluated by detailed ultrasound examination with use of PFS-TV and PFU-4D.

Further follow-up for more patients is needed to determine the long-term results. It is important to follow up also the patients with stress urinary incontinence to evaluate the results of suburethral sling implantation after mesh implantation.

CONCLUSIONS

It seems that six-arm OPUR mesh, if implanted under strict surgical rules, gives low risk of complications and high chance to successfully reduce POP symptoms in short term after the operation. It seems that OPUR mesh should not have negative influence on the results after anti-incontinence suburethral sling.

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