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CLINICAL STUDY

Implants in operative therapy in women with pelvic organ prolapse – two years of experience

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Abstract: *Objectives:* The authors present their first experience with a new operative method (within two years' period in 18 patients) solving pelvic prolapse in women by means of installation of polypropylene (Prolene) mesh implant.
Materials and methods: The authors corrected various forms and stages of POP, particularly prolapse of the vaginal stump after hysterectomy, through the installation of Prolene mesh implants or the systems Prolift Anterior, Prolift Posterior and Prolift Total.
Results: Short-term results (follow-up 24 months) are promising. The patients present no significant subjective complaints and the objective findings are considerably improved. The authors report one particular case of point perforation of the urinary bladder with no side effects and they have not noticed any serious postoperative complications so far.
Conclusion: Nowadays, considering a new methodology the following factors are required: multicentre data collection, determination of rational indicating criteria (together with contraindications), analysis of per- and postoperative complications and publishing continuous clinical outcomes. This is the way how to find an adequate place for implants in a wide spectrum of operations regarding pelvic floor repair *(Tab. 4, Fig. 5, Ref. 13).* Full Text (Free, PDF) *www.bmj.sk.*
Key words: pelvic organ prolapse (POP), implant, Prolene mesh implant, Prolift

The frequency of pelvic floor disorders in women is high (approximately every second woman experiences a various degree of vaginal prolapse in her life). Roughly each tenth woman – 11.1 % (1) needs to be operated on pelvic organ prolapse (POP) or urine incontinence or a combination of both conditions. The most negative fact is that every third patient after POP operation experiences a relapse with necessity of reoperation. Uterovaginal descent or even prolapse is nothing new. Gynaecologists have been struggling with it for more than a hundred years. Numerous operative methods have been developed (vaginal, laparotomic, laparoscopic approach, suspension or fixation on various anatomical structures), but among them there is no preferable generally used methodology, which is not afflicted by a postoperative failure.

However, being familiar with the wide range of operations poses many problems. Neither standardised criteria of their effectiveness nor collaborative clinical studies exist. The new modalities of corrections emerge and the previous ones are not assessed. Concerning operations on POP the memento should be: although the vaginal prolapse itself causes complications of gastrointestinal tract, urinary bladder or miction and sexual dysfunctions, its surgical repair can afflict it as well – more particular in an unpredictable way. This warning should be thoroughly considered any time in introducing and applying a new operative approach, using artificial implants in particular.

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Materials and methods

Between November 2006 and October 2008 there were 18 patients surgically treated for the vaginal wall prolapse or vaginal stump after hysterectomy at 2nd Department of Gynaecology and Obstetrics, Faculty of Medicine, Comenius University and Faculty Hospital in Ružinov, Bratislava. The age range of the operated patients was wide. The youngest patient was 41, the oldest 72, the mean age was 57.9.

The clinical group comprised the patients with a severe stage of descent even vaginal wall prolapse after abdominal or vaginal hysterectomy (stage II and III according to

ICS POP-Q, Pelvic Organ Prolapse Quantification System of International Continence Society) (Figs 1, 2). According to medical history 9 patients underwent abdominal hysterectomy 2–24 years ago (mean 13.5 years ago), 8 patients underwent vaginal hysterectomy (from 3 months to 10 years ago, mean 3.2 years

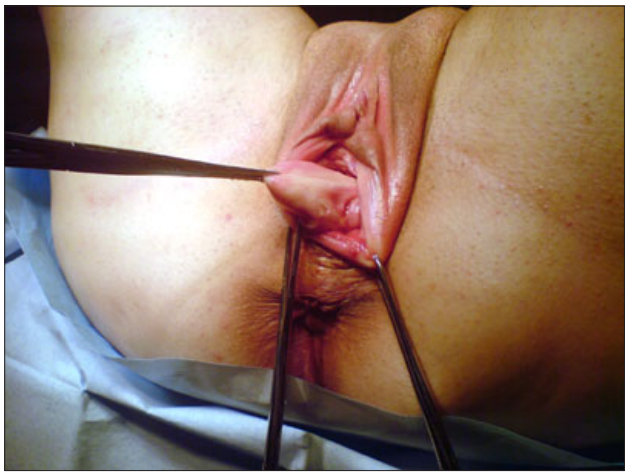

Fig. 1. Pre-operative condition (remarkable enterorectocele) – I.

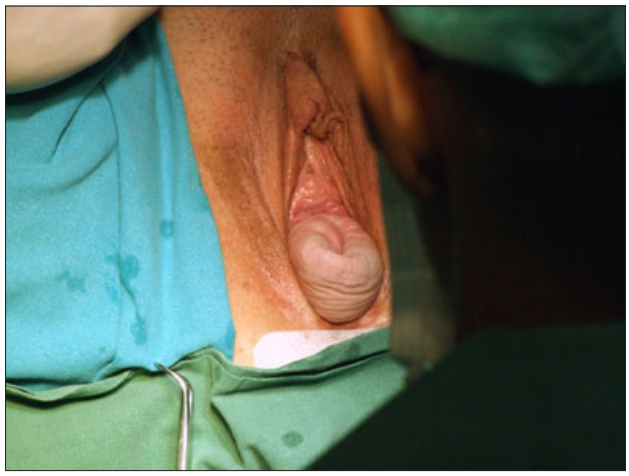

Fig. 2. Pre-operative condition (remarkable enterorectocele) – II.

ago) and 1 patient underwent removal of the uterus via laparoscopic assisted vaginal hysterectomy (LAVH) 17 months ago. 14 patients underwent prior operative repair of POP (1x laparoscopic culdoplasty, 13x vaginal plastics) (Tab. 1).

In 8 cases the isolated distinct vaginal wall prolapse without vaginal stump descent was corrected (all of stage II according to ICS POP-Q), in 10 patients the cause of operation was descent or prolapse of vaginal stump (4x stage II of ICS POP-Q and 6x stage III of ICS POP-Q) (Tab. 2).

The operation spectrum involved 5 cases of Prolene mesh installation with adjusting its shape to a local situation by cutting the mesh from the preformed format 15x15 cm. Such a "suo modo" formed implant was applied by a guide to Prolift Posterior via puncturing the sacrospinous ligament. In 3 cases the installation of the mesh itself was performed, in 2 cases the application of suburethral tape by the TOT (transobturatory tape) procedure was added due to accompanying severe level of stress incontinence.

In 4 cases the complex defect of all compartments of pelvic floor was resolved by the Prolift Total implant, in one case the TOT procedure was added due to urinary stress incontinence stage II.

Tab. 1. Previous operations of the patients included in the group.

Type of operation	Number	Follow-up (mean)
Abdominal hysterectomy	9	2–24 years (13.5 years)
Vaginal hysterectomy	8	3 months–10 years (3.2 years)
LAVH	1	17 months
Laparoscopic culdoplasty	1	
Colpoplasty	13	

LAVH – laparoscopic assisted vaginal hysterectomy

Tab. 2. Objective findings prior to the operation.

ICS POP-Q stage	Vaginal stump	Vaginal walls
Stage II	4x	8x
Stage III	6x	0

In 7 cases due to the defect of posterior compartment the installation of Prolift Posterior implant was performed, in 2 cases TOT procedure was added (indicated as the above mentioned cases).

The remaining 2 patients presented isolated distinct cystocele (without urinary incontinence) that was resolved by using Prolift Anterior mesh. The operation spectrum is demonstrated in Table 3.

It is necessary to say that self-adjusting of mesh (cutting a desired shape due to the local conditions) was performed only at the beginning of our study – in 5 cases.

On operative procedure: the patients were in total (14 cases) or spinal (4 cases) anaesthesia, preparation and positioning of the patients was usual as prior to vaginal operations. In the cases of posterior compartment repair due to better orientation (and concerning possible rectum damage) the rectum was thoroughly tamponed by gauze. Prior to the incision of vaginal mucosa (using cold scalpel or electric knife) hydrodissection with vasoconstrictive agents (Supracaine solution) was employed. It was followed by sharp and predominantly blunt preparation to membrana obturatoria (in the case of cystocele resolution) (Fig. 3), or forming the access in pararectal region to spinae ischiadicae and the sacrospinous ligament (in recto-enterocele repair).

The guides were inserted through foramen obturatus, or through ischiorectal region (Figs 4, 5).

The particular operative principles were observed with respect to recommended intention to reduce the likelihood of im-

Tab. 3. Types of operation procedures.

Implant type	Number	With TOT addition
Mesh posterior	3	2
Prolift Posterior	5	2
Prolift Anterior	2	0
Prolift Total	3	1

TOT – transobturatory tape

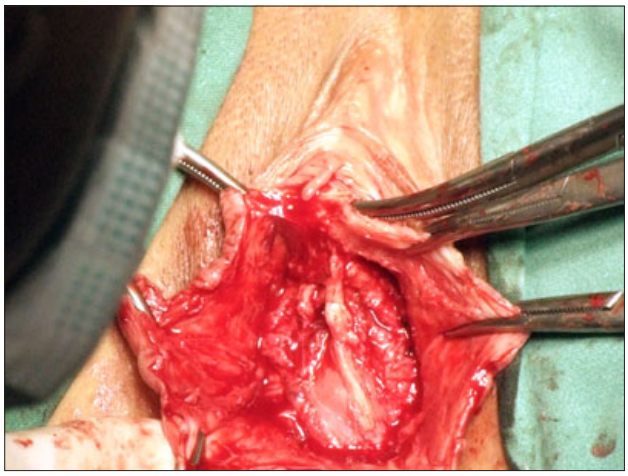

Fig. 3. Cystocele preparation for Anterior mesh implant installation.

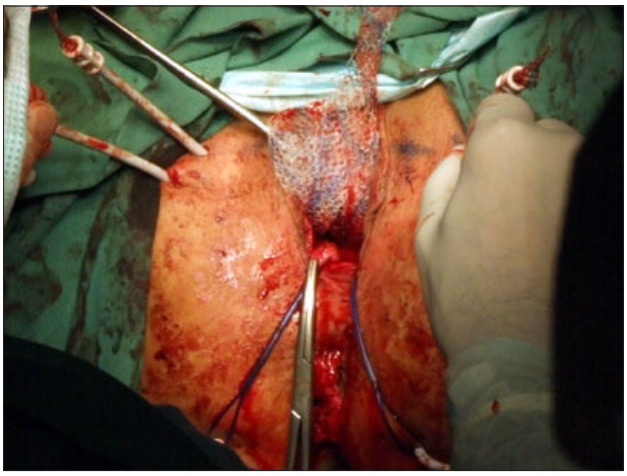

Fig. 5. Part anterior of Prolift Total installation.

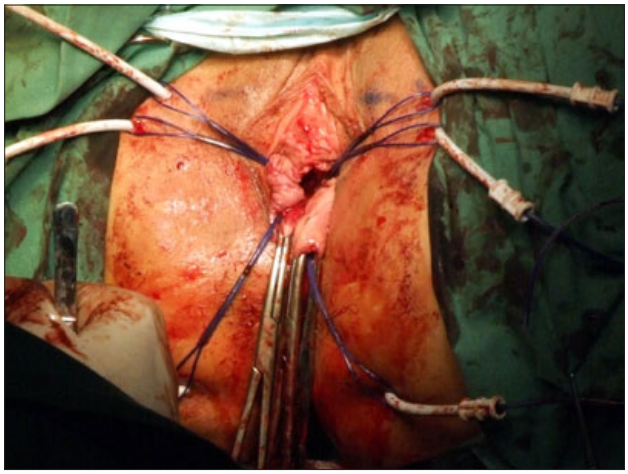

Fig. 4. 6 ports for Prolift Total application.

plant erosion, or to set up optimal conditions of the healing process (not to place the mesh within the lower third of posterior vaginal wall, to suture the vaginal mucosa in 2 layers, to resect the vaginal mucosa in the least scope possible, to irrigate the operation field frequently with disinfectant solution, to operate on under antibiotic cover and to continue in treatment for 5–6 days, during the first two days to change the tamponade in the vagina).

The hospitalization of patients lasted 3–5 days; the outpatient follow-up was after 1, 3, 6, 12 and 18 months after the operation.

Results

Outcome assessment of the operative procedure that is aimed to restore the impaired fibromuscular structure of pelvic floor cannot be responsibly carried out within a two-year period. The authors are aware of a limiting role of a short-term follow-up. However, they assume that also a two-year experience of a small group of 18 operated women can be beneficial to the professional community.

Regarding the conclusion of several forum discussions the outcome assessment of various operation procedures for resolution of impaired/defected pelvic floor fails being unified. The authors decided to characterise the postoperative state in two ways: an objective finding assessed similarly as prior to the operation through ICS POP-Q and a subjective evaluation by the patient.

In objective assessment within the short period of 24 months after the operation the significant decline in determining the stage due to ICS POP-Q was presented in 14 cases of 18 operated patients. In 3 cases the operation outcome was unsatisfactory: in one case 3 months after the installation of Prolift Anterior the mild descent of anterior vaginal wall and vaginal stump was reported; in another case it was vice versa – after posterior mesh implantation the mild descent of anterior vaginal wall and vaginal stump was reported and in the third case one year after the installation of Prolift Total together with TOT the mild descent of anterior vaginal wall was reported due to ICS POP-Q stage II associated with the relapse of urinary stress incontinence (the last 18th patient has not been followed up yet due to the short-term period after the procedure).

In subjective evaluation of the postoperative state the patients in most cases reported the considerable satisfaction. Two patients complained of dyspareunia (jabbing pain in posterior vaginal wall region), one patient had problems with obstipation yet reported before the operation; the next patient had sporadic painful defecation. In three patients the postoperative urinary incontinence was reported. In one case it was an urge type (persistence of urge component secondary to primarily/initially mixed type incontinence after Prolift Anterior), in another patient “de novo” stress incontinence occurred after Prolift Posterior. The last case dealt with recurrent incontinence although TOT was installed together with Prolift Total.

It is necessary to analyse thoroughly also complications of operative procedures that are inseparable part of their outcome evaluation. These complications were observed in detail and clas-

Tab. 4. Complications of operations.

Type of complication	Characteristics	Incidence
peroperative	adjacent organ lesion	1x bladder perforation
	bleeding over 300 ml	1x
early – during hospitalisation	dysuria, defecation disorder, fever	0
postoperative	mesh protrusion	1x after 2 months not present after 6 months
	pelvic pain	1x
	obstipation	1x
	pain in defecation	1x
	dyspareunia	2x
	urgent urination	1x
	stress incontinence	2x (1x „de novo“, 1x recurrence)
	urgent incontinence	1x persistence (after resolving stress componentin mixed incontinence)

sified as intraoperative, early (within hospitalization) and late; all are demonstrated in Table 4.

Discussion

The reported frequency of recurrence after standardised operative corrections varies widely. Cervigni and Natale (2) present defect recurrence of anterior compartment after anterior colporrhaphy in 3–20 %, after anterior colporrhaphy and suspension on the sacrospinous ligament in 22–92 % and after vaginal repair of a paravaginal defect in 5–50 % of cases.

Deval and Haab (3) present prolapse of vaginal stump after hysterectomy in 0.1–45 % of cases.

Data discrepancies are due to lack of clinical studies comparing various techniques. The mentioned data are in addition predominantly retrospective and no standard inclusion criteria and outcome assessment exist. The studies present a relatively short-term follow-up and a considerable amount of patients are lost to follow-up.

Pelvic surgeons often prefer flab and damaged proper – autologous tissue for repairing of pelvic floor defects. They are concerned namely about complications caused by artificial material, including response to a foreign body, infection, rejection and erosion.

In the literature the use of synthetic biocompatible materials in vaginal pelvic floor reconstructive surgery has been known since 1990 (4, 5, 6).

According to different origin implants are classified into 4 groups: 1) autologous, 2) allograft, 3) xenograft, 4) synthetic (3). Currently the use of synthetic implants is absolutely predominant in urogynaecology.

Carey et al (1) quote that risk factors of POP recurrence are not fully known, but women under the age of 60 with a higher stage of POP (ICS POP-Q stage III and IV) have higher likelihood of POP recurrence after vaginal operative correction.

Concomitant hysterectomy is considered by several authors to be a risk factor (7) of complicated healing process with implant erosion. According to other authors also the age over 70 and cystocele beyond the introitus are self-existent risk factors for erosion occurrence (8). Carey et al (1) reported POP recurrence after operation in 15 % of cases within a 6–12 month follow-up (between 12.6–28.4 %). A much considerable fact, on the other hand quite obvious, is that “de novo” prolapse in compartment not corrected within a primary operation occurred more often. It has not been resolved yet whether it is advisable (and indicated!) to treat surgically also a compartment that has not been affected by prolapse prior to the primary operation (how should be the indication for such a procedure justified and possible complications interpreted?).

Carey et al (1) trying to minimize complications and secure a long-term effect after the mesh installation insert into the vagina a vaginal support device (VSD) for three weeks. Within this period of time the mesh incorporates into the tissue. Not only does VSD support vaginal tissue, but it also secures the mesh placement. In such way it is possible to avoid placing sutures in the sacrospinous ligament or paravaginal area and the dissection of the pelvic cavity is not needed. The operation itself is easier; the risk of specific complications is reduced, i.e. complications occurring during suture insertion or in using tunnelling devices (perforators, guides, etc.) off the pelvis.

Baessler and Maher (9) draw attention to the need of considering risks and benefits of the mesh use in reconstructive urogynaecological operations. Implants are capable of shrinking and expanding as well. Openings in a monofilament polypropylene mesh can change their size between -40 and +16 %. In addition, it seems that currently used meshes are not inert as they can form scales (to stratify, to shed) and they can crack (to form fissures, cracks) that has been proven by electron microscopy.

Host responses vary according to the type of mesh, placement and method of installation, age and gender. All meshes evidently elicit the host response presented by chronic inflammation resulting in forming enormous cells around a foreign body, lymphocytes and T-cells (10, 11). However, it became apparent that multifilament meshes could elicit more fibrosis together with acute inflammation (e.g. confirmed after complications following intravaginal sling!) with a great number of neutrophils. But after removing a tensionfree vaginal tape (TVT) due to urinary retention only chronic inflammatory changes were detected.

According to a recent review of randomized control studies (12) currently no evidence exists to support a routine use of non-absorbable synthetic meshes for operative strengthening of both anterior and posterior vaginal wall. Failure of standard operative procedures (anterior and posterior vaginal plasty) ranges between 37–100 % (13). Prolene mesh used in cystocele repair is effective in particular studies between 75–100 %. However, the technique itself fails to guarantee a long-term effect and moreover the reports on complications have been on rise. Although the information also on strengthening the posterior compartment by a mesh was published, the benefits have been even less convincing than in cystocele resolution. Effectiveness of the standard correction of posterior compartment varies between 56–96 % and most studies report on approximately 80 % of effectiveness (13), which refers to considerably higher percentage than in standard anterior plasty. The above mentioned data involve more complications and doubts of competent use of meshes for rectocele correction, as in this case there is a higher risk of their use.

Cochrane Database of Systemic Reviews does not include a single one study promoting the use of mesh for the correction of posterior vaginal wall.

What does a comparison of our experience to the literature data look like? Since we operated only on the patients with the advanced stages of descent or prolapse the objective improvement would have been expected. Nevertheless, we proved the opinion from different workplaces (1) stating that the artificial support of one of the compartments by an implant can eventually cause "decompensation" – a descent of the non repaired region. We convinced ourselves that after installing Prolift Anterior the rectoenterocele not having been present so far can develop relatively quickly and vice versa, after the installation of Prolift Posterior the newly developed cystocele can occur. We include also the patient in who after undergoing the installation of Prolift Posterior "de novo" urinary stress incontinence occurred.

In conclusion we want to stress one essential (though controversial) point**.** The use of synthetic implants was exclusively scheduled for patients with **severe stages of descent or prolapse of vaginal walls or vaginal stump after hysterectomy**. Nearly all patients already underwent (without a desirable effect) several standard reconstructive operations. It is possible to say that our proposal/offer was for them to some extent the last chance. We think that a distinct indicative restraint from our point of view is in order regarding two reasons: the first one is the fact that the use of meshes at 2nd Department of Gynaecology and Obstetrics is a newly introduced procedure and so some caution is sound and obvious. The essential point is a thorough instruction of the patient including a controversial effect of the operation together with its possible serious adverse effects. Another reason of indicative caution is the fact that problems of implant use in pelvic floor disorder have not been concluded worldwide and is still in progress.

At foreign workplaces the implants in resolving POP are used also in the uterus preservation. The above-mentioned indicative restrictions respected by us are the reason that in patients with uterus descent or even prolapse as the first option was proposed hysterectomy and implants were planned for a possible alternative of the following correction. Due to this fact the women with the unfinished reproductive function were excluded from our group in advance.

Conclusion

The authors publish their first experience with a novel operative procedure for resolving pelvic organ prolapse in pelvic floor through installation of synthetic implants. They emphasize the necessity of multicentric studies aimed at assessing complications, risks and effectiveness of these procedures together with establishing their indications and contraindications.

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