

THE PELVIC FLOOR REPAIR WITH THE USE OF PROSIMA™ IMPLANT – THE ASSESSMENT OF COMPLICATIONS AND LIFE QUALITY.

Hypothesis / aims of study – to evaluate long-term results of the pelvic floor repair with the use of Proxima™ implant and the life quality of the patients after 12 months after the surgery.

Study design, materials and methods. In the period from October 2010 to December 2012 in the department of operative gynecology 56 patients have been operated on genital prolapse of II-IV stages with the use of the system Proxima™. The surgery was performed according to standardized method. All patients were evaluated according to the system of POP-Q (ICS,1996). Assessment of complications after the operation and the quality of life of women before and after the treatment was made. The average time of observation was 11,8±3 months. The middle age of the patients was 62,9±3,5 years old. Genital prolapsed of II stage was diagnosed in 33,9% cases, III stage in 60,7%, IV stage in 5,4% cases. Proxima™ anterior was fixed in 62,5%, the implant Proxima™ posterior was fixed in 7,1%, and Proxima™ combined in 30,4% (Table 1). The average time of the operation amounted to 93±20 minutes. 21 (37,5%) patients were operated out under general anaesthesia, 35 (62,5%) - under combined spinal-epidural anaesthesia. 29 patients had accompanying stress urinary incontinence, therefore suburethral plastic with TVT®-Obturator was made in 26 (46%) cases, TVT®-ABBREVO in 3 (5,4%) cases. 12 (21,4%) patients had elongation of the cervix and amputation of the cervix was made. Hysterectomy was applied to 6 (10,7%) patients. VSD (Vaginal support device) was deleted on the 21-23-d day after the surgery.

Table 1

Anatomic results and success of varying degrees in genital prolapse correction with the use of the implant Proxima™

Prolapse stage	Total (n=56)		Anterior (n=35)		Posterior (n=4)		Combined (n=17)	
	Before	In a year (n=56)	Before	In a year (n=35)	Before	In a year (n=4)	Before	In a year (n=17)
0	-	52 (92,8%)	-	32	-	4	-	16
I	-	2 (3,6%)	-	1	-	0	-	1
II	19 (33,9%)	1 (1,8%)	15	1	0	0	4	0
III	34 (60,7%)	1 (1,8%)	19	1	3	0	12	0
IV	3 (5,4%)	0	1	0	1	0	1	0
Points in POP-Q	Before	In a year	Before	In a year	Before	In a year	Before	In a year
Average meanings are given, sm.								
Aa	0,44	-1,9	1,0	-1,8	-1,5	-1,7	1,8	-2,2
Ba	0,44	-1,9	1,7	-1,7	-1,4	-1,8	1,0	-2,2
Ap	0,14	-2,24	-2,1	-2,0	1,5	-2,6	1,0	-2,1
Bp	-0,37	-2,27	-1,9	-2,0	1,4	-2,5	0,6	-2,3
C	-4,44	-6,04	-4,5	-5,9	-4,8	-6,0	-4,0	-6,2
TVL	9,04	8,74	8,8	8,6	9,1	8,8	9,2	8,8

Results. A 21-23 day VSD location in the vagina was endured satisfactorily by all patients. In no case the VSD was removed earlier. The frequency of mucous membrane vagina erosion amounted to 14,3%, which is associated by us with the technique of repairing the mucous membrane of the vagina - all erosions appeared on the stage of development of the methodology. It can also be connected with the necessity of a long-term (3-4 weeks) VSD location in the vagina. This, firstly, can lead to local disturbances of microcirculation, dysbiosis of the vagina and, secondly, it practically eliminates the possibility of full-scale use of local antiseptic (antibacterial) and estrogencontaining means that leads to the reduction of repairing capacity of tissues and promotes the formation of ischemia and erosion of the mucous membrane of the vagina. In our series there appeared one case of recurrence of prolapse of the III degree (1,8%) in a year after the operation with the use of Proxima™ anterior. To eliminate this complication anterior kolporrafiya was carried out. In one case there happened bleeding from perivesical venous plexus with the formation of retroperitoneal hematomas of 10x6sm after Proxima™ anterior system installation, of a 60 – year-old patient with genital prolapsed of the II degree and cystocele II. After the hematoma was diagnosed, re-operation was performed in 3 hours and 50 minutes, removing of the anterior implant, opening and drainage of the hematoma, anterior kolporrafiya was completed. Total blood loss amounted to 1000 ml. The patient was discharged on the 16-th day in satisfactory condition. While the control examination after 2 months there was diagnosed the prolapse of stage 0. One patient had deep veins thrombosis of a left hip in the late postoperative period after vaginal pangisterektomi and the correction of genital prolapse of the III stage with the use of the system Proxima™ anterior. Deep veins thrombosis of the left hip appeared in 3 weeks after the operation, conservative treatment in the surgical hospital was made. In one case, there occurred a bladder atony after the operation Proxima™ anterior, suburethral plastic with TVT-Obturator. The patient received the physiotherapy during the period of 7 days, antiholinergics with a positive effect, a complication was stopped on the 13-th day.

At the same time the evaluation of the life quality of the operated patients was done with the use of questionnaires PEDI-20, PFIQ-7, Wexner scale of anal incontinence, PISQ-12. Table 2 gives the dynamics of life quality changes after the prolapse correction using the implant Proxima™. It indicates the average figures for each questionnaire, and options of maximum and minimum figures of the questionnaire.

Table 2

Quality of life after correction of prolapse with the use of implant Proxima™ (n=56)

Average, scores Questionnaire	Before surgery	1 month after surgery	6 month after surgery	12 month after surgery	Change (from baseline)
PFIQ-7*, scores	210 (±30)	180 (±40)	30 (±10)	0 (+10)	-210
PEDI-20*, scores	180 (±30)	160 (±30)	40 (±10)	0 (+20)	-180
POPDI-6**, scores	70 (±30)	35 (±25)	5 (±2)	0 (+20)	-70
CRADI-8**, scores	50 (±15)	45 (±15)	15 (±10)	0 (+5)	-50
UDI-6**, scores	60 (±20)	80 (±20)	20 (±15)	0 (+5)	-60
Wexner scale, scores	6 (±2)	5 (±2)	3 (±2)	3 (±2)	-3

* best scores 0, worst scores 300.

** best scores 0, worst scores 100.

Wexner scale: 20 points - complete anal incontinence, 0 points - the norm.

Interpretation of results. Anatomic success consists in the fact that in the stage of the POP-Q 0-1 one year after the surgery the patients do not require subsequent surgical treatment in 96,4%. All the patients showed a significant increase in quality of life after the correction with the implant Prosima™ (Table 2). According to the questionnaire PISQ-12 in 8-12 months after surgery Prosima™ 23 (41,1%) patients resumed sexual activity, only one patient notes dyspareunia (the patient had this symptom before surgery), and 5 (8,9%) patients started sexual intercourse after a long break (about 8 years), with no mark of pain and dyspareunia. These patients scored 6±2 points on PISQ-12 before surgery, 6-8 months later they had 27±6 points.

Concluding message. PROSIMA™ system demonstrates the success of the operation, both for anatomical and functional recovery of the pelvic organs, their safety because of the low invasiveness and a small amount of complications, satisfaction of the patients with the results of the treatment connected with the disappearance of the complaints related to violation of defecation, urination, as well as improved quality of life and the resumption of sexual activity.

Disclosures

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