EVALUATION AND COMPARISON EFFICIENCY OF THE TROCAR AND TROCAR FREE METHODOLOGY OF RECONSTRUCTION OF THE FRONT AND APICAL COMPARTMENTS OF THE PELVIC FLOOR USING SYNTHETIC MESH WITH PELVIC PROLAPSE

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Introduction

Pelvic floor reconstruction with vaginal access using synthetic mesh is a common and effective approach to the treatment of pelvic prolapse positive forms. The current stage in the mesh pelvic surgery development is the best-practice implant placement technique emergence - SIMS (single-incision mesh system).

SIMS fundamental differences: mesh system fixing with harpoon elements (anchor) to the most durable connective tissue structures of the pelvis (sacrospinal ligament, obturator membrane); less traumatization due to the absence need to carry out trocars through the pelvic surface tissues.

According to the recent studies (Lukban JC et al., 2012; RD Moore et al., 2012; EJ Stanford et al., 2013), objective efficacy of the Elevate ™ system using during the year with anterior plastic is from 88% to 92%, the apical - from 89% to 96%, back to 93% [1,2,3]. Comparing SIMS with traditional mesh plastic (210 patients, the follow-up period is 1 year): the anatomical efficiency for the anterior part was 98% versus 87% ($p = 0.006$), for the apical 99% versus 96% ($p = 0.317$), and for the posterior 100% versus 97% ($p = 0.367$) [4]. Nevertheless, there are questions about the reliability of harpoon elements fixing and the new operational methodology safety remain.

Objective. Trocar free and trocar techniques for the reconstruction of the anterior and apical sections of the pelvic floor using a synthetic mesh efficacy and safety comparison.

Materials and methods. The study was approved by the clinic ethics committee; all patients signed the corresponding informed consent.

The criteria for inclusion in the study: the presence of a prolapse of the vaginal anterior wall ≥3 degree, isolated or in combination with the apical department fall ≤2 degree.

Exclusion criteria: positive swabs on cervical cancer, neoplasm of uterus, absence of pelvic organs prolapse, presence of the anterior vaginal wall prolapse ≥3 degree in combination with prolapse in the apical department ≥3 degree (these patients were performed

the installation of a posterior intravaginal sling simultaneously). Presence in the anamnesis of gynecological operations (hysterectomy, plastic with own tissues) was not a contraindication to the operation.

The first stage of the study was the examination of safety of "avascular zones" for fixing the harpoon elements of the endoprosthesis in the best-case technique of the device, in the sacro-ovar area ligament and obturatorial apertures by analyzing 50 CT angiographies of patients undergoing examination in the radiation diagnostics department.

The second stage of the study was X-rayanatomical study for the correlation identify between interspinalia and transobturator distances with anthropometric data (height, weight), in order to determine the optimal size of a synthetic mesh in trocar free technique of the unit, this part of the study included 65 patients. Each patient underwent an overview radiograph of the pelvic bones in a direct projection. For the measurement errors corrections of the distances between the anatomical structures, the errors of the radiographic image were corrected with reference object of the patient fixed on the inner thigh of the femur before the examination. In the experimental part of the study, the examination of the main properties of the harpoon element developed (study of the separation load of implanted harpoon elements from the sacro-spinal cord and obturator membranes of 10 "fresh" female corpses) was performed. An evaluation of the separation load of the harpoon lock was carried out using an electronic dynamometer (MEGEON 04050 - min5H / max50H ± 1%).

In the final stage of the clinical part of the study, patients were divided into 2 groups (138 patients), depending on the operating procedure used, with further comparison of treatment results. The first group of patients (69 patients) underwent a trocarfree installation of a synthetic reticular mesh in patients with isolated cystocele of 3-4 grade or cystocele of 3-4 degrees in combination with apical prolapse of 1-2 degrees (POP-Q). In the second group (69 patients) classical surgical reconstruction of cystocele with the use of a synthetic reticular mesh was carried out, in occasion of isolated cystocele of 3-4 degrees or cystocele of 3-4 degrees in combination with apical prolapse of 1-2 degrees (POP-Q). Statistically significant differences between the compared groups of patients by age, anthropometric indicators, the degree of prolapse and the history of surgical interventions for urogynecological pathology have not been obtained.

All patients underwent transvaginal reconstruction of the anterior and apical sections of the pelvic floor with the Pelvix Anterior endoprosthesis using trocar and non-trocar techniques. The mean age of patients was 63.12 ± 7.08 years (from 47 to 85) observation period was 9 months (from 6 to 12). Assessment of subjective complaints was carried out

using validated questionnaires: PFDI-20 (Pelvic Floor Distress Inventory), PFIQ-7 (Pelvic Floor Impact Questionnaire). The degree of prolapsed expression was determined by the POP-Q system (Pelvic Organ Prolapse Quantification). Relapse was the presence of prolapse in the operated compartment ≥2 degree. All patients underwent uroflowmetry with determination of residual urine volume.

In most cases, endotracheal or intravenous anesthesia was used as an anesthetic (epidural anesthesia according to indications).

The operating procedure used.

First group patients underwent synthetic endoprosthesis implantation, established according to the trocar free technique. Harpoon elements fixation was carried out in the sacrospinal ligaments and obturator membranes.

Second group patients were performed by the the synthetic endoprosthesis installation of "Pelvix Front" according to the standard trocar technique described earlier [5].

All patients underwent standard intraoperative antibiotic prophylaxis according to the results of urine culture on flora, sensitivity to antibiotic and allergic anamnesis. In case of the absence of growth of bacterial flora, according to the urine culture data, antibacterial prophylaxis was carried out with the use of cefoperazone - 1 g intravenously, 30-90 minutes prior to the beginning of the operation.

The complex of descriptive statistics for the results obtained, taking into account the number of observations, included mean values, standard deviations, minimum and maximum values, and medians. Statistically significant was the value of $p < 0.05$. All calculations were carried out using the system StatisticaforWindows version 10 (StatSoftInc., Tulsa, OK, USA).

Results and discussion.

In the course of the analysis of the received information, the absence of a statistically significant correlation between the anthropometric data of patients with interobtrusive and interstitial distances was revealed.

However, it is determined that these distances have minimal variability. The results of the statistical analysis of the obtained data are presented in Table 1.

Table 1 - Statistical characteristics for interobturation and interstitial distances

	mean±sd	Minimum ÷ maximum	Me (LQ;UQ)
Height, cm	162,55±6,24	147÷175	162 (158;167)
Weight, kg	72,89±12,63	50÷115	72 (65;80)

Interstitial distance, mm	108,03±5,91	96,14÷124,04	107,54 (104,21;111,85)
Interobtrator distance, mm	61,09±4,71	49,2÷71,67	61,19 (57,67;64,87)

The data are presented as the average standard deviation or the number represented by the upper and lower limit.

According to the calculations, it is determined that the average interstitial distance is equal to 108.03 ± 5.91 mm, and the statistical median is 107.54 mm. For the interobtrator distance, the mean values are 61.09 ± 4.71 mm, the statistical median is 61.19 mm.

Studying the vascular architectonics of implantation zones of harpoon elements, it is determined that the harpoon element optimal zone of implantation in the sacrospinal ligament is 1.5-2.5 cm from the sciatic forearm towards the sacrum (due to the variants of the passage of the lower gluteal artery).

And "avascular" zone in the obturator hole, the most suitable for the installation of the harpoon element, is in the lower medial corner, since the vascular-neural bundle passes through the upper-lateral angle. 4. The data obtained coincide with the results of C. Chen et al. (2007) [6].

Analyzing the received information concerning the average statistical value of inter-partum and interobtrusive distances and safe points of installation of harpoon elements, calculation of the optimal length of the mesh legs for the non-stunning technique of installing a synthetic mesh using harpoon elements was performed. When calculating the necessary length of the prosthetic legs, consideration was given to the location of nearby anatomical structures (rectum, bladder neck, urethra). The optimal size of the interstitial part of the prosthesis to avoid squeezing the rectum with a prosthesis from the outside exceeds the inter-active distance by an average of 3 cm, the data are shown in Figure 5 (projection line).

The optimal size of the anterior part of the implant prosthesis is 4 cm higher than the intertubator distance. This reserve is necessary to bypass the urethra and neck of the bladder, which will eliminate the risk of obstruction of the above structures.

To evaluate the tear load of harpoon element in postmortem compartment with 10 fresh female cadavers after performed before complete Shore evisceration through vagina, there was manual identification sacro-spinous ligaments and obturator membranes with subsequent implantation in the aforementioned connective structure harpoon elements via a universal fixing device with subsequent by determining the separation load of the anchor elements performed. Total 20 holds spear successful implantations latches in the sacrospinous ligament

(CBS) and the obturator membrane (OM). During the analysis of the obtained data, it was established that the average tear-off load for the sacro-ovary ligament is 40.34 ± 1.45 N, and for the obturator membrane 22.44 ± 0.63 N. There were no statistically significant differences in septic load between the sacro-osteous ligaments of different corpses and between the right and left sacro-neural ligaments of corpses (p >> 0.05 Wilcoxon). There were also no statistically significant differences between the septic load of the obturator membranes of various corpses and between the right and left corpse membranes (p >> 0.05 Wilcoxon). Taking into account the absence of the cases of harpoons breaking from the ligaments and membranes during their installation, Fisher's angular transformation equal to 0 ÷ 2.4% was used to calculate 95% of the confidence interval. According to a study by M. Cosson et al., (2003) [7], where the pelvic ligament strength was assessed on corpses, the minimum ligament strength was 20H. Considering that all the measured peel loadings of the PFCs were over 20N, it can be concluded that the harpoon elements have sufficient fixing capacity and their ability to withstand the necessary loads.

Comparison of the anatomical and subjective efficacy of the performed surgical correction in patients of groups 1 and 2**.**

The results of comparison of anatomical efficacy are presented in Table 2.

Table 2 - Comparison of anatomic efficacy of surgical correction performed in groups 1 and 2 (POP-Q), n = 138

	Meanings±CO				
	Before surgery		After 1 month		After 12
Точки POP-Q, см	1 group n, 69	2 group n, 69	1 group n, 69	2 group n, 69	1 group n, 69
Aa*	+2,0±0,9	+2,0±0,6	−2,5±0,6	−2,0±0,6	−2,4±0,5
Ba*	+3,5±1,1	+3,4±1,0	−2,5±0,8	−2,2±0,6	−2,5±0,6
C*	-0,2±1,9	-0,1±1,8	−6,8±1,6	−5,7±0,9	−6,9±0,6
Ap†	-2,8±0,3	-2,7±0,2	−2,7±0,6	−2,4±0,6	−2,7±0,7
Bp†	-2,9±0,2	-2,8±0,2	−2,6±0,7	−2,0±0,8	−2,6±0,7
Gh†	3,7±0,8	3,7±0,9	3,2±1,3	3,2±1,3	3,2±1,1
Pb†	2,5±0,5	2,4±0,5	2,6±0,4	2,6±0,4	2,6±0,5
Tvl†	7,4±0,9	7,3±0,8	7,4±1,0	7,4±1,0	7,3±1,5

* p <0.05, † (p> 0.05). The data are presented as the mean value of standard deviation.

Analyzing the obtained results, it is determined that the frequency of relapses of prolapse in patients of the second group (trocar technique) is significantly greater than in patients of the first group (trocar free technique) (p <0.05). Thus, in the first group of patients, 2 cases of prolapse recurrence were recorded, which determined the value of anatomical efficacy in 97.1%, while in the second group there were 10 cases of prolapse relapse, indicating 85.5% of the effectiveness of this technique.

In comparing the subjective effectiveness of operational procedures, the PFDI-20 and PFIQ-7 questionnaire data were compared before and after treatment in Group 1 and 2 patients. The results are shown in Table 3.

Table 3 - Results of comparison of subjective efficacy of performed surgical correction in patients of the first and second groups, n = 138

	Meanings±CO					
	Before surgery		After 1 month		After 12 months	
	1 group	2 group	1 group	2 group	1 group	2 group
PFDI-20	126,3±49,5 (12,5-262,5)*	124,6±61,2 (29-236) *	27,4±30,4 (0-156,2)*	23,5±19,0 (0-83,3) *	8,6±13,4 (0-46,8)*	9,4±14,4 0-87,5)*
PFIQ-7	123,2±58,9 (37,5-275)*	117,2±46,9 (28,5-217,1)*	11,4±18,4 (0-87,5)*	19,9±34,5 (0-185,7)*	3,5±9,7 (0-50)*	44,2±47,8 (0-257) *

* p <0.05, † (p> 0.05) The data are presented as the mean standard deviation, or the number represented by the upper and lower limit.

Analyzing the results obtained, a statistically significant, higher subjective effectiveness of the non-trocar reconstructive technique is shown, which is manifested by a smaller number of points in the completed PFDI-20 and PFIQ-7 specific questionnaires at follow-ups of 12 months (p <0.05).

When analyzing the operating time, bed-day, intraoperative blood loss, there were no statistically significant differences between the groups. The results of comparison of intraoperative, early postoperative complications of patients of the first and second groups are presented in Table 4.

Table 4 - Intra-, early surgical complications of patients of the first and second groups

Operational complications	1 group	2 group
Damage to the bladder, n	0 †	2†

Damage to the rectum, n	0†	0†
Hematoma in operation area (>50 ml), n	1†	0†
Bleeding (> 100 мл), n	1†	1†
Retention of urine (>50 ml), n	2†	0†
Urinary incontinence de novo, n	10†	7†
Overactive blader, n	7†	3†
Pain syndrome, n	2†	4†
Relapse of prolapse, n	2†	0†
De novo prolapse, n	0 †	0 †
Erosion of the mucosa, n	0†	0†
Urinary tract infection, n	1†	0†

* p <0.05, † (p> 0.05). The data are presented as the number of cases.

The results of comparison of late postoperative complications of patients of the first and second groups are presented in Table 5.

Table 5 - Late surgical complications of patients of the first and second groups

Operational complications	1 group	2 group
Urinary retention (>50 ml), n	1†	0†
Urinary incontinence de novo, n	10†	7†
Overactive blader, n	0 †	0 †
Pain syndrome, n	1†	0†
Relapse of prolapse, n	0 *	10*
«de novo» prolapse, n	1†	4†
Эрозии слизистой, n	0†	1†
Urinary tract infection, n	0†	0†

* p <0.05, † (p> 0.05) Data are presented as the number of cases.

During the analysis of intraoperative, early (<30 days) and late postoperative complications (> 30 days), a statistically significant difference in the incidence of complication was noted only in the index of prolapse relapse in the late postoperative period (p <0.05). For the remaining comparable indicators, no statistically significant differences were obtained.

Discussion: With the non-trocar technique of pelvic prolapse reconstruction, the risk of recurrence of pelvic prolapse in the apical compartment is significantly reduced in comparison with the trocar implantation method (2.79% vs. 14.49%), (p <0.05).

The results obtained in assessing the anatomical and subjective efficacy of the trocar free technique of reconstructing the anterior and apical compartments of the pelvic floor with the Pelvix Anterior prosthesis are similar to those obtained in foreign studies conducted to assess the effectiveness of SIMS. Thus, in the Anterior Elevate System (AES) study [8], the anatomical efficacy with the prosthesis (PP) was 97.1%, versus 90% (AES). Urine retention developed in 2 cases (2.89%) with prosthesis (PP), versus 1 case (3.0%) (AES). The pain syndrome requiring NSAID prescription in 2 cases (2.89%) (PP), versus 1 case (3.0%) (AES). Rectocele de novo - 1 case (1.44%) (PP) vs (3.0%) (AES). It should be noted that there was not any case of erosion of the vaginal wall detected during the whole period of the observation of the prosthesis (PP), against 2 cases (5.0%) (AES). Most likely, this fact is due to subfascial implantation of the prosthesis (PP) and its super-light structure. Similar performance data and complication rates during installation (AES) are presented in the work of other authors (Kuan-Hui Huang etal., 2015) [9]. The average duration of this study observation is 27 months. Anatomical efficacy was 95% (POP-Q), relapse of prolapse occurred in 5 patients (2.5%), pain syndrome in 6 cases (3.0%), 3 episodes of urinary retention (1.5%), urgency of 19 cases (9.5%), internal bleeding - 1 case (0.5%), hematoma in the operation area - 3 cases (1.5%), erosion 4 cases (2%). According to the study (Tsia-Shu Lo etal., 2014), with observation duration up to 1 year, the objective efficacy was 96.9% (POP-Q), subjective 93.8% (assessed using the POPDI-6, UDI-6, PISQ-12 questionnaires , IIQ-7) [10]. In this study, there was also no case of erosion of the vaginal wall. The authors suggest that this fact is due to the subfascial technique of installing the prosthesis. In the study (Rogowski A.et al., 2015), with a observation period up to 18 months: with a similar anatomical system efficiency (AES) of 88 to 92%, subjective efficacy in setting this system is 76%, and the incidence of dyspareunia is equated to 11.3% [11]. In this study, during the entire observation period, there are no cases of erosion identified. Authors relate this fact to the size / material intensity of the prosthesis. Comparing the results of the study with the work (Gregory P. Et al., 2012), a shorter operating time was noted: 40.5 minutes (20-205) - (with the non-coarse method of setting the PP), against 69 minutes (52, 123) - (Elevate). At the same time, with the installation of Elevate prosthesis, the average bed-day is 1.0 (1.5, 2.0), against 3.1 (2.0, 13.0). Hematomas in the area of operation were encountered in 1 case (1.44%) with installation (PP), versus 2 (5.7%) Elevate. Urinary retention in the early postoperative period - 4 episodes (3%) when installed (PP) and in 7 cases (19%) when Elevate is installed [12].

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