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SUBJECTIVE AND OBJECTIVE ASSESSMENT OF THE STATUS OF QUALITY OF LIFE BEFORE AND AFTER SURGERY USING MESH IMPLANTS

Hypothesis/Aims of study:
Quality of life after the reconstructive pelvic surgery is currently one of the most followed criteria of success of these operations. When using conventional surgical techniques was a major sign of the success the resulting anatomical effect. After spreading the new generation of synthetic mesh implants, which seek to achieve maximum success in minimally invasive way, the requirement of substantial improvement in quality of life of patients has become a fundamental parameter of evaluation of surgical procedures. Our urogynecological department research with this issue systematically since the first operations carried out in 2005. Currently we have a representative sample of patients who have compared the quality of life before and after reconstructive surgery performed by a series of standardized questionnaires but also by the subjective opinion of a patient. The aim of this paper is to present the results of subjective and objective assessment of the status of quality of life before and after surgery using mesh implants.
Study design, materials and methods:
This is an open, prospective, observational study of patients operated with the Prolift^{TM} technique at one center between June 2005 and April 2009. A total of 161 women were included in the study (drop out 16 patients - 9.9%). Overall, 145 patients were available for 1-year follow-up. The pre- and postoperative evaluation (6 weeks, 3 months, 6 months and 1 year) comprised of a vaginal examination with the grading of the defect according to the POP-Q system of the ICS. Patients self-evaluated the severity of their symptoms with the use of a visual analog scale (VAS) ranging from 0 to 10 as well as with the use of subjective evaluation (SE) in four grades as excellent, very good, good and poor. The quality of life evaluation was performed with standardised questionnaires (PISQ 12, UIQ, CRAIQ, POPIQ, UDI, POPDI and CRADI) distributed before and one year after the surgery. Examination program consisted of history including exclusion criteria (patients with evidence of malignant lesion in small pelvis, history of radiotherapy in small pelvis, patients suffering from any form of PID within inclusion process, pregnancy, lactation, total eversion of uterus and vagina, serious internal disorders, history of recto- or vesicovaginal fistula, history of rejection of any arteficial material, symptoms of primary genuine stress urinary incontinence, patients who were not able to subscribe the informed consent and patients, who couldn´t be reached for follow-up) and inclusion criteria (female sex, age 18 and more, subscribed informed consent, objective symptoms of prolapse-POP-Q 2 and more according to ICS standards, compliance of the patients), urodynamics and perineal ultrasound. The surgical procedures were: Total Prolift repair - 50 (34.5%), Anterior Prolift repair 33 (22.8%) and Posterior Prolift repair 62 (42.8%). Overall, 78.6% women had a prior hysterectomy and 80.7% had a previous POP surgery. Concurrent procedures (vaginal hysterectomy, sacrospinous fixation, enterocele repair, levator ani myorrhaphy and sling procedures) were not performed. For statistical evaluation paired t-test with 95% confidence interval has been used.
Results
The results are listed in tables below.
Table 1

SE (n/%)	6 weeks	3 months	6 months	12 months	missing
excellent	21/14,5	24/16,6	32/22,1	26/17,9	13/9,0
very good	88/60,7	82/56,6	71/49,0	77/53,1	10/6,9
good	21/15,9	29/20,0	30/20,7	29/20,0	12/8,3
poor	-/-	-/-	-/-	2/1,4	11/7,6

SE: Subjective Evaluation
Table 2

	VAS-BO	VAS-AO 6w	VAS-AO 3m	VAS-AO 6m	VAS-AO 12m
mean	7,202	3,327	2,809	2,802	2,889
n	139	136	137	140	140
SD	2,0702	2,2267	1,8462	1,9706	2,1430

VAS: Visual Analogue Scale, BO-before operation, AO- after operation
Table 3

	mean	SD	sig. (2-tailed)
PISQ 12 BO- PISQ12 AO	-,97	10,78	,443
UIQ BO- UIQ AO	36,580	83,632	,001
CRAIQ BO- CRAIQ AO	14,075	69,703	,111
POPIQ BO- POPIQ AO	42,483	90,337	<,001
UDI BO-UDI AO	21,171	37,133	<,001
POPDI BO- POPDI AO	28,051	39,863	<,001
CRADI BO- CRADI AO	11,142	35,989	,010

SD- standard deviation, BO- before operation, AO- after operation
Interpretation of results
All evaluation methods except PISQ 12 showed statistically significant improvement of patients´ quality of life after the procedure compared to the conditions before the surgery. The possible explanation is that most of the patients don´t have the sexual intercourse and that the mesh procedures are not primary used for the the treatment of urinary inkontinence.
Concluding message

The results of this study proved patients´satisfaction with new mesh procedures as well as usefulness of chosen methods for evaluation of quality of life after the pelvic reconstructive surgery.

Specify source of funding or grant	**NONE external fundings or grants were used for performing this study**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**The Local Ethics Committee of The Institute for the Care of Mother and Child**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**