526

Krcmar M[1], Krofta L[1], Otcenasek M[1], Kasikova E[1], Feyereisl J[1]
1. *Institute for the care of mother and child*

QUALITY OF LIFE AFTER PELVIC FLOOR RECONSTRUCTIVE SURGERY USING SYNTHETIC IMPLANTS: 1-YEAR FOLLOW-UP

Hypothesis / aims of study

The general effort in reconstructive surgery is to operate in physiological way- considered on anatomy of the target structures. The last decades of twentieth century brought a wide range of new discoveries of the pelvic floor anatomy. The biomedical research in the area of inertial materials turned out specific arteficial implants (meshes).The implantation of such meshes allows site-specific repair of injured areas of endopelvic fascia. Pilote studies mostly proved superior anatomical effext with the minimum of side-effects. But those studies were frequently performed on statistically insignificant population with unclear long-term effects. The quality-of-life (QOL) hasn´t been systematically reviewed but nowadays QOL has become the main topic of research interest in all respected urogynecology centers around the world.Aim of the study verification of practical efficiency of the implants on satistically significant population through objective evaluation by standardised QOL-questionnaires distributed before and after the performed reconstructive operation.

Study design, materials and methods

Our study was held as open, prospective and non-randomised. 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 1 and more according to ICS standards, compliance of the patients), urodynamics and perineal ultrasound. A total of 123 women were included in the study (drop out 8 patients-6.5%). Overall, 115 patients were available for 1-year follow-up, which has been operated from 2005 to 2008. For the operations we used Prolift meshes (Gynecare, Johnson and Johnson) in all versions (anterior, posterior or total Prolift) according to the dominant type of defect. The quality of life evaluation was performed with standardised questionnaires (PISQ 12, ICIQ-UI, UIQ, CRAIQ, POPIQ, UDI, POPDI and CRADI) distributed before and one year after the surgery. For statistical evaluation paired t-test with 95% confidence interval has been used.

Results

The results are listed in table below, which contains standard deviations between questionnaire scores before and one year after the procedures.

PISQ 12 BO- PISQ12 AO	0.889
UIQ BO- UIQ AO	<.001
CRAIQ BO- CRAIQ AO	.015
POPIQ BO- POPIQ AO	.002
UDI BO- UDI AO	<.001
POPDI BO- POPDI AO	<.001
CRADI BO- CRADI AO	.002
ICIQ-UI BO- ICIQ –UI AO	.062

BO- before operation, AO- after operation

Interpretation of results

All questionnaires except PISQ 12 and ICIQ-UI 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 incontinence.

Concluding message

The results of this study proved patients´satisfaction with new mesh procedures as well as usefulness of chosen questionnaires for evaluation of quality of life after the pelvic reconstructive surgery. However, further analysis of anatomical and functional effects in the future will be needed

Specify source of funding or grant	**Internal Grant Agency, Mininstry of Health, Czech Republic, grant number NR 93 9309-3**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**NCT00572702, FDA**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Local Ethic Comitee, Institute for the care of mother and child**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**