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SIX YEARS EXPERIENCE OF USING MESH IMPLANTS IN PELVIC FLOOR RECONSTRUCTIVE SURGERY

Hypothesis / aims of study
The aim of this prospective study was to assess long term outcome (5 to 6 years) of the trocar-guided mesh surgery to correct POP by the vaginal approach.
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 December 2010. A total number of 213 women were included in the study during this period. Overall, 61 patients have been operated during 2005 and 2006 with drop-out of 8 patients (13%) for follow-up. The pre- and postoperative evaluation (1 month, 3 months, 6 months, 1 year and once per year) comprised of a vaginal examination with the grading of the defect according to the POP-Q system of the ICS, completing PFDI, PFIQ, ICIQ and PISQ questionnaires and MRI scan before and after the procedure. Patients self-evaluated the severity of their symptoms with the use of a visual analog scale (VAS) ranging from 0 to 10. All the patients had stage 2 or greater POP-Q prolapse preoperatively. The surgical procedures were: total Prolift - 20 (37.8%), anterior Prolift 13 (24.5%) and posterior Prolift repair 20 (37.8%). Overall, 43 (81%) women had a prior hysterectomy and 47 (89%) had a previous POP surgery. Concurrent procedures were not performed. For statistical evaluation paired t-test with 95% confidence interval has been used.
Results
The mean age was 60.6 years (32-84), mean BMI 25.6 (20.2-39,3) kg/m^2, and mean parity was 2.5 (1-8). The mean operating time was 73,1 min (20-135), and mean blood loss 83,77 ml (20-250). There was one (0,53%) major peroperative complication: bladder perforation recognized during surgery. There were no other complications such as urethral, nerve or bowel injury or serious bleeding. Early postoperative complications (day 0-7): urinary tract infection-1 (0,53%), febrile morbidity-0%, deep hematoma-0%, urinary retention-0%.
After 6 and 5 years follow-up of those patients 44 women (83%) were anatomically cured of prolapse, whereas 9 (27%) women had a POP defect ≥ Gr. II. However 6 (11.3%) had the recurrent defect, while 3 (5.7%) patients developed symptomatic POP on the opposite side of the previously well-supported compartment. In the anatomically cured group, where mesh was inserted only in the anterior compartment, we found statistically significant changes in POP-Q points: Aa, Ba, C and D. Points Ap, Bp, TVL, gh and pb were not statistically different. In the anatomically cured group, where mesh was inserted only in the posterior compartment, we found statistically significant changes in POP-Q points: Ap, Bp and D. Points Aa, Ba, C, TVL, gh and pb were not statistically different. In the anatomically cured group where mesh was inserted in both compartments, we found statistically significant changes in POP-Q points: Aa, Ba, C, D, Ap, Bp, TVL. Points gh and pb were not statistically different. The mesh exposure rate was 3,78%. Mean time to exposure was 12 months. De novo stress urinary incontinence (SUI) occurred in 18 (34%) patients. Mean time to SUI was 1.03 months. De novo urgency occurred in 7,55%. One year after the procedure 54% of women were not sexual active, 44% had normal sexual activity and 2% sufferred from de novo dyspareunia. There was a significant decrease in the mean VAS score from 8.52 to 3.36 in the anatomically cured group without de novo SUI, urgency, pelipathia and dyspareunia (p<. 001). The results of MRI as well as QoL questionnaires are not included in this text.
Interpretation of results
The anatomically cured group in our surgically high-risk population was 83%. This number could be decreased by 3 cases (5,66%) where POP developed on the contralateral side to where the primary implant was inserted. This raised the question of whether we are able to accurately estimate the degree and extent of prolapse in all patients in the framework of clinical examination. Perhaps utilization of other imaging techniques could help (US, MRI). Nevertheless, recurrence may occur despite mesh repair. The low mesh exposure rate is associated with proper mesh placement and uterus preservation. The high incidence of de novo SUI must be included in the informed consent.
Concluding message
Our findings suggest that the interposition of a monofilament polypropylene mesh by the vaginal route seems to be an effective procedure for repair of recurrent vaginal wall prolapse. The new methods are associated with low morbidity in the surgically high-risk population. However, some of these complications can be serious and need highly specialized management and highly skilled surgeons.

Specify source of funding or grant	**NONE**
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 Institute for the care of mother and child**
Was the Declaration of Helsinki followed?	**Yes**

Was informed consent obtained from the patients?	**Yes**