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MESH IMPLANTS IN PELVIC ORGAN PROLAPSE SURGERY: PROSPECTIVE STUDY - ONE YEAR FOLLOW-UP

Hypothesis / aims of study
The use of vaginal synthetic mesh procedures to correct pelvic organ prolapse (POP) have become increasingly popular. There is still a paucity of studies evaluating long-term outcomes and complications of these procedures. The aim of this prospective study was to assess one-year outcome of the Prolift™ technique 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™ 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 (1 month, 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. All the patients had stage 2 or greater POP-Q prolapse preoperatively. 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 mean age was 59.1±9.2 years (range 32-84), mean BMI 27.4±3.7 (range 19.8-38.9) kg/m^2, and mean parity was 2.3±1.15 (range 0-8). The mean operating time was 81.9±37.7 min. (range 30-260), and mean blood loss 113±228 ml (range 10-2600). There were four (2.8%) major peroperative complications: one (0.7%) bladder perforation recognized during surgery and three (2.1%) severe bleeding episodes (paravesical vein varices, with blood loss of 800, 1200 and 2600 ml) requiring laparotomy. There were no other complications such as urethral, nerve or bowel injury. Early postoperative complications (day 0-7): a) urinary tract infection-12%, b) febrile morbidity-5.5%, c) deep hematoma-0.7%, urinary retention-0%. At the 1-year follow-up 117 women (80.7%) were anatomically cured of prolapse, whereas 28 (19.3%) women had a POP defect ≥ Gr. II. However only 21 (14.5%) had the recurrent defect, while 7 (4.8%) 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 4.2%. The defect was mostly localized in the posterior compartment - 2,8%. Mean time to exposure was 5.5 months. De novo stress urinary incontinence (SUI) occurred in 28.2% patients. Mean time to SUI was 1.03 months. De novo urgency occurred in 23.4%. De novo pelipathia occurred in 11% of patients. One year after the procedure 46.9% of women were not sexual active, 40.7% had normal sexual activity and 10.3% sufferred from de novo dyspareunia. There was a significant decrease in the mean VAS score from 7.2±2.07 to 2.8 ±2.14 in the anatomically cured group without de novo SUI, urgency, pelipathia and dyspareunia (p<. 001).
Interpretation of results
The anatomically cured group in our surgically high-risk population was 80.7%. This number could be decreased by 7 cases 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 (4.2%) 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.

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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 Ethic 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**