

MESH IMPLANTS IN PELVIC ORGAN PROLAPSED SURGERY: ONE YEAR FOLLOW-UPHypothesis / 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 March 2008. 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. The pre- and postoperative evaluation (1 month, 3 months, 6 months and 1 year) comprised 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 a stage 2 or greater POP-Q prolapse preoperatively. The evaluation also included the QoL questionnaire; the results will be presented in another study. The surgical procedures were Total Prolift repair (32.2%), Anterior Prolift repair (22.6%) and Posterior Prolift repair (45.2%). Overall, 83.5% women had a prior hysterectomy and 86.1% had a previous POP surgery. Concurrent procedures (vaginal hysterectomy, sacrospinous fixation, enterocele repair, levator ani myorrhaphy and sling procedures) were not performed. The evaluation of quality of life is the subject of another study.

Results

The mean age was 59.23±9.6 years (range 32-84), mean BMI 27.41±3.9 (range 19.8-38.8) kg/m², and mean parity was 2.29±1.15 (range 0-8). The mean operating time was 77.43±33.9 min. (range 30-260), and mean blood loss 113.8±254.3 ml (range 10-2600). There were three major peroperative complications: one bladder perforation recognized at surgery and two severe bleeding episodes (paravesical vein varices, with blood loss of 1200 and 2600 ml) requiring laparotomy. There were no other complications such as urethral, nerve or bowel injury. Patients who needed further repair for recurrence (7.8%) or patients with stage 2 POP-Q prolapse in any compartment at follow-up (9.5%) were considered as failure. Three patients had recurrence in another previously well-supported compartment (2.6%). Mesh exposure rate was 3.47%. Mean time to exposure was 7.2 months. De novo stress urinary incontinence (SUI) occurred in 28.6% patients. De novo dyspareunia and pelipathia occurred in 4 (3.4%) and 5 (4.3%) patients, respectively. There was a significant decrease in the mean VAS score from 7.47±2.04 to 2.18 ±2.18 (p<. 001).

Interpretation of results

The objective success rate in our surgically high-risk population was 82.6%. Nevertheless, recurrence may occur despite mesh repair. The low mesh exposure rate (3.47%) 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 definitive 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

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<i>Is this study registered in a public clinical trials registry?</i>	Yes
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<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	Local Ethic Comitee, Institute for the care of mother and child
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes