



**Karolinska  
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# Transvaginal Mesh for Pelvic Organ Prolapse – Clinical and Histological Aspects

AKADEMISK AVHANDLING

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av

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## ABSTRACT

The objectives of this thesis were to assess the objective, clinical, and sexual outcomes after transvaginal surgery for pelvic organ prolapse using a trocar guided mesh kit, to ascertain the vaginal in vivo histological inflammatory response to large mesh, and to identify possible risk factors associated with exposures after transvaginal mesh surgery.

A prospective multicenter cohort study was performed between June 2006 and March 2007 throughout 26 clinics in the Nordic countries. The 261 women included underwent pelvic organ prolapse surgery with the Prolift® mesh kit and were examined at baseline, two months and one year regarding objective anatomic prolapse stage, signs of vaginal inflammation and subjective symptom assessment. We found satisfactory anatomic cure rates (between 79 and 86%), few serious complications (3.4%) and exposures in 11%. Subjective improvements were seen in both questionnaire scores though not specifically for stress urinary incontinence.

Among women undergoing the above prospective multicenter cohort study, sexually active women were separately analyzed with regard to sexual function before and one year after surgery using a specific questionnaire. Overall symptom scores deteriorated at one year after surgery irrespective of the surgically corrected compartment and of anatomical corrective success. The deterioration was attributed primarily to behavioral/emotive and partner related items and not specifically to dyspareunia.

To determine the histological inflammatory response to large vaginal mesh, a histological study was performed. Ten women undergoing prolapse surgery using mesh from the prospective cohort study above underwent vaginal punch biopsy sampling prior to surgery and one year after. The specimens were analyzed microscopically regarding inflammatory response and compared to 8 healthy controls. At one year, a persisting low grade host-implant reaction was seen in patients.

Data from the above prospective cohort study was combined with data from a randomized controlled study comparing transvaginal mesh surgery for anterior prolapse with traditional plication techniques. Only women undergoing anterior repair with mesh were analyzed and potential risk factors for developing exposures were assessed. We found that women who smoked, had given birth to more than two children and who had systemic inflammatory disease had greater odds of developing exposures.

In conclusion, the four studies in this thesis have shown that transvaginal mesh for pelvic organ prolapse provides satisfactory anatomical and subjective cure rates at one year with relatively few serious adverse events. However there are significant risks of deteriorated sexual function (especially in behavioral/emotive and partner related aspects), vaginal non infectious inflammation and mesh exposures. We have shown that women who smoke, have more than two children and suffer from somatic inflammatory disease are at greater risk of mesh exposures. In spite of partly encouraging results, the findings pose significant challenges to the overall success and acceptance of the procedure. Prior to recommending the use of mesh for pelvic floor correction, all available information on symptoms, the nature of the prolapse, surgical short and longterm outcomes as well as potential risks and benefits must be adequately analyzed and considered.