

## LONG TERM EFFICACY AND PATIENT SATISFACTION OF PELVIC ORGAN PROLAPSE REDUCTION USING TRANS-VAGINAL MESH

### Hypothesis / aims of study

The use of synthetic trans-vaginal mesh for surgical reduction of pelvic organ prolapse (POP) has been proven to be safe and effective (1). However, the American Food and Drug Association (FDA), as well as Health Canada, have published various warnings (2,3) concerning the safety of these meshes. When compared to traditional non-mesh POP repair, they report similar efficacy, but with increased risk of adverse events, such as vaginal mesh extrusion and chronic pelvic pain.

Our objective is to present our center's data on POP reduction surgery using synthetic trans-vaginal mesh, focusing on recurrence and complication rates, as well as patient subjective satisfaction.

### Study design, materials and methods

We retrospectively reviewed the charts of 225 patients, aged between 44 and 95 years (mean age 70.1 years), who underwent POP reduction surgery using trans-vaginal mesh in our center, between 2000 and 2013. 211 (93.7%) of our patients had POP affecting multiple compartments. 204 (90.7%) suffered from anterior compartment prolapse (cystocele) of which 68.4% were considered high grade (grade  $\geq 3$ ). 203 (90.2%) had middle compartment prolapse (uterine prolapse or vaginal vault prolapse) of which 44.4% were high grade, and 196 (87.1%) had posterior compartment prolapse (rectocele), of which 44.4% were high grade. 69 (30.7%) of patients had an associated enterocele. A single fellowship-trained urologist performed all surgeries.

The most frequent types of mesh used were: Prolift (54.6%), Exair (13.3%), Dexon (10.2%), Elevate (8.9%) and Avaulta (5.7%).

Post-operative follow-up consisted of visits at 2 months, 6 months, then yearly for a total of 3 to 5 years. After ethics committee consent, patients were contacted via telephone and asked to participate in a long-term follow-up clinic, consisting of a questionnaire and a gynecological exam. Patients who declined follow-up had the option to answer the questionnaire by telephone.

Collected information included patient pre-operative characteristics, type of surgery and mesh used, post-operative gynecological exams (S-POPQ) performed by an independent examiner, and patient subjective satisfaction (Patient Global Impression of Improvement score - PGI-I).

### Results

Median post-operative follow up was 36 months (2 – 154 months) for gynecological exam, and 38 months (2 – 154 months) for questionnaire/PGI-I. Of these 225 patients, follow-up gynecological exam revealed that 45 (20.0%) patients suffered from recurrent prolapse of a compartment previously reduced using trans-vaginal mesh. Of these patients, 8 (3.6%) were symptomatic of their recurrent POP. 20 patients (8.9%) developed POP in a new compartment, which had not been addressed during initial mesh repair. A total of 17 (7.5%) of patients required subsequent surgery: 8 (3.6%) for recurrent/persistent POP, 4 (1.8%) for unmasked/persistent urinary incontinence, and 5 (2.2%) for both.

There was no statistically significant difference in the rates of prolapse recurrence and post-operative complications in regard to the type of mesh used.

6 patients (2.6%) suffered from vaginal mesh extrusion, of which 3 patients (1.3%) were symptomatic and 4 (1.8%) required surgical revision. No cases of urethral or bladder erosion were reported.

There were 5 accounted cases of post-operative dyspareunia, 2 cases of chronic pelvic pain, and 2 cases of vaginal bleeding not explained by mesh extrusion nor another urogynecological pathology. Globally, 194 (86.2%) of patients reported that they were subjectively improved by their surgical intervention, with 160 (71.1%) patients reporting that they were very much improved (PGI-I score of 1).

### Interpretation of results

The FDA reported multiple and severe adverse events occurring after placement of trans-vaginal mesh for POP repair, including : a vaginal extrusion rate of 10%, with half of these patients requiring surgical excision ; chronic pelvic pain and dyspareunia occurring in up to 50% of patients.

In our center, the vast majority of patients presented with high grade and multiple compartment POP. The rate of post-operative adverse events were much lower than reported by the FDA, symptomatic recurrence requiring re-operation was rare, and patient subjective satisfaction was high.

### Concluding message

The use of trans-vaginal synthetic mesh for surgical reduction of symptomatic and severe POP, in the hands of a trained surgeon and with appropriate indication, is a safe and effective option. Post-operative patient subjective satisfaction is high. The rates of post-operative adverse events, such as vaginal mesh extrusion and chronic pain, are lower than previously reported by the FDA.

### References

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### Disclosures

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