

## ANATOMIC, FUNCTIONAL AND ULTRASOUND OUTCOMES AFTER VAGINAL PROLAPSE SURGERY USING NON-ANCHORED MESH

### Hypothesis / aims of study

The objective of this study was to evaluate the anatomical and functional success rates at one year following vaginal surgery for symptomatic prolapse using non-anchored mesh and vaginal splint device (GYNECARE PROSIMA™). Secondary objectives included ultrasound assessment, Quality of life/ sexual function assessment, and complications.

### Study design, materials and methods

This was a prospective single-arm study of women with symptomatic prolapse surgically treated with non-anchored mesh and a vaginal support device. Additionally, a two layered closure of vaginal incision was employed in an effort to reduce the prevalence of mesh exposure. At baseline and 1 year 116 subjects underwent examination (ICS POP-Q) and completed questionnaires (PFDI-20, PISQ-12). Subjects completed a subjective global impression of success at 1 year. 118 patients were required for the 95% upper confidence interval assuming a failure rate of up to 20%. A subset of 72 women underwent a trans-labial ultrasound at their 1 year visit.

### Results

Of the 130 patients who completed the baseline analysis, 116 patients (89.2%) returned for follow up at one year. The mean age of women studied was 58.6 years. Anterior, posterior or combined compartment repair was performed in 6.0%, 18.1% and 75.9% of women respectively.

**Primary Outcome:** The success rate at 1 year was 92.2% (95% CI (85.8% - 96.4%). Success was defined as no symptom of bulge *with* the leading vaginal edge above the hymen *and* no re-intervention for prolapse,

**Secondary Outcome:** No intraoperative adverse events occurred. The prevalence of mesh exposure was 2.6%. There were significant improvements in QoL and sexual function at 1 year compared to baseline (PFDI-20  $P < 0.001$ , PISQ-12  $P = 0.008$ ). Good correlation noted between anatomical and functional outcomes (McNemars correlation test  $p = 0.7905$ , Cohen's Kappa coefficient = 0.2316). Transperineal ultrasound had a poorer correlation to clinical findings (McNemars correlation test  $p = 0.0313$ , Cohen's Kappa coefficient = 0.1577). Anterior mesh and the tapes (in women who had concomitant anti-incontinence surgery) were well visualised on ultrasound whereas there was difficulty in visualising mesh in the posterior compartment especially in patients with faecal loading. There appeared to be good mesh coverage over the repair site as noted on ultrasound in all the 72 patients. Levator avulsion was noted in 21 patients and 26 patients had a hiatal area  $> 30 \text{ cm}^2$  of which 12 patients had stage 2 prolapse on POPQ at follow-up.

### Interpretation of results

Cure rates after prolapse surgery can vary depending on the definition used. POP-Q stage 0 and 1 no longer seem appropriate because a substantial proportion of women in the general population without symptoms of POP would not meet these criteria. Therefore using the hymen as a threshold for anatomic success seems a reasonable approach<sup>1</sup>. Our study demonstrated good correlation between anatomical and functional outcomes and a 92.2% success rate using the primary objective as defined. This is comparable to the 91.4% anatomic success rate and 81% functional success rate reported by a previous study<sup>2</sup>. There was also a satisfactory safety profile at 1 year following pelvic organ prolapse surgery using the non-anchored mesh. There was a low mesh exposure rate of 2.6% which is less than the 4.6–10.7% mesh exposure rate noted in a recent systematic review<sup>3</sup>. This may be related to the double layered closure used in this study and the relatively thick suture line which resulted. The presence of levator avulsion or enlargement of the levator hiatus on ultrasound was not significantly associated with surgical failure at 1 year, possibly because of the low number of surgical failures in this study.

### Concluding message:

Vaginal surgery using non-anchored mesh and a vaginal support device provided good anatomic, functional and ultrasound outcomes 1 year following surgery with few complications. Significant improvements in QoL and sexual function were also observed. Trans-labial ultrasound assessment had a poorer correlation with anatomic outcomes than the correlation between anatomic and functional outcomes. This would suggest that clinical assessment of pelvic organ support is superior to trans-labial ultrasound.

### References

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### Disclosures

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