

## SHORT-TERM RESULTS OF SACROCOLPOPEXY WITH A NOVEL MESH DESIGN

### Hypothesis / aims of study:

To evaluate the short term safety and effectiveness of a new stronger lightweight mesh for the treatment of vaginal vault prolapse via sacrocolpopexy.

Study design, materials and methods: Prospective, observational single-center study of patients who have Stage III-IV vault prolapse and underwent sacrocolpopexy using a new polypropylene mesh. Short-term follow-up is reported at 6 weeks. Single-center study with one senior surgeon performing all procedures in an academic setting. Data was collected from 48 women with symptomatic pelvic organ prolapse over a 9 month period. The main eligibility requirements were women >18 years old, undergoing sacrocolpopexy for correction of vaginal vault prolapse. Patients were implanted with the Vertessa® Lite Polypropylene Mesh for Sacrocolpopexy (Caldera Medical, Agoura Hills, CA) via laparotomy. Data was collected pre-operatively, intra-operatively, and at 6-8 weeks follow-up. The primary outcome measure was post-op POP-Q stage. Secondary outcome measures were complications and patient satisfaction with surgery using the Patient Global Impression of Improvement (PGI-I).

Results: A total of 48 women with a mean age of 64 years (range 44 – 79) underwent sacrocolpopexy surgery utilizing a new stronger lightweight polypropylene mesh. Mean BMI was 28 (25-31), Mean Estimated Operative Time was 137 mins (85-165), Median Parity 2, Mean Estimated Blood Loss 81cc (75-95). Pre-op POP-Q Stage was either III (N=46) or IV (N=2). Concomitant hysterectomy was performed in 88% (42), suburethral tension free sling in 25% (12), anterior anterior in 75% (36) and posterior repair in 17% (8). Follow-up was 100% and mean follow-up time was 43 days (range 12 – 55 days). Outcomes show a significant improvement with  $\leq$  Stage I POP-Q in 97.9% of patients (47/48) and asymptomatic Stage II POP-Q in 2% (1/48). All but one patient completed the PGI-I questionnaire. Of the 47 who completed the PGI-I questionnaire, 60% (29/48) were Very Much Better and 38% (18/48) were Much Better after surgery. There were no mesh related complications. Complications included post-op ileus in 1 patient (2%) and superficial wound infection (seromas) in 2 patients (4%) that resolved with drainage, daily wound care and oral antibiotics.

### Interpretation of results/Concluding message:

Short-term results show that a new stronger lightweight mesh is safe and effective in for use in sacrocolpopexy procedures. Additional studies with large sample sizes and longer-term follow-up are needed.

### Disclosures

**Funding:** None **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** IRB Exempt Status **Helsinki:** Yes **Informed Consent:** Yes