

Lucente V¹, Jacquetin B², Miller D³, Berrocal J⁴, Clavé H⁵, Cosson M⁶, Debodinance P⁷, Garbin O⁸, Robinson D⁹, Rosenthal C¹⁰, Salet Lizée D¹¹, Villet R¹¹

1. Institute for Female Pelvic Medicine and Reconstructive Surgery, 2. Maternité Hôtel Dieu, CHRU de Clermont Ferrand , 3. Advanced Health Care, 4. Clinique de l'Europe, Rouen , 5. Clinique Saint George , Nice , 6. Hôpital Jeanne de Flandre, CHRU de Lille , 7. Maternité Les Bazennes, CH de Dunkerque , 8. SIHCUS- Centre Médico Chirurgical & Obstétrical, Schiltigheim , 9. Lincoln Center OB/GYN , 10. Clinique Saint Germain, Brive-La Gaillarde , 11. Groupe Hospitalier Des Diaconesses Croix St Simon, Paris

TRANS-VAGINAL MESH (TVM): AN INNOVATIVE APPROACH TO PLACING SYNTHETIC MESH TRANSVAGINALLY FOR SURGICAL CORRECTION OF PELVIC SUPPORT DEFECTS – PERI-OPERATIVE SAFETY RESULTS

Synopsis of video and aims of study

In response to a significant percentage of patients experiencing recurrent pelvic organ prolapse (POP) after pelvic reconstructive surgery, pelvic floor surgeons in France set out in 1998 to develop a single placement of synthetic mesh to address anterior, posterior, and vault prolapse concurrently. The technique that evolved involves a polypropylene mesh of specific size and shape that is secured tension free by extension arms that pass through the arcus tendineus via a transobturator approach anteriorly and through the sacrospinous ligament via a transgluteal approach posteriorly to create an anatomically correct repair. Surgeons may modify the mesh by cutting it in half to repair isolated defects of the anterior or posterior compartments. The objective of this presentation is to provide an effective video demonstration of the TVM technique with instrumentation that was subsequently developed since study completion. The instruments include a unique cannula system for deployment of the mesh with the intention of minimizing tissue trauma. Early safety results including peri-operative complications are also reported. Long-term data will be presented in the future to assess post-operative complications and effectiveness at 6 months, 1, 3, and 5 years.

Study design, materials and methods

The study is a prospective multi-center evaluation of 90 French and 90 US women with symptomatic POP (POP-Q stage II–IV). Evaluations are conducted pre-operatively and at 6 weeks, 6 months, 1, 3 and 5 years postoperatively. Peri-operative complications are reported on 180 subjects receiving treatment.

Results

To date, the early safety results are as follows:

| Peri-operative Complication | Incidence | Comment |
|------------------------------------|------------------|--|
| hematoma | 6/180 (3.3%) | one during oophorectomy procedure one resulted in abscess |
| hemorrhage | 3/180 (1.6%) | |
| rectal injury/wound | 2/180 (1%) | |
| urinary retention | 2/180 (1%) | |
| recto-vaginal fistula | 1/180 (0.5%) | |
| vesico-vaginal fistula | 1/180 (0.5%) | |
| ureteral stricture | 1/180 (0.5%) | with dissection |
| ureteral injury | 1/180 (0.5%) | with hysterectomy procedure |

Interpretation of results

The peri-operative safety results of the TVM technique are favorable. Complication rates are consistent with other POP repairs (both mesh and non-mesh).

Concluding message

These results support the peri-operative safety of the TVM technique. Long-term follow-up evaluations are ongoing to provide more insight into post-operative complications as well as the effectiveness of the TVM technique.

FUNDING: Gynecare, Division of Ethicon, Inc.