571

Khandwala S[1], Lucente V[2], Van Drie D[3], Gauld J[4], Hinoul P[5]

1. *Advanced Urogynecology of Michigan, Dearborn, MI, US,* ***2.*** *The Institute for Female Pelvic Medicine & Reconstructive Surgery, Allentown, PA, US,* ***3.*** *Female Pelvic Medicine&Urogynecology Institute of Michigan, Grand Rapids, MI, US,* ***4.*** *Ethicon Women's Health & Urology, Livingston, Scotland,* ***5.*** *Ethicon Women's Health & Urology, Somerville, NJ, US*

CLINICAL OUTCOMES OF AN OBSERVATIONAL REGISTRY UTILIZING A TROCAR-GUIDED MESH REPAIR OF VAGINAL PROLAPSE USING PARTIALLY ABSORBABLE MESH

Hypothesis / aims of study

To obtain clinical outcomes in a real-life setting following the use of a partially absorbable lightweight mesh in women with symptomatic pelvic organ prolapse (POP).

Study design, materials and methods

Women with symptomatic POP were invited to participate in this Institutional Review Board approved registry at 3 US centres. They underwent the standardized trans-vaginal mesh placement (GYNECARE Prolift+M™ Pelvic Floor Repair System, Ethicon, Somerville, NJ). Concurrent pelvic surgeries were allowed at the surgeon's discretion and follow up was as dictated by local practice. Anatomy was assessed using the Pelvic Organ Prolapse Quantification (POP-Q) system, performed at baseline and follow up visits. Anatomic success was defined as a POP stage of ≤ I in the treated compartment. Sexual activity, dyspareunia and incontinence were evaluated pre and post-operatively and adverse events were collected. A Patient Global Impression of Change (PGI-C) was administered to evaluate patient perception of overall improvement following the procedure.

Results

One hundred thirty women were included; 119 completed the registry. Median follow-up was 11 months. Mean age at surgery was 63.9 years. Thirty three had previous POP repair and 64 (had a prior hysterectomy. Fifty four women underwent an anterior mesh repair, 28 a posterior and 48 a total pelvic floor repair. POP-Q stages are presented in Table 1. Concurrent hysterectomies were performed in 3 patients, incontinence procedures in 81, colporrhaphy in 21, perineal repair in 32, enterocele repair in 16, rectocele repair in 6, and revision of TVT sling in 1. Results of PGI-C indicated that 117 of the patients felt "very much better" or "much better" since their surgery.

At baseline, 52 patients were sexually active, 18 of who reported dyspareunia. Following surgery, 9 of these patients reported resolved dyspareunia. Four patients reported de novo dyspareunia following surgery. Nine patients of the 55 patients who were not sexually active at baseline resumed sexual activity, 2 of whom reported dyspareunia following surgery.

Mesh exposure was reported in 7 patients and four were treated. De novo incontinence occurred in 1 patient. There were a total of 4 re-operations for prolapse. Intraoperative adverse events included 1 rectotomy and 1 urethrolysis procedure.

Interpretation of results

Our results indicate good anatomic outcomes following surgery for pelvic organ prolapse using the Prolift +M system. The procedure is safe and patients reported a high degree of satisfaction with surgery. The low rate of de novo dyspareunia together with the improvement in sexual function is encouraging.

Concluding message

The results of this registry suggest sustained, good anatomic support consistent with the original polypropylene mesh, with high patient perception of improvement.

Specify source of funding or grant	**Fully supported by Ethicon Inc**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Oakwood Hospital IRB**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**