

## A TROCAR-FREE PROCEDURE FOR VAGINAL PROLAPSE REPAIR USING MESH AND A VAGINAL SUPPORT DEVICE - AN OBSERVATIONAL REGISTRY.

### Hypothesis / aims of study

A previous prospective, multicenter study provided evidence that a vaginal repair using non anchored mesh and a vaginal support device (VSD) was safe and led to improved vaginal support, pelvic symptoms, and sexual function compared to baseline at 1 year in women with symptomatic POP-Q stage II and III prolapse<sup>1</sup>.

The aim of this registry is to report the peri-operative and routine post operative outcomes of this pelvic floor repair system across international sites.

### Study design, materials and methods

This was a prospective, observational, multi-centre registry. The population were from 6 sites in Europe (3), United States (2) and Australia (1), diagnosed with vaginal prolapse, who were suitable candidates for this mesh repair (GYNECARE PROSIMA™ Pelvic Floor Repair System, Ethicon, Somerville, US). Patients were evaluated at baseline, peri-operatively, post-operatively at 3-4 weeks and at any further visits dictated by local clinical practice. All investigators who were participating in the registry had previously completed training in the PROSIMA procedure. All investigators performed the procedure according to the IFU.

Anatomy was assessed using the 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

94 women were included with a mean age of 61.0 years (SD 11.9) and mean BMI 27.1 (5.3). Pre-operatively, 65.4% were Stage II, 30.8% Stage III and 3.8% a Stage IV. 38.5% had undergone prior prolapse surgery and 58.8% a prior hysterectomy. 14 (14.9%) had an anterior, 20 (21.3%) a posterior and 60 (63.8%) combined repairs using the PROSIMA system. 85 women (91.4%) had a general anaesthetic, 8 (8.6%) had a regional block. 60% of women had suture plication of the prevesical and/or pre-rectal tissue. Vaginal hysterectomy, perineal repair and a mid-urethral sling was performed on 18.5%, 37.0% and 17.4% of patients respectively. For women with no concomitant procedures, mean duration of surgery was 46.1 mins (SD 15.0). The median duration for VSD wear was 22 days (range 16-36).

Follow up POP-Q data were available for 55.3% of patients. 82.7% (95% CI 69.7%-91.8%) of these women were POP-Q Stage 0/I following surgery. Nine (17.3%) were Stage II, with a leading edge within the hymen in 8 patients. Based on Patient Global Assessment, 51.1% patients reported they were "very much better" and an additional 38.6% "much better" after surgery. At baseline, dyspareunia was reported in 8 / 35 (22.9%) sexually active patients. Post procedure, 4 of these 8 cases reported resolution of dyspareunia. There were 2 reports of *de novo* dyspareunia. Mesh exposure related to this surgery occurred in 5 patients (5.3%). 2 cases resolved following partial mesh excision; 1 resolved with vaginal estrogen. 2 cases were ongoing at the last recorded post procedure visit whilst being treated with topical estrogen. No patients required a re-intervention for prolapse post procedure. *De novo* stress urinary incontinence was reported in 2 patients and urinary urge symptoms in 4 patients.

### Interpretation of results

Our results indicate good anatomic outcomes following surgery for pelvic organ prolapse using the PROSIMA 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 registry confirms the results from the prospective multicenter study; this method of vaginal repair using non-anchored mesh and a VSD was safe and led to good anatomic outcomes.

### References

1. Zyczynski HM, Carey MP, Smith ARB, et al. One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device. *Am J Obstet Gynecol* 2010;203:587.e1-8.

<b>Specify source of funding or grant</b>	<b>Fully funded and supported by Ethicon</b>
<b>Is this a clinical trial?</b>	<b>No</b>
<b>What were the subjects in the study?</b>	<b>HUMAN</b>
<b>Was this study approved by an ethics committee?</b>	<b>Yes</b>
<b>Specify Name of Ethics Committee</b>	<b>Cambridgeshire 1 Research Ethics Committee</b>
<b>Was the Declaration of Helsinki followed?</b>	<b>Yes</b>
<b>Was informed consent obtained from the patients?</b>	<b>Yes</b>

