810

Tommaselli G A[1], D'Afiero A[2], Nazzaro G[1], Formisano C[1], Fabozzi A[1], De Placido G[1], Nappi C[1]
1. *Dept. Ob/Gyn University of Naples Federico II - Italy,* ***2.*** *Service of Urogynecology – Hospital "S. Maria della Pietà" – Casoria, Italy*

3D ULTRASONOGRAPHIC VISUALIZATION AND SHORT TERM EVALUATION OF A TENSION-FREE, SINGLE INCISION VAGINAL MESH (PROSIMA() FOR THE SURGICAL CORRECTION OF MODERATE SYMPTOMATIC VAGINAL WALL PROLAPSE CONTINENCE: A SYSTEMATIC REVIEW

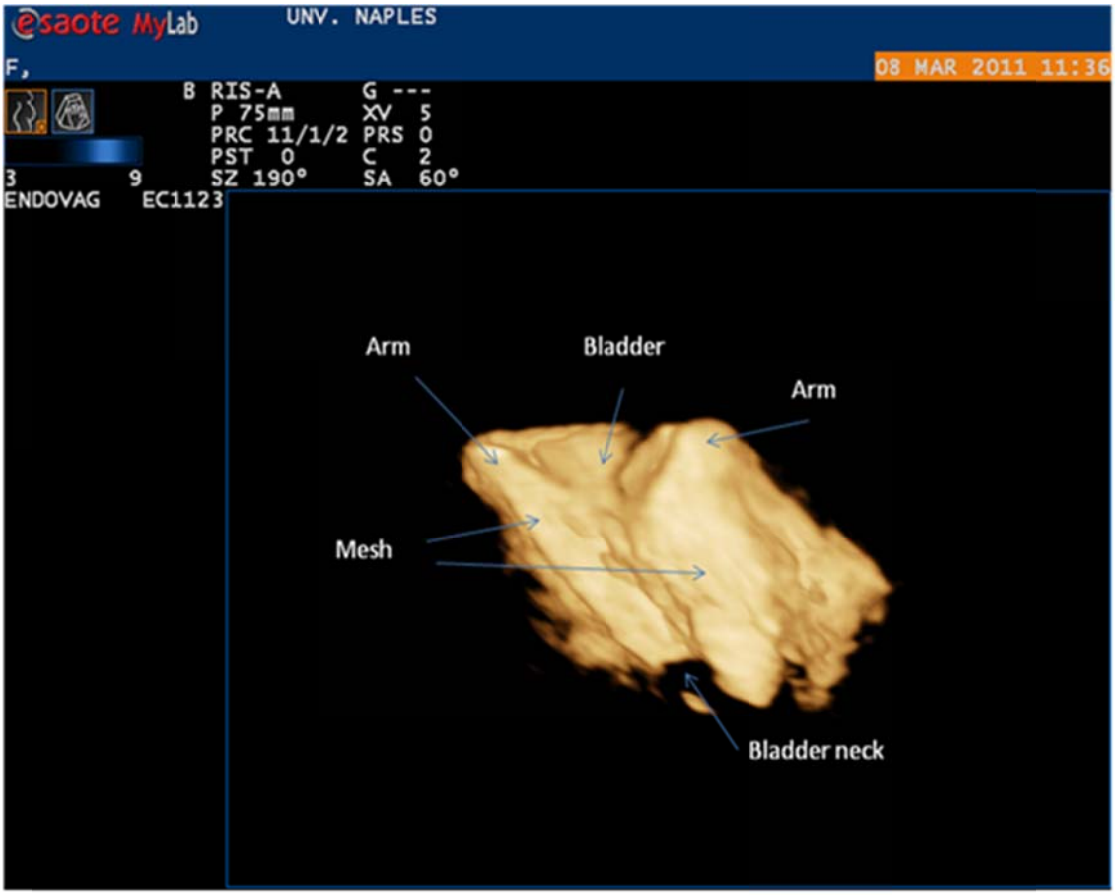
Hypothesis / aims of study
Prosthetic materials seems to have reduced the number of recurrences after surgical procedures for the correction of pelvic organ prolapse, with good anatomical outcomes. On the other hand, the use of synthetic meshes seems not to be suitable for moderate pelvic organ prolapsed (symptomatic stage II-II anterior and posterior vaginal wall prolapse) and they may have a high incidence of specific complications, such as mesh shrinkage, erosion/exposure and vascular and organ lesions caused by the blind passage of trocars. To identify a simple method for the surgical management of symptomatic moderate anterior and/or posterior vaginal wall prolapsed, a type I polypropylene, single-incision, tension-free mesh with reduced size and post-operative use of vaginal support device (VSD) has been developed (Prosima™, Ethicon Women's Health and Urology, Sommerville, NJ, USA). Since this device is not anchored to any anatomical structure and relies its effect on tissue fibrotic reaction, aim of this study was to study mesh positioning using 3D ultrasonography to verify if the mesh position was stable during short-term follow-up and to correlate the imaging data with post-operative follow-up outcomes.

Study design, materials and methods
Prospective study evaluating 22 patients affected by anterior and/or posterior vaginal wall prolapse and undergone Prosima™ procedure. Inclusion criteria were: moderate and symptomatic anterior and/or posterior vaginal wall prolapse (stage II-III) as diagnosed by PoP-Q staging; eligibility for surgical procedures (ASA ≤ 2). Exclusion criteria were: stage IV pelvic organ prolapsed; apical defect (≥ stage II); obstructed defecation syndrome; contraindication to surgical procedures (ASA > 3); diabetes; immunodeficiency. All patients signed an informed consent. Before the procedure, patients underwent gynaecologic and proctologic evaluation, pelvic ultrasonography, and QoL questionnaires were completed. Eleven patients underwent anterior Prosima™, 11 anterior and posterior Prosima™. VSD was left in place for a minimum of 21 days and a maximum of 28 days, ad a visual analog scale (VAS) for tolerance of the device was recorded when withdrawing the VSD. Operative times, blood loss, and perioperative complications were recorded, as well as VASfor pain the day after the procedure. At follow-up visits (3, 6 and 12 months after the procedure), PoP-Score, QoL questionnaires, VAS score for pain and the onset of complications were evaluated. Seven days and 3, 6, and 12 months after the procedure, patients underwent perineal ultrasonography with 3D visualization of the mesh using an Esaote Twice System with a 3.5 MHz transvaginal 3D probe with an introital approach and a 3-5 MHz multifrequency transabdominal 3D probe using a translabial approach. Data distribution was assessed with the Shapiro-Wilk's test. PoP-Q scoring displayed a non-normal distribution and differences in the values observed at the follow-up visit were evaluated using the Wilcoxon test. Statistical significance was set for a P value of .05.

Results
Median follow-up times was 6 months (range 3-12 months; [95%IC 4.7-7.2]). Mean age was 49.1 (range 38-74). Eighteen patients (90%) were post-menopausal and four (22.2%) were on hormonal replacement therapy. Mean operative time was 31 ± 11 minutes for the isolated anterior procedure and 42 ± 12 minutes for the combined procedure. During the procedure, only one case of bleeding > 200 ml was observed and two vaginal injuries were reported. Post-operative complications were a case of vaginal hematoma, one case of urinary tract infection and one case of vaginal infection. We did not observe any case of mesh erosion. Using the definition of cure (vaginal wall prolapse above the hymen), 95% patients were objectively cured, with only one failure (stage III cystocele and rectocele in the same patient). QoL scores were significantly lower three months after the procedure. Mean VAS pain score was 2.5 ± 1.1 24 hours after the procedure, while mean VSD tolerance VAS score was 8.5 ± 2.3. Pain VAS score was 0 at all post-operative follow-up visits. In all cases the mesh was identified with ultrasonography (Fig. 1). In all cured patient the mesh was correctly positioned and stayed in a stable position throughout all post-operative follow-up visits.

Interpretation of results
The number of subjects studied is limited, but the procedure was performed without any major difficulty or intra-operative complication. Clinical outcomes seem to be promising and can be correlated with ultrasonographic studies that indicate that the mesh remains in a stable position at least up to 12 months.

Concluding message
Correction of anterior and posterior vaginal wall prolapse using the tension-free, single incision Prosima™ device seems to be feasible with good, short-term anatomical results and limited intra- or post-operative short-term complications. The position of the mesh can be studied using 3D ultrasound and seems to be stable at least in the shor-term. The number of patients is limited and the follow-u limited, thus no definitive conclusion can be drawn. Nevertheless, this cohort demonstrated that the mesh, even without any support to anatomical structure, remains in its position. More studies are need to better evaluate the efficacy and safety of Prosima and the role of ultrasonography in determining the reasons for failure.



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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require ethics committee approval because	**Patients underwent a diagnostic and surgical procedures indicated for their pathology**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**