

## SHORT-TERM ASSESSMENT OF PATIENTS UNDERGOING ANTERIOR VAGINAL REPAIR WITH A POLYPROPYLENE MESH REINFORCEMENT: EFFICACY AND SAFETY

### Hypothesis / aims of study

The purpose of this study was to evaluate the short-term safety, functional and anatomic efficacy of anterior vaginal repair with a synthetic mesh (Gynamesh™).

### Study design, materials and methods

Women with stage 2 or more (ICS-POP-Q) cystocele were offered to undergo anterior vaginal repair with Gynamesh™ between February and November 2007. Ethics approval was obtained. Anamnesis, physical examination (POP-Q), validated sexual function and quality of life questionnaires were performed preoperatively, and at 1,3,6,9 and 12 months postoperatively. Primary outcome was the absence of stage 2 or more prolapse at any site. Secondary outcomes included complications and impact on sexual function.

### Results

Time of inclusion was 63 years, dyspareunia was reported by 67% of patients and 33% presented abdominal or vaginal pain. One patient complained of SUI that was not confirmed by urodynamics and one of urge incontinence. Concomitant vaginal hysterectomy was performed in 1 patient (16,5%) because of uterine prolapse, another 2 patients (33%) were submitted to sacrospinal hysteropexia for the same reason; 50% of patients received a posterior **fascial** repair due to enterocele. There were no intraoperative complications. The average hospital stay was 2 days. The mean follow up period was 9,5 months, and only one patient had less than 6 months follow up. Most of the women were satisfied of their condition. Unsatisfactory anatomic outcomes at any vaginal site (POP-Q > 1) were recorded in 15%, 67%, 83%, 40% and 50% of patients respectively after 7 days, 1,3,6 and 9 month of follow up. The recurrence of anterior vaginal wall prolapse were present in 15%, 33%, 16% after respectively 7 days, 1 and 3 months, no such recurrence was noticed after 3 months of follow up. The main responsible for prolapse at any site were enterocele and uterine prolapse. Postoperative complications included: 4 mesh exposures (67%), 1 mesh shrinkage (16%), 1 urge incontinence once again (16%), 1 de novo hysterocele, 1 enterocele once again and 1 recurrence of hysterocele. No vaginal or abdominal infection was found. There was improvement on sexual function despite patients reporting fear of intercourse until 3 months after surgery, no dyspareunia was related. Two patients (33%) were reoperated at 9 months due to symptomatic enterocele (1) and uterine prolapse (1). One patient was reoperated due to mesh exposure. Mesh erosions responded to treatment with vaginal estrogen in most of cases.

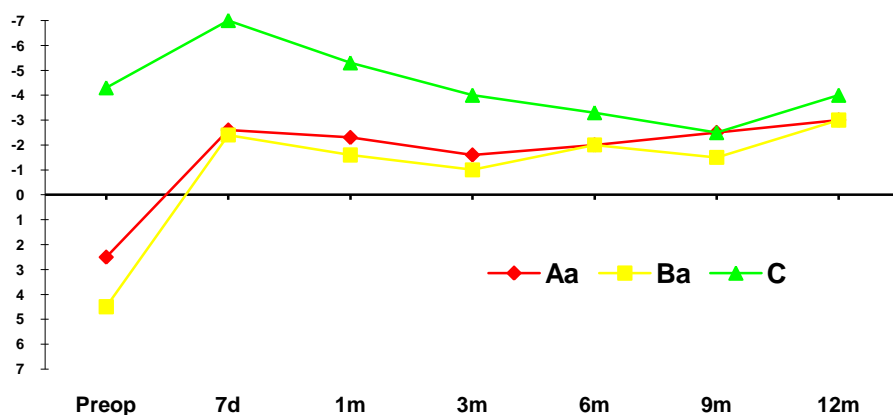
### Interpretation of results

Our data suggests that the transvaginal mesh repair of anterior wall prolapse is a promising and safe technique with encouraging results in a short run. It may predispose to other perineal defects descompensation, as enterocele and uterine prolapse. Mesh exposure is a frequent complication that can be solved with vaginal estrogen in most of cases.

### Concluding message

Future studies with a larger number of patients and follow up are needed to address the long term efficacy and safety of meshes in transvaginal repairs

<b>Specify source of funding or grant</b>	J& J provided 10 Gynamesh for our surgical procedures.
<b>Is this a clinical trial?</b>	Yes
<b>Is this study registered in a public clinical trials registry?</b>	Yes
<b>Specify Name of Public Registry, Registration Number</b>	CAFPEP - University of S Paulo by author's name
<b>What were the subjects in the study?</b>	HUMAN
<b>Was this study approved by an ethics committee?</b>	Yes



<b>Specify Name of Ethics Committee</b>	Ethics Committee of Hospital das Clinicas University of S Paulo
<b>Was the Declaration of Helsinki followed?</b>	Yes
<b>Was informed consent obtained from the patients?</b>	Yes