

## PROLAPSE CYSTOCELE SURGICAL REPAIR WITH SITE-SPECIFIC CORRECTION REINFORCED WITH SOFT VAGINAL TENSION-FREE POLYPROPYLENE MESH COMPARED WITH TROCAR-GUIDED SOFT TENSION FREE POLYPROPYLENE MESH WITHOUT SITE-SPECIFIC CORRECTION.

### Hypothesis / aims of study

The traditional techniques provided a good correction of female genital prolapse, however it present a high percentages of recurrence. For that reason was introduced the use of mesh imitating the reinforcement that surgeons perform in abdominal wall hernias to decrease recurrence. The first study with polypropylene mesh for correction of the cystocele was published by Julian during 1996 using Marlex.<sup>1</sup> All patients obtained a good anatomical correction, however was reported a high number of complications due to the mesh. Actually is accept that the best mesh for prolapse correction is macropore, monofilament, soft polypropylene type I, but it is not free of complications. The first technique used in our work-group was the traditional classic colpoperineoplasty and site-specific correction. Then we began to use the polypropylene mesh to reinforce the site specific correction.<sup>2</sup> Actually when we use meshes we prefer to use the standardized kit like Prolift system. We hypothesise that the surgical correction of female genital prolapse with the trocar-guide tension-free vaginal polypropylene mesh has more benefits than using vaginal tension-free polypropylene mesh for treating female prolapse, and both system are safety and effectiveness. This study aims to compare the safety and effectiveness using the Gynemesh PS mesh and Prolift System in the genital prolapse surgery repair.

### Study design, materials and methods

Retrospective study with 300 women admitted for surgical repair of female genital prolapse, at Urogynecology Unit, Clínica Las Condes, Santiago, Chile. 140 women admitted from November 2004 to June 2006 in who the surgical prolapse repair was closing in situ defects of the fascia and reinforced with Gynemesh PS mesh. The in situ defects were closing using vicryl 3/0. Cut out pieces of Gynemesh PS with scissors, leaving two tabs on each side to positioning in paravaginal spaces, tension free, without sutures. This group was compared with a second group of 160 women admitted for surgical repair of genital prolapse with trocar-guided tension-free standardized Prolift system, during January 2007 and January 2008, without close the site-specific defect.

**In Gynemesh PS:** the media age was 54 years old (range 45 to 73), with a weight of 64 kg (54 to 82). BMI was 28 (23 to 35) and vaginal parity 3 (0 to 5).

**In Prolift System:** the media age was 56 years old (range 44 to 72), with a weight of 65 kg (56 to 85). BMI was 28 (23 to 34) and vaginal parity 3 (0 to 5).

Both groups were compared determining complications during intraoperative, immediate postoperative and late postoperative time until 12 month after surgery. The cure or failure results were compared using the pelvic organ prolapse quantification (POP-Q).

### Results

**In 140 women admitted for correction with Gynemesh PS:** 81 corresponded to cystocele. Type II 10 women, type III 45 women and type IV 26. 78 were rectocele, corresponding to type III 51 women and type IV 27 women. The media surgical time was 25 minutes for cystocele (range 20 to 40 minutes) and 25 minutes for rectocele (range 24 to 37 minutes). There were no complications related to the placement of mesh for the correction of cystocele or rectocele. There were no immediate or late postoperative complications. No hematoma or infection was observed in the operative area. Hospital discharge occurred 48 hours after surgery in all patients. During the follow-up until 12 month: vaginal erosion was observed in 3 (3/159, 1.9%) women with Gynemesh PS mesh corresponding to erosion from 3 milimeters to 5 milimeters. All cases corresponded to cystocele repair surgeries and the erosion was observed in the anterior vaginal wall. All cases were successfully treated only with oestrogen cream. When the women of the Gynemesh Ps group were evaluated at 12 months: 3.1% (5/159 cases) presented recurrence, 2 from III degree to II degree of POP-Q stages and 3 from IV to III. All cases corresponded to cystocele and only 1 case was symptomatic.

**In 160 women admitted for correction with Prolift System:** 90 corresponded to cystocele. Type II 5 women, type III 51 women and type IV 14. 70 were rectocele, corresponding to type III 43 cases and type IV 27 cases. The media surgical time was 40 minutes for cystocele (range 30 to 50 minutes) and 30 minutes for rectocele (range 20 to 40 minutes). There was 1 (1/160, 0.6%) complication related to the placement of mesh corresponding to bladder perforation during the needle passage for the correction of cystocele. One (1/160, 0.6%) woman presented a hematoma observed in the space of Retzius with hemodynamic impact. Hospital discharge occurred 48 hours after surgery in all patients. During the late postoperative time, there was 1 case of dyspareunia without vaginal erosion.

During the follow-up until 12 month: vaginal erosion was observed in 5 (5/160, 3.1%) women with Prolift System mesh corresponding to erosion from 5 milimeters to 15 milimeters. 3 (3/160, 1.9%) cases in the anterior vaginal wall (cystocele correction) were successfully treated only with oestrogen cream and 2 (2/160, 1.3%) cases required surgical excision of the extrusion mesh corresponding 1 in the anterior vaginal wall (cystocele correction) and 1 in the posterior vaginal wall (rectocele correction). All women after surgery used preventive local therapy with oestrogen. None women required repeated resection because of recurrence.

When the women were evaluated at 12 months: 3.1% (5/160 cases) women presented recurrence corresponding 4 cases from III degree to II degree of POP-Q stage and 1 cases from III to III. All cases corresponded to cystocele and 2 cases were symptomatic.

### Interpretation of results

Both systems for the female genital prolapse correction use the same type of mesh. The difference is comparing the use of mesh as a reinforcement of a site-specific correction (group of women with Gynemesh Ps only) with cases in which was used trocar-guided mesh with the Prolift System without site-specific correction.

About complications one case of bladder perforation and one case of hematoma in the Retzius space were presented as a complication to the passage of the needle to insert the Prolift System, in the case of the mesh on the specific site correction is not required the use of needle to pass the mesh. Second, the amount of mesh that is left is greater in the Prolift system compared with the other system, this could increase the number of complications. This is demonstrated in cases of vaginal erosion which were of greater size in women with Prolift. However, in general the erosion was presented in few cases in both groups and most required only oestrogen cream. The majority of erosion cases corresponded to anterior vaginal wall in women with cystocele repair. In this experience only one case corresponded to posterior vaginal wall erosion. The greater size of the mesh could also explain the case of dyspareunia. The cases of prolapse recurrence were similar in both groups during the one year follow-up. However, requires a long term follow-up to determine if cases of erosion or recurrence continue to appear. We must not forget that synthetic materials must be shown to improve anatomical outcomes and at least maintain, but graft material still have disadvantages as vaginal erosion. Several factors contribute to the wide range of vaginal erosion rates, including patient characteristics such as age and oestrogen deficiency; operative technique; implant size; and the specific properties of the mesh (pore size, elasticity, stiffness, compatibility).<sup>9</sup> For successful results is important to choose the surgical technique, the mesh and the patient.

### Concluding message

Both techniques, site-specific correction reinforced with mesh and trocar-guided mesh Prolift System are safe and effective in treating female genital prolapse with similar results. According this series both systems have similar number of recurrence cases in a one year follow-up. However, the use of needle to pass the trocar to introduce the mesh might be associated with complications, so training is required and taking necessary precautions to avoid these complications. The larger size of the mesh in Prolift could explain the increase number of vaginal erosions, but are easily treated with low morbidity.

### References

1. . Julian TM. The efficacy of Marlex mesh in the repair of severe, recurrent vaginal prolapse of anterior midvaginal wall. Am J Obstet Gynecol. 1996;175(6):1472-1475.
2. Solà V, Pardo J, Ricci P, Guiloff E. Tension free monofilament macropore polypropylene mesh (Gynemesh PS) in female genital prolapse repair. Int Braz J Urol.2006;32(4):410-415.
3. Mistrangelo E, Mancuso S, Nadalini C, Lijoi D, Costantini S. Rising use of synthetic mesh in transvaginal pelvic reconstructive surgery: a review of the risk of vaginal erosion. J Minim Invasive Gynecol.2007;14(5):564-569.

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<b><i>This study did not require ethics committee approval because</i></b>	<b>Because is retrospective revision</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
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