

## TRANSVAGINAL GENITAL PROLAPSE REPAIR WITH TENSION FREE VAGINAL TAPE: A CASE SERIES MULTICENTRIC STUDY WITH PROLIFT MESH.

### Hypothesis / aims of study

Vaginal prolapse is common source of morbidity with negative impact on quality of life. The classic surgeries have a high chance of recurrence.<sup>1</sup> Unfortunately, the incidence of pelvic disorders is increasing. This had led to new techniques for reducing the incidence. The use of tension free vaginal polypropylene mesh may be a treatment option. Any type of mesh not the same, should be a polypropylene soft, macropore, monofilament mesh.<sup>2</sup> This material has already been tested successfully in the treatment of urinary incontinence. However, in the surgical treatment of prolapse requires a larger mesh. This motive could increase the possibility of extrusion mesh in the vaginal mucosa. Using kit allows standardize the technique and minimize complications. To know the benefits of using mesh in the correction of prolapses studies are needed to determine complications and long follow-up.

We hypothesise that the use of polypropylene mesh is safety and effective for treating female prolapse. This study aims to determine the safety and effectiveness using the trocar-guide tension-free vaginal mesh Prolift System in the genital prolapse surgery repair.

### Study design, materials and methods

Prospective observational cohort study involved 334 women underwent Prolift surgery. Between January 06 and January 2010 149 patients with genital symptomatic prolapse were admitted at Urogynecology Unit of Hospital Italiano, Buenos Aires, Argentina. During the same months 185 women were admitted for the same motive at Urogynecology Unit of Clínica Las Condes, Santiago, Chile.

In the 334 women range of age was 40 and 81 years old, media 63 years old. The BMI was between 27 and 33, media 26. The vaginal parity was between 0 and 5, media 3.

The prolapse was corrected in both medical centers with Prolift System under the standardized technique.

The intraoperative and postoperative complications were reviewed. Immediate postoperative complications were considered until seven days after surgery. Late postoperative complications were considered after seven days.

The vaginal prolapse was measured pre-operatively according to pelvic organ prolapse quantification (POP-Q) and compared with the same quantification at 12 months and at the time of closure of the study (January 2010). The complications during intraoperative, immediate postoperative (until 7 days after surgery) and late postoperative (after 7 days from surgery) time were observed.

### Results

The preoperative quantification and classification of the genital prolapse in the 334 women admitted to surgery was: 30 IIBa, 95 IIIBa, 60 IIIC, 35 IIBp, 51 IIIBp, and 63 IV.

During the intraoperative time 1.5% (5 cases) women presented complications: 0.3% case of abnormal bleeding (1 case) and 1.2% vaginal perforation (4 cases).

During the immediate postoperative time 2.4% (8 cases) women presented complications: 0.6% haematoma (2 cases), 0.3% infection (1 case), 0.3% urinary infection (1 case), 0.3% urinary retention (1 case), 0.9% dehiscence (3 cases).

During the late postoperative time 27.5% (92 cases) women presented complications: 11.1% (37 cases) extrusion/erosion of the mesh in vagina, 9.3% (31 cases) asymptomatic retraction, 0.9% (3 cases) symptomatic retraction, 1.8% (6 cases) dyspareunia, 2.1% (7 cases) de novo urgency incontinence, 2.1% (7 cases) de novo stress urinary incontinence and 0.3% (1 case) of hispareunia (partner dyspareunia secondary to mesh).

In the 37 cases of extrusion/erosion: 11 cases were successfully treated only with oestrogen cream, 13 cases required ambulatory surgical excision in operating room, and 13 cases required excision in office.

When the women completed the follow-up period until January 2010, with a media of 19 months (range between 1 and 38 months), 30 (9%) cases presented prolapse recurrence, corresponding to partial recurrence in 27 (8.1%) women and total recurrence (complete failure) in 3 (0.9%) cases. Partial recurrence: 20 cases from III to II and 7 cases IV to II. Total recurrence: 2 case from IV to IV and 1 case from III to III. Only 7 cases of 30 recurrences were symptomatic. Only 2 women were underwent a second surgery.

The cases of recurrence were:

After surgery	Before surgery	Cases
III Ba	II Ba	8
III Ba	II c	5
III Ba	II Bp	2
III Bp	II c	1
III Bp	II Bp	2
III Ba	III Ba	1
III c	II Ba	1
IIIc	IIc	1

IV	IIC	4
IV	IIBp	1
IV	Ila	2
IV	IV	2
		<b>30 cases</b>

#### Interpretation of results

The use of mesh in the surgical correction of female genital prolapse is not free of complications. In our experience, during the intraoperative time complications were recorded in 1.5% and during the immediate postoperative time was 2.4%. Only one complication was important corresponding to hematoma in the prevesical space with hemodynamic compromise. During the late postoperative time the most frequent complication was related with the mesh. Extrusion and erosion in the vaginal mucosa was recorded in 11.1% (37 cases). 11 cases were successfully treated only with oestrogen cream, 13 cases required excision in office and 13 cases required ambulatory surgical excision of the extrusion mesh in operating room. One of the major concerns that industry should take in the future is to provide mesh for anatomic correction reducing the rates of extrusion. However, we must not forget that several factors contribute to the vaginal erosion rates. The characteristics such as oestrogen deficiency, age and implant size are important for successful results. For this reason is important choose the surgical technique, the mesh and the appropriate patient.

The women undergoing transvaginal prolapse repair with the Prolift system showed significant improvement during the follow-up with objective measures by POP-Q quantification observing 0.9% of total recurrence and 8.1% of partial recurrence. In the subjective quantification only 7 of the 30 women with recurrence were symptomatic. No doubt that longer follow-up is required to determine the persistence of these results, after the year new cases of recurrence were recorded in our series.

According our experience the Prolift system is successful in the treatment of cystocele, rectocele and vaginal cuff prolapse. Other publication compared the anatomic outcomes of Prolift with uterosacral ligament suspension and abdominal sacrocolpopexy for pelvic organ prolapse concluding similar results between the three techniques.<sup>3</sup> The main advantage of surgical treatment of genital prolapse using Prolift consists in a low percentage of total recurrence.

#### Concluding message

According our experience developed in both urogynecologic centers, the trocar-guided Prolift system is safe and effective technique for vaginal reconstruction of pelvic organ prolapse. The Prolift system provided an effective anatomic cure with low percentage of total recurrence. According our observation the main risk associated to use of synthetic mesh is the extrusion/erosion and shrinking of vaginal mucosa. However, the cases of extrusion/erosion of the mesh in vaginal wall were easy to solve.

#### References

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<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>Clínica Las Condes and Hospital Italiano</b>
<b>Was the Declaration of Helsinki followed?</b>	<b>Yes</b>
<b>Was informed consent obtained from the patients?</b>	<b>Yes</b>