



Full length article

Long-term experience with a novel uterine-sparing transvaginal mesh procedure for uterovaginal prolapse



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ARTICLE INFO

Article history:

Received 26 February 2017

Received in revised form 3 November 2017

Accepted 8 January 2018

Keywords:

Mesh

Pelvic organ prolapse

Quality of life

Transvaginal surgery

Uterus sparing surgery

ABSTRACT

Objectives: To evaluate outcomes and quality of life in patients operated transvaginally with an original mesh shape for uterus-sparing prolapse surgery and to demonstrate the safety and efficacy of the technique.

Study design: We prospectively evaluated 66 postmenopausal patients (POP-Q Stage III: 32, IV: 34) operated between May 2008 and December 2013. We used wide weave polypropylene monofilament mesh that functions as a hammock anchored posteriorly to sacrospinous ligaments, its anterior wings exit the pelvis through the obturator membrane.

Follow-up was scheduled at 3-, 12- months and in May 2016. Prolapse-Quality of Life Questionnaire (P-QoL) was administered preoperatively, at 12 months and in May 2016. The chi square and Wilcoxon test were used for statistical analysis.

Results: Mean follow-up was 5.6 (SD: 1.6, Range: 1.1–8.1) years. The overall success rate (POP-Q ≤ 2) was 92.5% at 12 months and 84.4% at May 2016, these data remained stable over time ($p > 0.05$). Early complications occurred in 2 (3%) patients, late in 5 (7.8%) of which mesh extrusion in 4 (6.3%). Data from P-QoL showed significant improvement between preoperative and postoperative data ($P < 0.01$ for all domains) and they remained stable with time ($p > 0.05$). De-novo dyspareunia was 17.6% at 12 months and 10.3% at May 2016.

Conclusions: The low rate and grade of complications demonstrates the safety of the procedure, which offers stable anatomical correction with significant improvement in QoL.

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Introduction

Patients diagnosed with high-grade uterine prolapse, either III–IV according to the Pelvic Organ Prolapse Staging System (POP-Q), often require surgical treatment to correct their anatomic-functional defect. There are many surgical options, such as vaginal hysterectomy combined with native tissue repair including uterosacral or sacrospinous ligament suspension. Another option is to use synthetic materials in the repair or apical suspension. Further still, uterus-sparing surgery may be performed, again with various combinations and options for repair and suspension using native tissue and/or synthetic materials [1]. Recently the U.S. Food and Drug Administration (FDA) increased data requirements for the use of surgical meshes for pelvic organ prolapse (POP) repair through the vagina, and such meshes were re-categorized as class

III instead of class II which made them high-risk devices [2]. The FDA policy decision affected trans-vaginal procedures employing synthetic meshes, even outside the USA. Yet, is it realistic that many studies describing the anatomical rationale for the use of a mesh in POP and the thousands of patients who have successfully undergone this treatment have all been an error?

Our two decades' experience with mesh surgery prompts a critique of the FDA reclassification. We began to repair POP with mesh in the 1990s [3], and have persisted to the present because our results have been consistently more than satisfactory. In fact, we report only a modest rate of minor complications.

In our center we adopt two original vaginal techniques, one for single prolapse of the anterior segment (cystocele) [3], and the other for prolapse of the middle segment (cystocele and uterus or vaginal vault) [4]. For each defect we use soft, macroporous, wide weave polypropylene monofilament mesh (type 1 according to the Amid classification [5]) from the commercial market. Specifically, from 2006 we selected Gynemesh (Ethicon) and used it until 2013 though in 2012 it had gone off the market. Now we use Restorelle[®]

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Flat Mesh which we cut into two different shapes particular to the two types of prolapse. The novelties of our procedure are the shape of the mesh and the method of anchoring it to the uterus.

The aims of the current study were to evaluate outcomes and patient satisfaction in cases of uterine prolapse (POP-Q stage III/IV) treated with vaginal mesh, while preserving the uterus.

The primary objective of the study was to assess the effectiveness of anatomical correction, safety and complications. The secondary objective was to evaluate the resolution of symptoms and the effect on quality of life (QoL).

Study design

We performed a prospective observational study between May 2008 and December 2013. In average, at our center 20 patients receive procedure for anterior prolapse yearly, while 10–12 patients receive operation for POP yearly; 2–3 patients are referred to the gynecology department either for patient's preference or for underlying gynecological pathologies such as uterine fibromatosis.

We enrolled 66 patients with high grade anterior and apical descensus, i.e. point Aa, Ba and point C at stage >2 according to the POP-Q. Absolute exclusion criteria were: hypersensitivity to synthetic materials, previous hysterectomy or POP surgery, postmenopausal bleeding, abnormal cervical smears, uterine disease, an adnexal masses, or BMI >30 kg/m².

For each patient the utility of a mesh implant was carefully evaluated. Informed consent, clarifying the novelty of the technique, the possibility of failure, and correlative risks was obtained from all participants.

The characteristics of the mesh are shown in Fig. 1. The mesh corrects the weakened fascial support that led to the POP by recreating the two levels of support for the bladder and the uterus theorized by DeLancey [6]. The dimensions conform to average pelvic diameters.

Preoperative patient assessment consisted of history, pelvic examination using POP-Q, supine stress test with prolapse reduced, to detect occult stress incontinence that was measured using the Ingelman-Sundberg scale [7]. Urodynamic evaluation

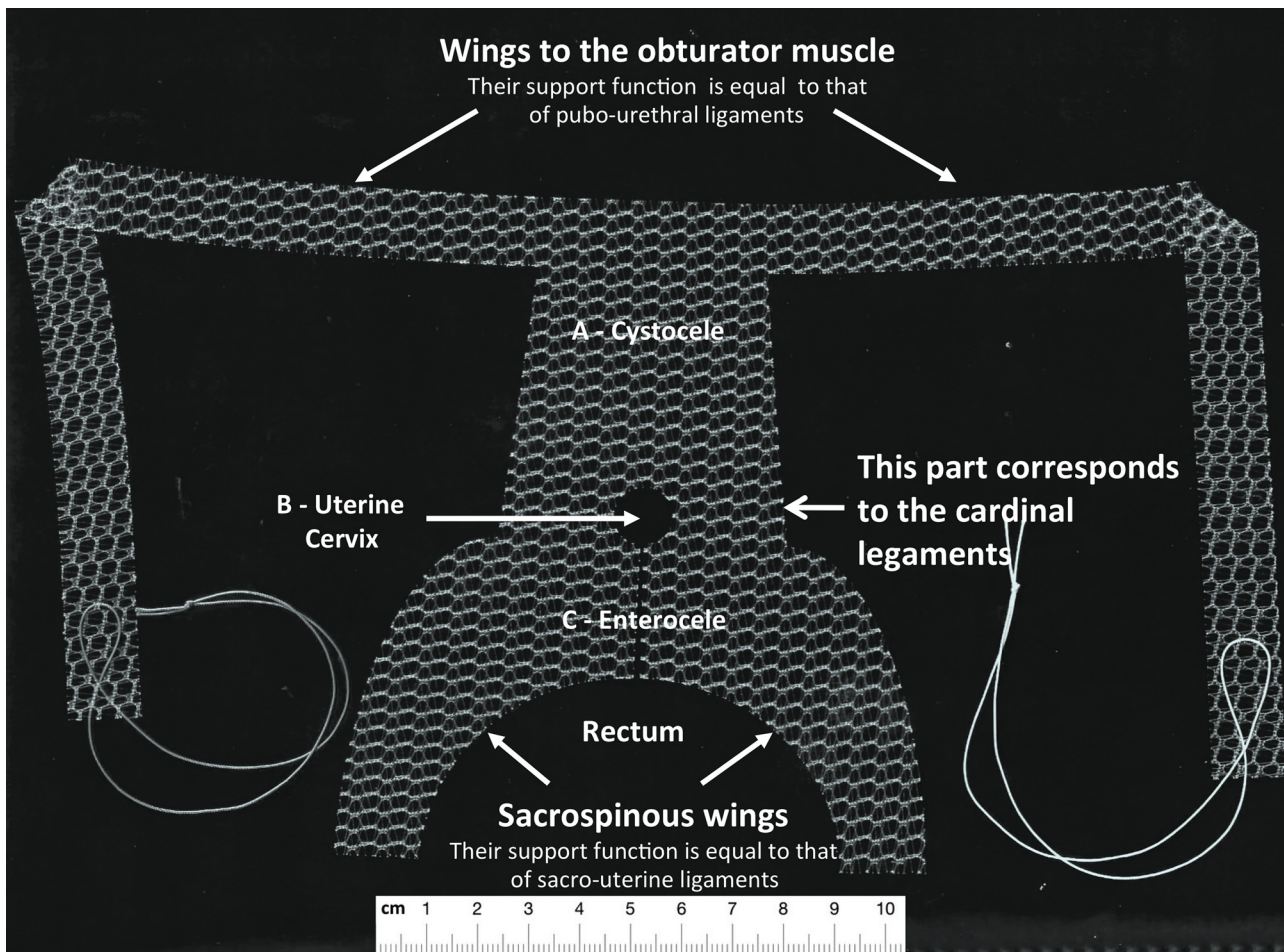


Fig. 1. The Rationale for the Shape of the Mesh.

The estimated area of the central body of the mesh (excluded wings) is 4500 mm² it is smaller than the area of Prolift (6770 mm² excluding the wings). The size facilitates drawing the mesh tautly without creases, which reduces the risk of extrusions. The shape: the cystocele lies in the anterior portion of the mesh (A). The neck of the uterus is placed in back of the central aperture (B) where it is encircled and sustained, like the cardinal ligaments, by the two posterior halves, as they are passed through a tunnel created on either side of the cervix. These halves, joined under the cervix with two stitches, make a surface that supports the enterocele (C). The stitches are placed immediately under the cervix but not so strict as to create tissue lesions. The diameter of the hole in the mesh is smaller than that of cervix to avoid that the uterus slide through it. The mesh fastening: two front wings exit the pelvis passing through the ipsilateral obturator foramen (they substitute the support of the pubo-urethral and urethropelvic ligaments). Two rear wings are fixed to the ipsilateral sacro-spinous ligament with a single stitch (they substitute the support of the sacro-uterine ligaments). Finally, the mesh, taught between the anchoring points forms a new stable floor for the organs lying above it. In orthostatism the mesh in the pelvis is similar to a hammock pulled tautly between the pubis and the sacrum.

included uroflowmetry, post-void residual volume, filling cystometry and pressure/flow study with and without prolapse reduction using a pessary, following the International Continence Society (ICS) standard [8]. All patients were asked to compile the Italian version of the Prolapse-Quality of Life Questionnaire (P-QoL) [9].

All patients were post-menopausal. Baseline patients' characteristics, LUTS and pre-operative urodynamic data are listed in Table 1.

Surgical technique

All patients, after general anaesthesia, were placed in the dorsal lithotomy position and a 16F bladder catheter was introduced. A Scott retractor was positioned and a midline longitudinal anterior colpotomy was made from the bladder neck to the cervix. The pubo-cervical fascia, that lies over the cystocele was exposed up to its insertion on the ischio-pubic branch at both the right and the left sides. Each front wing of the prosthesis, connected to an inside-out transobturator handle, was passed through the obturator membrane and the skin, and it was pulled out until the mesh reached the bladder. A midline posterior colpotomy was made from the fornix to the end of the enterocele, and by using a Kelly-type curved forceps, Fig. 2, a passage between the posterior and anterior vaginal segments was pierced as close as possible to the apex of the cervix. Each half of the mesh was passed through the ipsilateral passage until the cervix was placed at the center of the aperture in the mesh, to fasten it to the prosthesis. Two sutures joined the medial edges of the halves of the mesh to create a support plane for the enterocele. The rear wings were fixed to the ipsilateral sacrospinous ligaments with a stitch using the Capiro[®] instrument and the uterus was pushed up into its correct position. Eventually the colpotomies were sutured. Figs. 3 and 4 show the location of the mesh in the pelvis. Patients with stress urinary incontinence (SUI) received a single incision transvaginal sling. All procedures were performed by an expert surgeon (G.N.).

Postoperative follow-up and data analysis

Post-operative assessment was planned at 1 (functional data not considered for the study purposes), 3 and 12 months. All patients were offered a visit free of charge in May 2016. Each time the visit included a pelvic examination. P-QoL questionnaires were distributed at 12 months and in May 2016. Postoperative urodynamic analysis was performed only when needed.

We defined objective anatomical cure at POP-Q stage less than 2, satisfactory cure at POP-Q stage equal to 2, while unsuccessful repair was POP-Q stages of 3 or 4.

We used the Clavien-Dindo grade for surgical complications and the IUGA/ICS classification for mesh-related ones [10,11].

For statistical analysis, the chi-square test was used to compare data from POP-Q at different times, the Wilcoxon test was used for comparing the differences in P-QoL. Results were considered statistically significant when $p < 0.05$.

Methods, definitions and units conform to the standards recommended by the ICS [12].

No financial assistance was received from any company in the design or execution of this study.

Results

All patients were alive at 3 and 12 months follow-up. In May 2016, 64 (97%) patients were examined, 2 (3%) were lost at follow-up. The mean follow-up time was 5.6 (SD: 1.6, Range: 1.1–8.1) years. 21 (32%) patients with stress incontinence received contemporary SUI surgery using a single incision transvaginal sling. Mean operating time was 82 ± 20 min. Bladder catheter was removed on the third postoperative day. Median hospital stay was 3 (Range 3–5) days. The 30-day Clavien complication rate was 3%, due in both cases to grade III A complications: a pelvic hematoma in one patient and urinary retention requiring one week of self-catheterization in another who underwent concomitant SUI surgery. Late complications occurred in a total of 5 (7.8%) patients; specifically: 1 (1.5%) grade II de novo urge incontinence (without urodynamic detrusor overactivity) treated with antimuscarinics and, 4 (6.3%) grade III A small vaginal mesh extrusion (IUGA/ICS classification 1, T3, S1, a in all cases) treated with vaginal removal of the exposed portion of the mesh as an outpatient that did not require even local anaesthesia. No patient referred de novo subjective complaints related to bowel function.

Concerning the primary objective, the overall success rate (POP-Q ≤ 2) was 92.5% at 12 months and 84.4% at May 2016. We registered 3 (4.5%) stage IV cases at 3 months. We considered these cases as failures, not complications. In our experiences early recurrence of the prolapse is probably due to a technical mistake, loosening of the stitches, breakage of the mesh or of the anchorage structure. At 12 months after surgery 42 (63.6%) patients were cured: 9 (13.6%) stage 0, 33 (50%) stage I) and 19 (28.9%) presented satisfactory prolapse cure. 5 (7.6%) were considered unsuccessful (2 (3%) stage III and 3 (4.5%) stage IV). These values tended to remain stable over time, Table 2, in fact no statistical difference was observed comparing postoperative data between 3 and 12 months ($p > 0.05$) nor between 12 months and data collected in May 2016 ($p > 0.05$). In May 2016, 10 (15.6%) patients of 64 compliant with follow-up, presented unsuccessful repair (2 of them underwent hysterectomy in another hospital while 5 stage III, 3 stage IV did not receive other procedures), rendering an overall success rate of 84.4%.

Regarding the secondary objective, a statistical difference emerged between data from preoperative P-QoL questionnaires and from postoperative questioning ($p < 0.01$ for all domains). However, a comparison of follow-up data for patients in May 2016 with their 12 months postoperative data showed no statistical difference ($p > 0.05$ for all domains), Fig. 5. No patients developed de novo SUI. Concerning the personal relationships domain of the P-QoL questionnaire, 32 patients were sexually inactive, not for reasons attributable to POP (either for age, lacking of partner, ecc.). Among the remaining 34 patients, at 12 months 11 (32.4%) referred dyspareunia, 5 of them reported such symptom already before surgery; thus the de-novo dyspareunia rate was 17.6% (6 patients) at 12 months. At May 2016, 7 (20.6%) out of 29 sexually active patients complained of dyspareunia, 4 of them were already affected before surgery. The de-novo dyspareunia rate at May 2016 was 10.3%. At examination, the patients with de-novo dyspareunia presented vaginal dryness and/or vaginal rigidity.

Table 1

Baseline patients' characteristics, lower urinary tract symptoms (LUTS) and pre-operative urodynamic data.

Mean age (SD, Range), years	69.7 (7.7, 50–87)
Mean BMI (SD), kg/m ²	24.9 (5.2)
Median parity (IQR), n	2 (1–2)
Filling phase LUTS, n (%)	28 (42.4)
Voiding phase LUTS, n (%)	15 (22.7)
Mean Voided volume (SD), ml	348.75 (98.41)
Mean Maximal capacity (SD), ml	375.74 (75.48)
Mean Q max (SD), ml/min	18.07 (7.12)
Mean Q average (SD), ml/min	11.4 (4.94)
Mean PVR (SD), ml	44.81 (69.07)
Mean MUCP (SD), cmH ₂ O	54.26 (20.12)

SD: standard deviation; IQR: interquartile range; PVR: post-void residual; MUCP: Maximum urethral closure pressure.

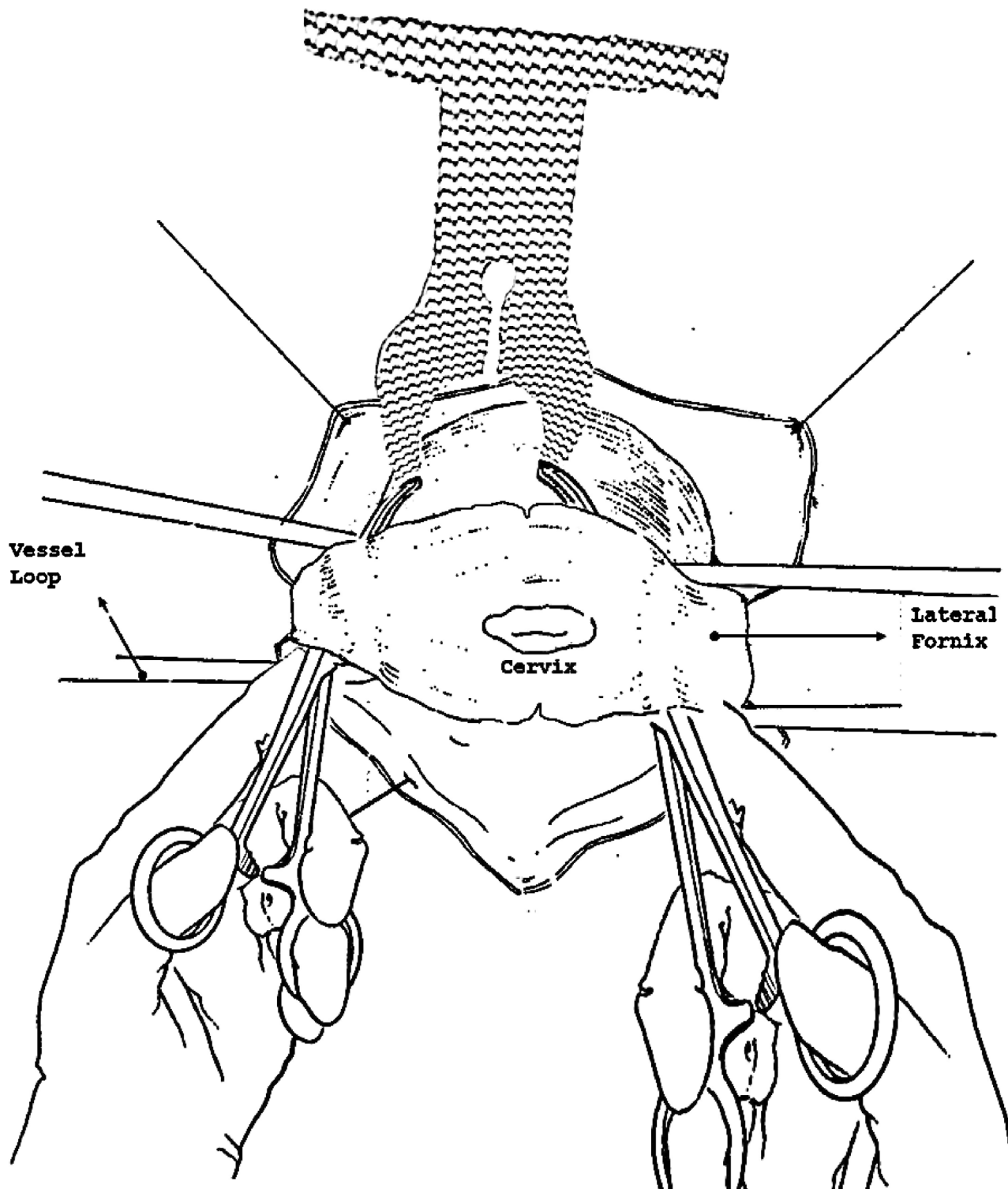


Fig. 2. Passage of the mesh between the posterior and anterior vaginal segments.

Discussion

Surgery aimed at pelvic floor reconstruction allows for different approaches: vaginal, open abdominal, laparoscopic or robotic. Operative time is generally shorter when the vaginal approach is adopted, as are hospital stay and recovery time [13,14]. Biocompatible or synthetic materials can be employed in pelvic floor reconstructive surgery, the debate about the best option is ongoing [15,16]. Synthetic meshes have been highly criticized in recent

years, but the use of mesh in pelvic floor surgery is the reconstructive technique that best corresponds to anatomy because the shape of the mesh correctly reproduces the human pelvic floor. Moreover literature has underlined the uterus sparing technique as a viable option for the surgical management of uterine prolapse, because it is best at retaining the original anatomy and statics of the pelvic floor [17].

The results of our study confirm the effectiveness of our uterus-sparing technique for the correction of high-grade anterior and

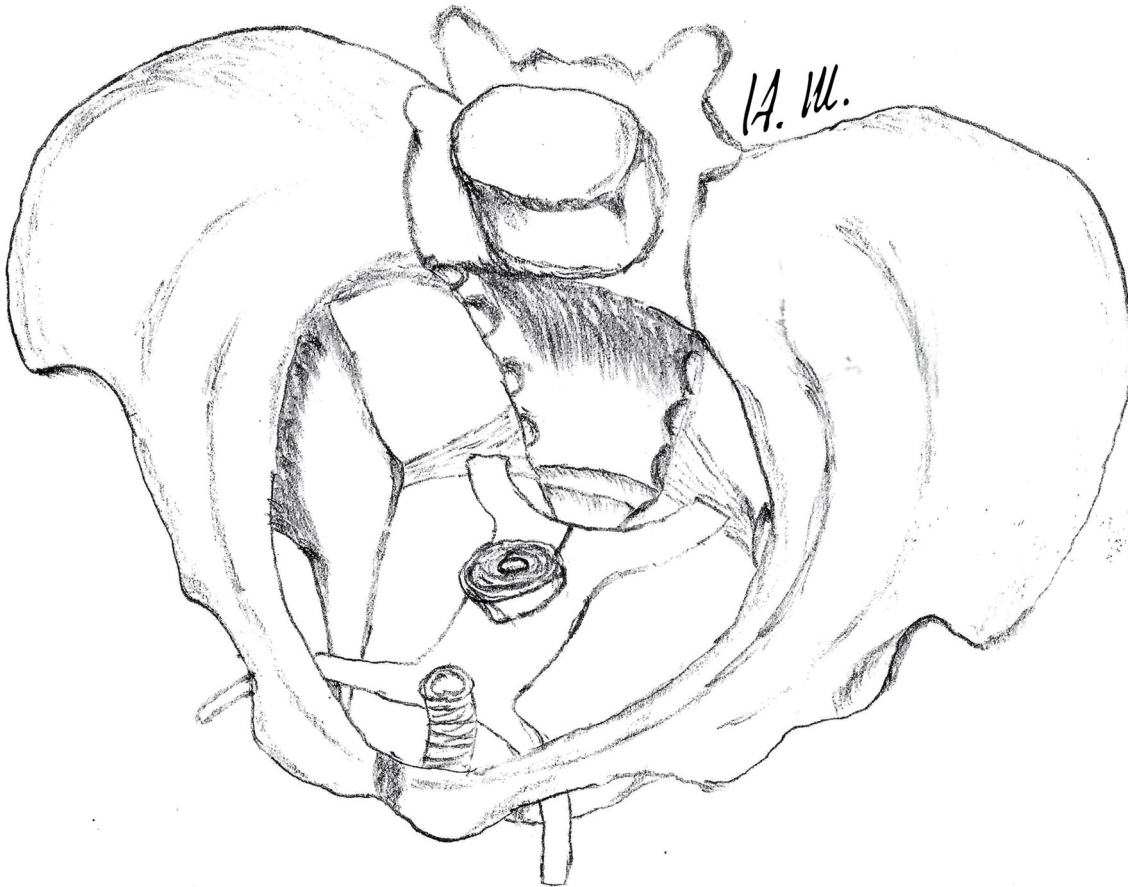


Fig. 3. Mesh in the pelvis. Upper view.

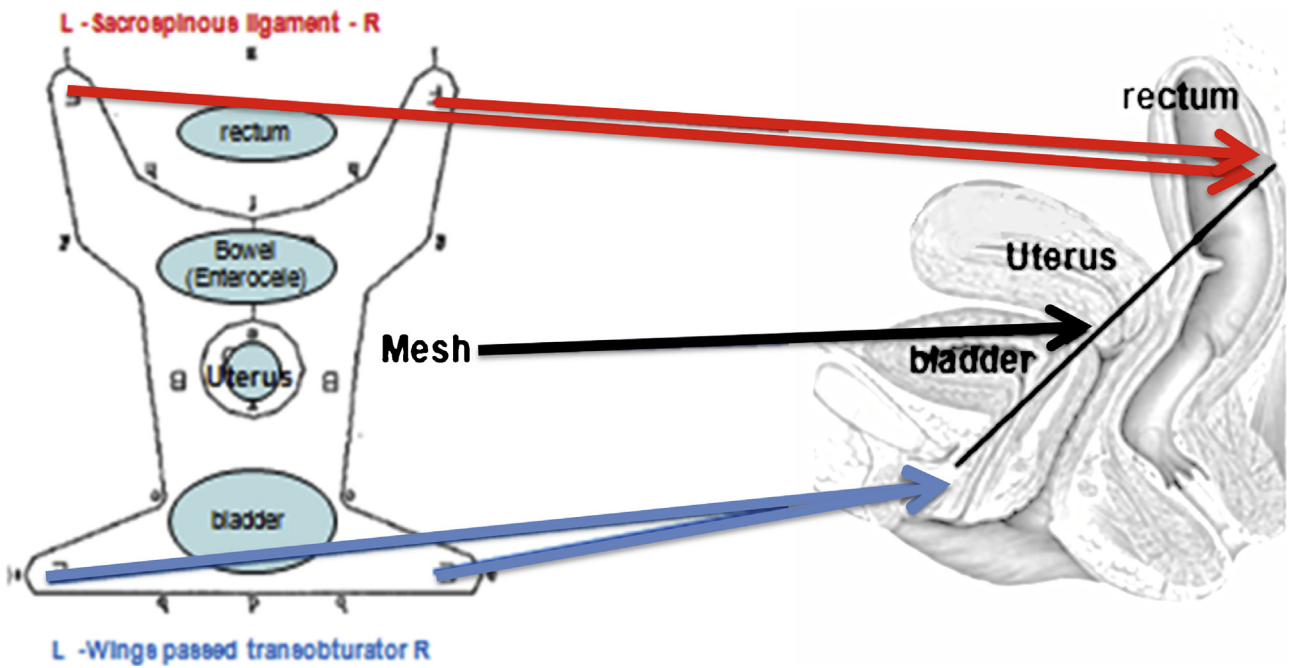


Fig. 4. Mesh in the pelvis. Schematic lateral view.

apical defects in terms of anatomical correction. Our rate of success is comparable to data reported in the literature for different procedures [1,18,19]. The length of our follow-up period suggests

that results are stable over time. We have also observed a significant improvement in prolapse symptoms and quality of life. Our positive results are due to the logic of the mesh, its shape, and

Table 2
Data from POP-Q at different follow-up times.

	Preoperative, n = 66	3 months postoperative, n = 66	12 months postoperative, n = 66	May 2016 ^a , n = 64 ^b
Stage 0, n (%)	–	10 (15.1)	9 (13.6)	7 (11.3)
Stage I, n (%)	–	32 (48.5)	33 (50)	31 (50)
Stage II, n (%)	–	19 (28.9)	19 (28.9)	16 (25.8)
Stage III, n (%)	32 (48.5)	2 (3)	2 (3)	5 (8.1)
Stage IV, n (%)	34 (51.5)	3 (4.5)	3 (4.5)	3 (4.8)

^a 2 patients were lost at May 2016 follow-up: one who had Stage IV POPQ at 12 months and another who had Stage II at 12 months.

^b 2 patients underwent hysterectomy in another hospital, after 2 and 4 years of surgery respectively and have been considered as unsuccessful repair.

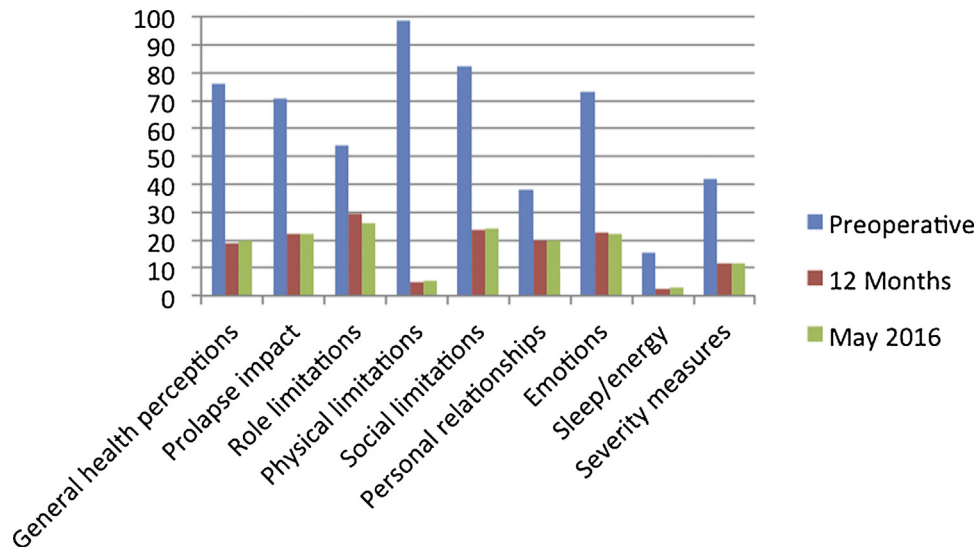


Fig. 5. Data from P – QoL.

also its correct implementation. The pubo-cervical fascia, interposed between mesh and bladder acts as a buffer avoiding direct contact between bladder and mesh. We prefer to interpose the fascia between the mesh and the bladder to add protection to this organ. The rare vesical erosions are much more serious than those of the vagina, which are easily repaired.

Moreover when the pubocervical fascia is isolated from the bladder and left attached to the vaginal wall, the weak site (where erosions often occurred), is exactly where the walls and fascia are cut and then sutured. The procedure counteracts the causes of prolapse by recreating a new pelvic floor support, and implies no organ removal. The mesh, ultimately lies on a plane with the posterior part higher than the anterior one, thus it reestablishes the anatomical floor of the levator ani muscle, it is placed tension-free in the pelvis, avoiding wrinkles that are the primary cause of vaginal erosions. The rectum, located between the posterior mesh wings, maintains its anatomical position and is under no pressure from the mesh.

Surgical correction of uterovaginal prolapse traditionally involves hysterectomy even if the uterus is believed to be passive in the disease. Removal of the uterus disrupts the equilibrium between the interactions of the pelvic organs regarding organ descent [20]. Additionally, hysterectomy cures the main “prolapse symptom”, but it is less efficient in treating the cause, which is weakened support from musculofascial structures [21]. The void created by hysterectomy can cause a weakened area through which vaginal segments may prolapse [22].

Over the past few decades, uterus-sparing surgery, which we were among the first to practice [3], has become more popular worldwide and there is growing consensus that the uterus can be preserved in pelvic reconstructive surgery in appropriate patients

[23,24]. In fact, when hysterectomy is associated with POP surgery, operation time grows, blood loss is greater, and there are generally more complications, above all when a mesh is inserted by a vaginal approach [24]. Moreover, there is debate about whether anatomical modifications induced by hysterectomy implicate sexuality [25].

The use of meshes in treating POP was prompted by their use in incontinence surgery: the ease of implementation and positive results obtained suggested that meshes might yield similar results in POP surgery. Many products appeared on the market without appropriate clinical trials due to their simple production technology and high profit margins [26]. Furthermore, surgeons with little experience in this field were attracted by the apparent simplicity of use offered by commercial kits, some of them were difficult to use due to dimensions and anchoring technique. All these factors are responsible for a great amount of complications in patients receiving trans-vaginal procedures, leading to lawsuits failed against surgeons and industries. These circumstances led the FDA to require strict pre-clinical validation of meshes, and to a re-classification of these devices. Now they must meet stricter standards of efficacy for resolving the anatomical problem they intend to correct before they reach the market. In addition, a focused training which, however, has not yet been standardized, should be required. Indeed surgical experience is of pivotal importance [1,27]. Kelly et al. found the risk of complications to be lower for surgeons performing 14 or more procedures per year [27]. We agree with the FDA restrictions on the use of meshes for POP, but we take issue on their designation as high risk devices [2]. A specific risk resulting from the use of mesh in pelvic floor reconstruction surgery is mesh exposure [26]. The modern soft polypropylene large weave meshes reduced this risk as our low

rate and grade of minor vaginal erosions demonstrate. Other risks such as dyspareunia and pelvic floor pain may also result from biocompatible materials [28]. Dyspareunia in post-menopausal women is not uncommon even without POP, its entity is usually difficult to evaluate. The rate of de-novo dyspareunia among our sexually active patients was 10.3%, which is comparable to values reported by other authors [15,29], none of our patients referred pelvic pain attributable to sacrospinous ligaments stitches.

Despite criticism of synthetic materials, recent Cochrane reviews, albeit with metanalyses biases, affirmed that the use of vaginal meshes lowers the risk of prolapse symptoms and of recurrent anterior vaginal prolapse when compared to biocompatible tissue and fascial repair [26,30]. Our results are in keeping with those findings, confirming stable success rate over the long-term.

The limits of this study are: its monocentric prospective observational structure with a limited number of patients and its lack of a comparison with other techniques, such as hysterectomy and fascial repair. Uterus sparing surgery does raise questions of most suitable approach, whether vaginal, abdominal, or laparoscopic.

In conclusion, our technique is feasible for a urogynecologist of average experience trained by taking a hand in a few procedures. The low rate of complications demonstrates the safety both of the material and the procedure, which offers a stable and notable anatomical correction of prolapse with improvements in patient QoL. This finding warrants prospective evaluation in clinical trials. More experience is needed to determine which approach is best for prolapse surgery.

Financial disclaimer/conflict of interest

None.

Acknowledgement

To Prof. Gail Solberg for linguistic revisions, with thanks.

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