Original article

Vaginal sacropexy achieved by eight tension-free fixing arms mesh- preliminary results

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Abstract: Objective: Surgical techniques utilizing six arm synthetic meshes for apical prolapse repair has been established, and debated in the last few years. Such vaginal hysteropexy (HPX) has several advantages over abdominal or laparoscopic HPX, although even through transsacrospinous fixation the apical reinforcement is not perfect. Our aim was to achieve optimal apical support by multivectoral apical suspension with the use of eight arm polypropylene vaginal mesh. *Methods:* In a prospective preliminary study design, 29 patients with pelvic organ prolapse quantification (POP-Q) system stage II-IV anterior and central compartment prolapse were included. They underwent the implantation of an eight arm polypropylene mesh, through a single anterior vaginal incision. The fixation has been achieved through dual transobturator and dual apical (sacrospinous and sacrotuberal) sutureless anchoring. *Results:* we experienced significant improvement in the prolapse after surgery in all patients. The mean Aa point was ascended from 1.1 cm to –2.9 cm, consequently the mean Ba point changed from 2.5 cm to –2.9 cm, and the mean C point climbed from 0.6 cm to –7.5 cm after the surgery. All patients were subjectively satisfied after the intervention. During the 12 week follow up period no mesh extrusion and no dyspareunia were noted. *Conclusions:* the vaginal implantation of the eight arm mesh comes with high patient satisfaction rates, and achieves vertical vector stabilization of the vaginal apex through sacrotuberal fixation, although further studies with more participants are required to assess the effectiveness of the approach.

Keywords: Pelvic organ prolapse; Sacropexy; Surgical treatment; Vaginal mesh; Pelvic reconstructive surgery.

INTRODUCTION

Pelvic organ prolapse (POP) is a relatively common disease, which is described as a loss of anatomical support of the pelvic organs leading to impairment of normal function and diminished quality of life[1]. The apical suspension of the pelvic organs is achieved by the attachment of the vaginal apex to the pelvic walls and the sacrum through the upper paracolpium, which has been reported to be the keystone of the female pelvic organ support as described in a landmark publication from Petros[2]. The loss of integrity in DeLancey Level I support is arise from several reasons ranging from obstetric related injuries, menopause, genetic factors, chronically increased intraabdominal pressure, pelvic floor trauma to spina bifida, and will eventually lead to apical vaginal prolapse[3].

The treatment of symptomatic apical defects can be conservative (pelvic floor exercise, vaginal pessary, electrostimulation and biofeedback therapy), or surgical, through pelvic reconstructive surgery. Currently sacral fixation of the uterus, or the vaginal vault after hysterectomy, via abdominal, laparoscopic and robotic approaches utilizing polypropylene xenograft , or abdominal fascia , or fascia lata autografts are considered to be the mainstream of interventions , despite vaginal sacrospinal fixation and vaginal mesh surgical techniques also provide good anatomical cure of prolapse[4,5]. However vaginal surgical approaches utilizing synthetic meshes for apical prolapse repair has been well established , they are also intensively debated in the last few years[6,7]. Although we are well aware of the recent findings about the mesh related complications reported in the literature , and the raising concerns about graft use in prolapse surgery , based on our results and experiences our study group is continuously devoted toward the use of vaginal grafts in POP surgery . Recently Guyomard and Delorme introduced a vaginal mesh with six transfixing pelvic straps providing anteroposterior and lateral suspension as a feasible and effective way of the anterior and central compartment reconstruction[8]. Despite the
respected results of the vaginal surgical technique, it not seemed to be optimal, because the apex is only suspended in a single vector direction toward the sacrospinous ligament. Therefore our aim was to mimic normal anatomy, and to establish an optimal surgical technique to enforce apical support by multivectoral (sacrospinous and sacrotuberal ligament anchored) suspension with the use of a partially absorbable polypropylene vaginal mesh with eight fixing arms.

MATERIALS AND METHODS

Study population and data collection

This study was approved by the Institutional Ethical Review Board. In a prospective cohort study, 29 women suffering from symptomatic POP-Q stage II-IV anterior and central compartment prolapse, who were intended to be treated with vaginal surgery, were included. Patients underwent diagnosis, therapy and follow up at the Vivantes Humboldt Clinic's Pelvic Floor and Incontinence Centre (Berlin, Germany) between January 1st 2017 and January 31st 2018. All patients provided their written informed consent to participate. All patients reported vagina bulging with correlated urinary symptoms (urgency, hesitency, frequency, prolonged urinary stream and feeling of incomplete emptying) or sexual dysfunction (dyspareunia, decreased lubrication and decreased sensation, arousal or orgasm). Patients with active infections of the pelvis or vagina, such as vaginitis, urinary tract infection or pelvic inflammatory disease, and patients who were noncompliant or unlikely to participate in the follow up (they did not attend their check ups) were excluded. Follow up examinations were carried out 3 month after surgery. Baseline demographic data, age, parity, medical history, menopausal state, sexual activity and BMI were recorded.

Evaluation of POP

All women were examined according to the International Urogynecological Association (IUGA) guidelines, and all terminology currently used refers to the recommendations of the International Continence Society (ICS). The level of altered pelvic anatomy was assessed by using the pelvic organ quantification system (POP-Q)[9]. All examinations were carried out in an outpatient setting, where patients were positioned in standard lithotomy position, physicians were utilizing anteri-

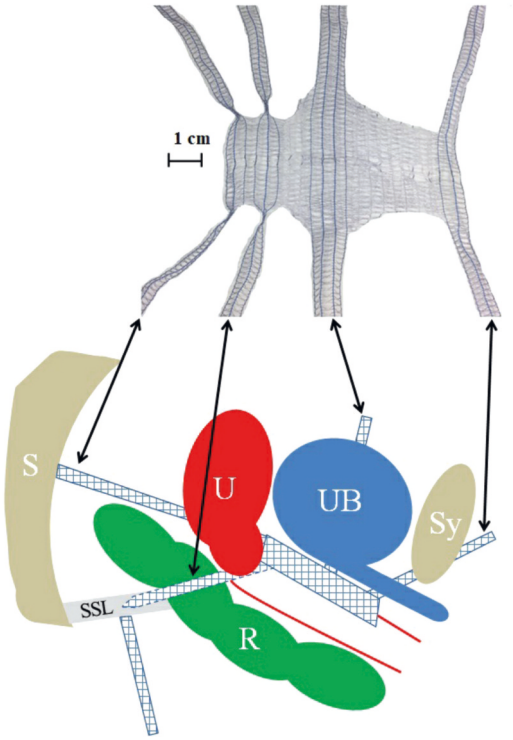

Figure 1. – Schematic picture of the mesh position and the anchoring points of the fixing arms. Abbreviations: S – sacral bone; Sy – symphysis bone; U – uterus; UB – urinary bladder; R – rectum; SSL – sacrospinous ligament.

or and posterior vaginal retractors, while patients performed Valsalva manoeuvres, in order to reveal the predominant compartment of prolapse. The POP-Q stage, the level of prolapse in each compartment, the genital hiatus, the vaginal length, and the vaginal introitus size (measured by fingerbreadths) were examined as described earlier by *Farkas* et al (2016). Involuntary loss of urin was assessed by stress test in lithothomy and upstand positions, and with the demonstration of urethral funnelling with ultrasound (US). Pelvic floor US also revealed the urethral length, level of prolapse and the pelvic anatomy. Post voiding residual volume was objectively assessed through catheterisation pre and postoperatively , moreover urin culture was carried out preoperatively.

Description of the surgical methods

The development of the method was based on the description of a six fixation straps nonanchored vaginal mesh by Goyumard and Delorme[8]. Patient underwent the antero-posterior placement of a partially absorbable polypropylene mesh with eight fixing straps, by an experienced surgeon (C. G.), who carried out all the operations in exactly the same manner. The position of the mesh is shown in Figure 1, and was as following: after infiltrating the anterior vaginal wall with *epinephrine* containing physiological saline (1 ampulla *epinephrine* in 500 ml in isotonic NaCl solution) a single incision midline colpotomy was carried out. The vaginal epithelium was then dissected bilaterally from the underlying pre-vesical tissue in a manner of intensive hydro dissection, fine scissor preparation (push- spread technique), and digital separation until reaching the obturator membranes , the sacrospinous , and sacrotuberal ligaments bilaterally . In the created space a 6 cm wide and 10 cm long cross-shaped piece of partially absorbable polypropylene mesh with a pore size of 2 x 4 mm (SERATOM® E+ PA MR, ref# SN218 MR,
Serag-Wiessner, Germany) was placed without fixing sutures under the pre-vesical tissue. The stabilizing tape arms were

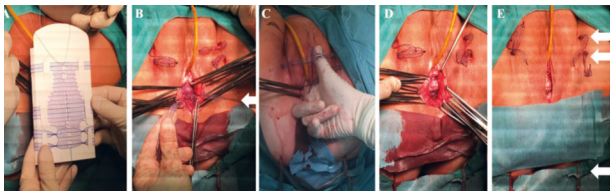

Figure 2. – Demonstration of the mesh introduction. A 6 x 10 cm long partially absorbable MR visible mesh with eight fixation straps was introduced (A) after midline colpotomy . The transobturator and the transgluteal trans-sacrospinous straps are inserted bilaterally as described by Guyomard and Delorme. The sutureless placement the final two tapes in direction sacrum are (B - arrow) carried out under manual guidance overlaying the sacrotuberal ligament (C). The final sub-vesical position of the partially absorbable tension-free mesh can be seen (D). As a final step the mesh is covered with vaginal ep- ithelium, arrows representing the visible transobturator and trans - sacrospinous fixing straps (E). No vaginal tamponade was used

placed in four positions: anterior (1-2.) and posterior (3-4.) transobturator, trans- sacrospinous (5-6.) and sacral-sacrotuberal ligament (7-8.) by out-in method, except for the last two straps, which were just placed under digital guidance over the anatomic structures retroperitoneal. As a final step the vaginal epithelium was closed with a nonlocking continuous everting mattress sutures (Figure 2).

Statistical analysis

Statistical analyses were performed by using IBM SPSS Statistic 20 (IBM Corporation, Armonk, NY, USA) at the University of Pecs, Institute of Bioanalysis. The sample size (n) was 29. Continuous measurements are summarized and presented as averages and standard deviations (SD), categorical data is presented as observed or as percentages. For the independence analysis between the categorical variables Mann-Whitney and Independent Student's t-test performed. To determine whether there is a significant difference between the expected frequencies and the observed frequencies in one or more categories Chi-square test was used. Statistical significance was set at $p < 0.05$.

Results Demographic data

The average age of the study population was 68 years ± 9 SD (min: 49, max: 77), and the mean parity was 2.0 ± 1.19 SD per patient (min: 0, max: 4). The study population had average weight of 72.41 kg and height of 1.63 m, resulting in a mean BMI of 27.14 ± 4.47 kg/m^2 (min: 21.77, max: 41.02). All patients were in menopause. A total of 13 patients (44) were sexually active, from which all of them

Table 1. Data related to the midurethral sling surgery.

Characteristics Prolapse POP-Q Stage	**Preoperative**	**Postoperative**	**p value**
Anterior compartment (cystocele) n (%)			
I	0	0	
II	3 (10)	0	
III	16 (56)	0	< 0.05
IV	10 (34)	0	< 0.05
Apical compartment (uterus or vaginal vault) n (%)			
I	7 (24)	0	< 0.05
II	7 (24)	0	< 0.05
III	5 (17)	0	
IV	3 (10)	0	
Posterior compartment (rectocele) n (%)			
I	14 (48)	14 (48)	
II	4 (14)	4 (14)	
III	1 (2)	1 (2)	
IV	1 (2)	1 (2)	

complained about sexual dysfunction. The majority of the participants (90%) had no prior gynecological surgeries, and all together 2 women (7%) underwent vaginal hysterectomy, with simultaneous anterior and posterior colporraphy due prolapse indication in their history, and one patient had a laparoscopic sacrohysteropexy (3%).

Evolution of POP-Q scores after tape implantation surgeries

We experienced major improvement in the anterior and in the central prolapse after surgery in all patients, but no change in the posterior compartment (Figure 3). We managed to observe significant shift in the Aa points (from –0.93 cm ±0.90 SD to –2.86 cm ±0.59 SD) and in the Ap points (from –1.71 cm ±1.38 SD to –2.54 cm ±0.74 SD). Moreover a major significant development was also observed in the C point (from –1.86 cm ±3.54 SD to –7.07 cm ±1.05 SD) and in the D point (from –3.17 cm ±3.72 SD to –7.68 cm ±2.70 SD) positions. Interestingly significant improvement was observed in the posterior compartment (Ba point from 2.36 cm ±0.95 SD to –2.93 cm ±0.26 SD; Bp point from –1.39 cm ±1.31 SD to –2.32 cm V 0.72 SD). In the further POP-Q variables (GH, PB and TVL) no significant differences were calculated before and after the surgery (Table 1).

Subjective and objective outcomes

All patients were subjectively satisfied after the intervention. The pre and postoperative functional urinary symptoms are listed in Table 2.

Those patients (n=11) who had positive stress cough test prior surgery were found to be stress incontinent after surgery. During the follow up period *de novo* SUI occurred in two patients (6%). We observed a significant fall in the amount of the rest urin after surgery , obtained by catheterisation , and in parallel the disappearance of urge symptoms (Table 2). Perioperatively no visceral injury and no haemorrhage was observed (preoperative mean Hgb lev - el 132 g/L ± 14 .4 SD , Htc 38 .93 L/L ± 10 .58 SD ; postoper - ative mean Hgb level 118 .5 g/L ± 14.8 SD , Htc 34 .6 L/L ± 11 .42 SD). The mean close - to - cut operation time was 60 .52 min ± 27 .56 SD . The mean hospital stay was 3 days / 2 nights. During the 3 month follow up period no mesh extru - sion and no prolapse recurrence were noted.

DISCUSSION

To our knowledge, this is the first study which demonstrates a vaginal surgical technique, utilizing a partially absorbable polypropylene vaginal mesh , in order to provide multivectoral apical suspension and successfully treat central and anterior zone prolapse in order to mimic normal anatomy . In the current study , 29 women with symptomatic stage II-IV apical prolapse and traction or pulsion cystoce - les underwent single incision vaginal mesh implantation with eight fixing straps , and after 3 month all of them were referred themselves to be symptomless.

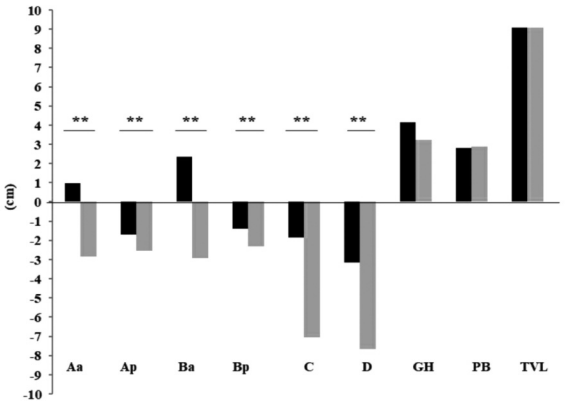

Figure 3. – Evolution of the POP-Q variables before (black diagrams) and after (grey diagrams) the surgery. The x axis represents the distances of the landmark points from the hymen in centimeters. Asterisks represent significant statistical difference between the values calculated by Mann-Whitney test (** $p < 0.01$).

TABLE 2. Functional symptoms of the study participants prior and after surgery.

Urinary symptoms	before surgery (n)	after surgery (n)	p value
No SUI (%)	62.1 (18)	58.6 (17)	
SUI	37.9 (11)	44.8 (13)†	
No urgency	55.2 (16)	0	<0.01
Urgency with incontinence	44.8 (13)	0	<0.01
Non-voiding dysfunction	0.06 (2)	0	
Voiding dysfunction with no residual	0	0	
Voiding dysfunction with residual	44.82 (13)	0	<0.01
Residual urin (mean ± SD ml)	64.44±60.97	15.41±19.33	< 0.05

The development of the currently used prosthesis incorporated the transobturator lateral suspension technique (to repair the pubecervical fascia deficiency) described by Eglin et al.[9], based on the theories of Petros[2], and the transgluteal sacrospinous ligament fixation technique[10], furthermore aimed to achieve sacral fixation. Since apical and paravaginal defects are manifestations of the same phenomenon, in this regard, the simultaneous correction of both defects is rational[11]. Moreover the proper apical support can only be achieved if the surgical repair is aimed to mock the normal anatomic force vectors, originate from the uterosacral ligament (USL) and cardinal ligament (CL), which ensures stability and flexibility of the uterus as well as provide apical support.

Concerns about the safety and morbidity of mesh and graft use in POP surgery ultimately questioned the justification of synthetic mesh materials in vaginal prolapse surgeries. Despite vaginal mesh placement provides better cure of prolapse then other techniques[6,12] the international debate is based on the mounting evidence reported in the literature about mesh related complications[13], and the US Food and Drug Administration (FDA) safety warning regarding transvaginal mesh complications[14]. The increased number of litigations led to a ban on the use of vaginal mesh in several countries (Scotland, UK), however the findings are not concordant. The PROSPECT study concluded that patients undergo primary transvaginal mesh placement has no symptomatic or anatomic benefit in short term[15], although other study groups found contradictory results and reported that vaginal mesh is feasible and effective way of treatment in medium term[16-18]. Despite the dilemma of the use of transvaginal mesh in POP surgeries, based on our experience our study group is not intending to discard the vaginal operative route from the surgical inventory.

A common reason against mesh is the high number of *de novo* SUI after mesh repair of the middle zone and apical defects, with an incidence ranging between 8.6-23%[19-21]. We found a persistency of stress symptoms in all preoperatively SUI patients and we experienced *de novo* stress appearance in 6 % (n=2) in the study group. Another contradictory view against synthetic allograft implantation is the high risk of mesh exposure[19]. Although in recent studies this complication is reported to occur between 7.7-10.1%[20-21], in our current study we found no tape exposure during

the relatively short follow up period, however long term follow up examination is necessary to evaluate the clinical outcome of the intervention from that perspective.

On the other hand there are several undoubted advantages of synthetic allograft use in the operative management of anterior and central compartment defects compared to other approaches. The above described method results high patient satisfaction, short hospitalization, and excellent stabilization of the vaginal apex and the anterior wall. The method is considered to be real minimal invasive techniques, with a preferred cosmetic result. While a recent study failed to report significant differences in cost between laparoscopic sacrohysteropexy and vaginal mesh correction for the treatment of POP (mean 5985.7 €, CI 95 %: 5613.14 versus mean 6534.31€, CI 95%: 6290.36), we found an average cost of 3840€ / mean 3 days/2 nights hospital stay per eight arm mesh implantation, therefore we concluded that single incision vaginal sacropexy is a cost effective surgical approach to treat anterior and central defects.

Self-critical considerations are highlighting the limitation of our preliminary study, which is the low number of participants, the short duration of follow up, the lack of comparative studies, and the long learning curve of the intervention. Therefore further long term studies with more participants, and in addition postoperative magnetic resolution scan verifications of the mesh position are required to assess the effectiveness of the approach. Disadvantage of the method is, that it has no impact on coexisting stress urinary incontinence (SUI), therefore a second step operation is required to overcome all the urinary symptoms.

The strongpoint of our study is the demonstration of new and innovative operative technique in order to overcome anterior and central compartment defects, through a multivectoral apical suspension, which allows vertical apex stabilization. In conclusion the vaginal implantation of the eight arm mesh comes with high patient satisfaction rates, results painless elevation, and achieves vertical vector stabilization of the vaginal apex through sacral fixation therefore it is a reasonable alternative of laparoscopic sacrohysteropexy.

DISCLOSURE STATEMENTS

The authors declare no personal o financial conflict of interest to disclose.

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