

Department of Obstetrics and Gynecology, School of Medicine, University of Zagreb, Croatia

CYSTOCELE REPAIR BY SYNTHETIC MESH SECURED THROUGH THE OBTURATOR FORAMEN (PERIGEE SYSTEM)

KOREKCIJA CISTOKELE SINTETSKOM MREŽICOM TRANSOBTURATORNIM PRISTUPOM (PERIGEE SISTEM)

*Slavko Orešković, Držislav Kalafatić, Helena Lovrić, Tomislav Župić,
Ante Gojević, Maja Banović*

Professional paper

Key words: cystocele, vaginal wall defects, incontinence repair, Perigee procedure

SUMMARY. Objectives. Our first short-term results of transobturator mesh interposition (Perigee System) for the correction of cystoceles are presented. **Methods.** This is our initial study on 22 women with cystocele > Grade 2 who underwent the Perigee procedure in our Center between January 2006 and March 2007. In 15 cases lateral cystocele defect was diagnosed, whereas other 7 patients had central anterior vaginal wall defect. All patients were assessed by POP-Q staging. **Results.** The anatomical and functional reconstruction of anterior vaginal wall was achieved in all patients. Preoperatively, mean POP-Q Aa value was +1.1 (\pm 0.3) and Ba value was +1.9 (\pm 1.3). No major intraoperative or immediate postoperative complications were observed. One and three months postoperatively, mean POP-Q Aa value was –2.9 (\pm 0.21) and –2.82 (\pm 0.1) respectively and Ba was –2.85 (\pm 0.4) and –2.8 (\pm 0.23) respectively. Patients' satisfaction and the imposing short-time surgical outcome were achieved in all cases after three months follow-up. **Conclusion.** We consider Perigee procedure to be highly efficacious, minimally invasive and easy technique for correction of anterior vaginal wall defects.

Stručni članak

Ključne riječi: cistocela, vaginalna stijenka – defekti, inkontinencija urina, Perigee postupak

SAŽETAK. Cilj rada. Prikazati preliminarne rezultate transobturatornog pristupa korekcije cistocela metodom Perigee. **Metode.** 22 bolesnice s cistocelom drugog stupnja podvrgnute su u našoj ustanovi metodi Perigee u vremenskom razdoblju između siječnja 2006. i ožujka 2007. godine. U 15 bolesnica dijagnosticirano je lateralno paravaginalno oštećenje, dok je u 7 bolesnica verificirano centralno oštećenje prednje vaginalne stijenke. **Rezultati.** Anatomska i funkcionalna korekcija prednje vaginalne stijenke ovom metodom postignuta je kod svih bolesnica. Preoperativno, srednja vrijednost POP-Q Aa točke bila je +1.1 (\pm 0.3) a Ba točke +1.9 (\pm 1.3). Nije bilo intraoperativnih ni perioperativnih komplikacija zahvata. Jedan i tri mjeseca nakon zahvata, srednja vrijednost točke POP-Q Aa bila je –2.9 (\pm 0.21) i –2.82 (\pm 0.1) dok je srednja vrijednost točke Ba bila –2.85 (\pm 0.4) i –2.8 (\pm 0.23). **Zaključak.** Smatramo da je Perigee metoda jednostavna, neinvazivna i učinkovita metoda korekcije defekata svih tipova cistocela.

Introduction

Graft augmentation repair of pelvic floor defects has recently become exceedingly attractive, since the traditional procedures resulted with failure rate from 40% to 60%.¹ Several innovative approaches using different grafts placed vaginally have been confirmed to be efficient and safe alternatives for anterior vaginal wall repair. The transobturator approach with the principles of biosurgery first described by Delorme allowed the development of innovative simple and minimally invasive method for severe and recurrent anterior vaginal wall prolapse.² The Perigee system uses polypropilen mesh placed without tension via strips through the obturator foramen, and appears to be valuable and time-efficient approach for all types of anterior vaginal wall defects: central, lateral, proximal and distal. The graft is strongly attached to four points in the arcus tendineus fasciae pelvis with intention to reestablish level II support of the

vagina. Unlike other vaginal approaches PERIGEE system ensures finest attachment of apical portion of the graft near the ischial spine which is crucial for strong vaginal reattachment and endopelvic reconstruction. The obturator route appears to be easy, safe and effective for mesh interposition. According to recent few initial reports the technique itself is accompanied by low perioperative risks and high satisfactory rate.^{3–5} The postoperative complications if occur are minimal and may be easily manageable. The initial good outcome reported in recent analysis is supposed to be permanent.

In this preliminary study we report our initial experience, efficacy and operative complications of the PERIGEE procedure for the cystocele correction. We tried to obtain and describe the optimal route of technique in order to reduce the complications reported in previous researches and also to prevent recurrent prolapse symptoms.

Methods

This is the initial descriptive study of the first 22 patients with anterior vaginal wall prolapse grade >2 who underwent PERIGEE procedure in our Department in the period between January 2006 and March 2007. Mean age of patients was 60,4 (range 50 – 71) and all were multiparous. 15 women were postmenopausal and 10 of them used vaginal estrogen therapy. All patients were assessed preoperatively by physical examination and prolapse evaluation by POP-Q staging. Regarding the urinary and prolapse symptoms 7 women complained on straining to void and feel of urinary retention preoperatively, and none of them suffered from incontinence, frequency and urgency. All patients had sterile urine before the surgery.

The procedure was performed under general (13) and spinal (9) anesthesia.

We used Perigee system composed of synthetic 5 cm × 10 cm macroporous polypropylen mesh for repairing central defects and four self-attached arms for correction of lateral vaginal detachments (*Figure 1*). Following a vertical incision from the bladder neck, around 4 cm from the apex of vagina the dissection is similar to that of the anterior colporaphy. Structure of the needle provides fixation of the mesh at the white line of arcus tendineus so there is no need for deep lateral sutures. After orientation about inferior needle pathway, lateral dissection toward the white line of the arcus tendineus may be done. Plication sutures in the midline are placed to reduce the cystocele but also to prevent the bladder perforation when the inferior needles pass by. Superior bilateral incisions are made in the genitofemoral folds at the base of the adductor longus tendon at the level of clitoris. The inferior incisions are made 2 cms lateral and 3 cms inferior to the superior. Narrow-diameter superior helical needles are guided at 45 degrees to patient's midline and perforate the obturator membrane laterally to the ischiopubic ramus under the finger guidance to

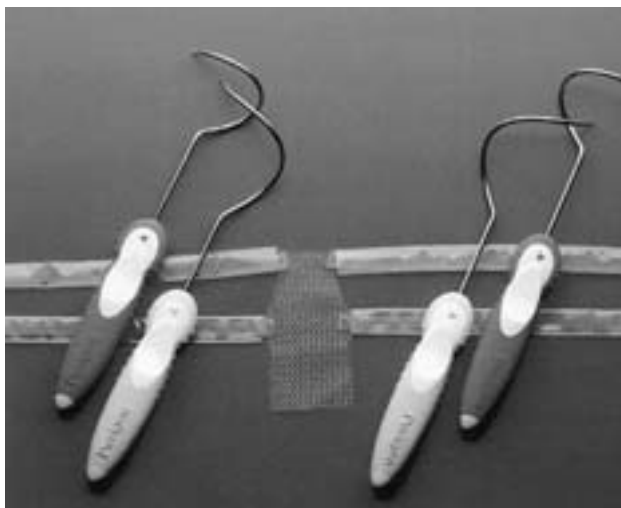


Figure 1. Four self attached arms and helical needles for mesh introduction
Slika 1. Četiri samostalne ručice-igle za uvođenje mrežice

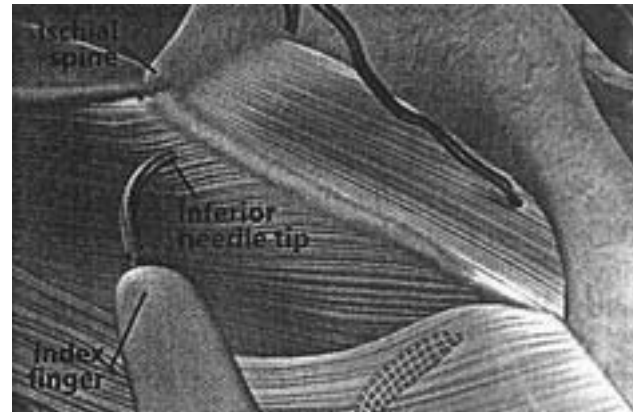


Figure 2. the inferior helical needle introduction under finger guidance
Slika 2. Uvođenje donje helikalne igle uz zaštitu prstom

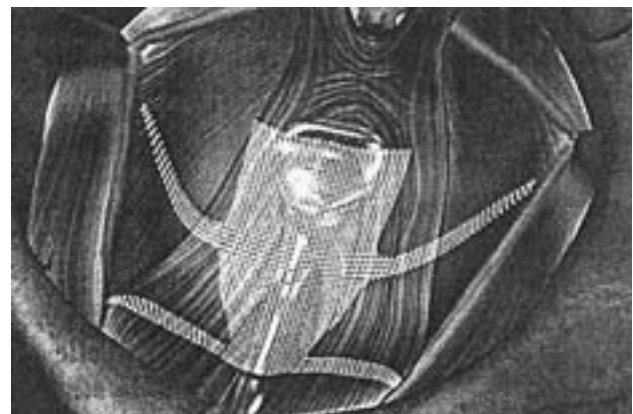


Figure 3. The mesh position before fixation
Slika 3. Postavljena mrežica prije njena učvršćenja

avoid the bladder perforation. The inferior helical needles (*Figure 2*) are inserted with the handle at 90 degrees and are driven under finger control directly to ischial spines in straightforward direction. After penetrating the levators they exit along white line at about 1.5–2 cms of the spines. It is extremely important to direct the needle tips proximally towards spines before rotation throughout the levator muscles. The mesh is subsequently adjusted to vaginal wall extent in a tension-free manner and the proximal tail is drawn to the lower-most portion of the cystocele. The distal arms are then adjusted with slight tension beneath the bladder neck, to return the anterior vaginal wall back to its natural anatomical position (*Figure 3*). Further step is the fixation of the apical edge of the graft to the pericervical ring by the sutures in order to fasten the attachment. The redundant tail of the mesh is additionally removed. After rolling over the mesh vaginal incision is closed, avoiding the superposition of the mesh and its exposure or infection. The outer plastic sheets are cut at the level of skin incision.

After the positioning of the mesh cystoscopy is obligatory to eliminate the bladder injury and verify potency of both ureters. The Foley catheter is inserted in the bladder for 24 hours in average. We practice one day perioperative antibiotic prophylaxis and analgetics if it

is necessary. Patients are recommended to avoid heavy lifting, exercise, and sexual activity for at least four weeks.

The incidence of perioperative complications (nerve, vessel, bladder or bowel injury) and postoperative complications (erosion, rejection, infection, voiding difficulties, retention, urgency, recurrence of prolapse, dyspareunia) were obtained throughout this study. Residual urine was measured by the catheterisation with cut-off point at 50 ml of urine. Also we estimated operating time, intraoperative blood loss and hospital stay. All patients were followed-up at the Department 7 days, 1 and 3 months postoperatively by urogynecologic inspection and with regard to postoperative subjective difficulties and satisfaction.

Results

Out of 22 patients who underwent PERIGEE repair in 15 cases lateral cystocele defect was diagnosed, whereas other 7 patients had central anterior vaginal wall defect. Four women had prior hysterectomy and 6 women underwent anterior colporaphy previously. None of patients suffered from stress urinary incontinence. Preoperatively, mean POP-Q Aa value was $+1.1 (\pm 0.3)$ and Ba value was $+1.9 (\pm 1.3)$. The obturator approach was feasible in all patients. Mean operating time was 21 min (from 15 to 27 min). No major intraoperative or immediate postoperative complications were experienced. The anatomical reconstruction of the anterior vaginal wall appeared ideal. No vascular damage or significant bleeding was noticed, and there was no alternations between preoperative and postoperative red blood cell count. Additionally, no bladder injury was observed during routine post-op cystoscopy.

After removal of Foley catheter all patients could void voluntarily with no residual urine. One and three months postoperatively, mean Aa value was $-2.9 (\pm 0.21)$ and $-2.82 (\pm 0.1)$ respectively and Ba was $-2.85 (\pm 0.4)$ and $-2.8 (\pm 0.23)$ respectively. Hospitalization interval ranged from 1 to 4 days. We observed no rejection or exposure of the mesh and subjectively none of patients complained on recurrent prolapse symptoms. Mild epithelial erosion was detected in one patient and has been resolved by reepithelisation after local estrogen therapy. Granulation tissue reaction was not experienced. No revision has been necessary. There was no incidence of post-op stress urinary incontinence or straining to void. In one patient de novo urinary infection developed immediately after releasing from the hospital and has been managed promptly by antibiotics. Two patients complained on urgency and frequency which dissolved within month after the surgery. Moderate levator pain and groin discomfort (5 patients) and dyspareunia (4 patients) were the most prominent postoperative problems but have disappeared gradually after analgetic and local estrogen therapy. All remarked postoperative difficulties occurred in women who previously underwent vaginal operation. At last follow-up visit none of patients

complained of any recurrent symptom or postoperative difficulty. Anatomical and functional integrity of the vaginal wall has been accomplished three months postoperatively.

All patients were satisfied with postoperative results and significantly improved their quality of life. Although we keep on with the follow-up after the Perigee procedure, we are now able to present maximal short-time success rate and impressively low complication incidence.

Discussion

Rather high failure rate of conventional vaginal repair of pelvic organ prolapse triggered the attempts and curiosity of pelvic surgeons for innovative vaginal approaches and development of new graft augmentation techniques. Therefore classical mechanical way of thinking turned out to be almost abandoned changing to a more creative and rational approach to surgery. Only recently has mesh been used transvaginally for correcting defects of the endopelvic fascia. First experiences have been reported by Julian in 1996 who compared anterior colporaphy with the Marlex graft reinforcement and exceeded 100% objective cure rate at 24 months follow up, versus 66% cure rate in conventional repair.⁶ Although he observed 25% erosion rate in the mesh group further investigators experienced low complication rate and excellent short-term outcome.⁷⁻⁹ A novel vaginal graft PERIGEE system has been constructed using transobturator approach in order to repair all types of anterior vaginal wall defects (proximal, distal, central and lateral). Bilateral superior and inferior needles allow the surgeon minimal lateral dissection and therefore reduce the blood loss and other healing abnormalities. The inferior helical needles provide the positioning of the proximal part of the mesh adjacent to the ischial spines which is fundamental route for the reattachment of the vaginal wall to its normal position at the level of the white line.¹⁰ Consequently, it could be the strongest explanation for high success rate and no recurrence of vaginal wall prolapse after the PERIGEE procedure reported in recent and in our study.^{3,11,12}

The graft is afterwards placed without tension beneath the bladder as a support of the cystocele instead of endopelvic fascia and is strongly fixed at four points by the polypropylene mesh. The advantage of this procedure is that the dissection is simple and there is no need for retropubic or sacrospinous ligament dissection. Moreover, the lateral dissection might become redundant with the surgeon's experience. Since the superior needles pass strictly adjacent to ischiopubic ramus under the finger guidance toward the level of bladder neck the risks of lower urinary tract, obturator nerve and vessels injury should be exceptionally decreased.

Concomitant sling methods (SPARC, MONARC) could be performed without disruption of the superior arms before removing of the plastic sheets. As well the

hysterectomy can be carried out simultaneously.¹⁰ It seems that strong anchoring of the mesh to the apical portion of the repair plays a key role in improved outcome and long lasting results of this technique.¹³

Polypropilen mesh carries the advantage over previous synthetic mesh composition with regard to infection and erosion. In general it has limited foreign body reaction, so it is probably the best choice for augmentation. According to some investigators vaginal mesh erosions continue to be the serious problems occurring in 2 to 13%.^{6,7,15,16} Usual symptoms include persistent pain and tenderness at the vaginal incision, irritative voiding, recurrent urinary tract infections, dyspareunia, vaginal bleeding or persistent SUI. Since this problem commonly results with recurrent prolapse, in most cases a reoperation is required. We observed only one mild erosion and no cases of granulations or rejection. Recurrence of anterior vaginal wall prolapse is well known after the anterior colporaphy and is predisposed by genetic factor, heavy lifting, smoking and obesity. Recent short-term pilot studies on Perigee procedure observed no cases of recurrent prolapse symptoms.^{3,12,13} If surgical failure and erosions do occur it is expected to happen within the first year of surgery, so the assurance and feasibility of this procedure might be confirmed in considerable time.

Conclusion

We consider Perigee procedure to be highly efficacious, minimally invasive and easy technique for correction of anterior vaginal wall defects. Our experience support initial good impressions of recent published studies, so we intend to evaluate this procedure in a large comparative well-designed clinical trial for anatomic and functional long term outcome.

References

1. Weber AM, Walter MD, Diedmonte MR et al. Anterior colporaphy: a randomised trial of three surgical techniques. *Am J Obstet Gynecol* 2004;185(6):1300–6.
2. Delorme E. Transobturator urethral suspension, mini-invasive procedure in the moment of the stress urinary incontinence in women. *Progress Urol* 2001;11:1306–13.
3. Palma P, Rane A, Ricceto C et al. Transobturator correction of cystocele. *Acta Urol Esp* 2005;29:89–92.
4. Yan A, Anne M, Karine A et al. Cystocele repair by synthetic vaginal mesh secured anteriorly through the obturator foramen. *Eur J Obstet Reprod Biol* 2004;115:90–4.
5. Palma P, Riccetto C, Dambros M et al. New trends in the transobturator management of cystoceles. *BJU Int* 2006;97(1):201–10.
6. Julian TM. The efficacy of marlex mesh in the repair of severe recurrent vaginal prolapse of the anterior mid vaginal wall. *Am J Obstet Gynecol* 1996;175:1472–5.
7. Flood CG, Drutz HP, Waja L. Anterior colporaphy reinforced with marlex mesh for the treatment of cystoceles. *Int Urogynecol J* 1998;9:200–4.
8. Natale F, Marziali S, Cervigni M. Tension-free cystocele repair (TRC): long term follow-up. Proceedings of the 25th Annual Meeting of the International Urogynecological Association 2000;120–3.
9. Birch C, Fynnes MM. The role of the synthetic and biological prostheses in reconstructive pelvic floor surgery. *Curr Opin Obstet Gynecol* 2002;14:527–35.
10. Davila GW. Current concepts in pelvic anatomy and reconstructive surgery. *Cleveland Clin J Med*, 2005;72:20–7.
11. Rane A. A novel transobturator system for the repair of anterior vaginal wall prolapse: A pilot study. European Association of the Urology, Annual Meeting 2005:357–9.
12. Moore RI, Miklos J. Cystocele repair utilizing anterior wall mesh graft placed via double trans-obturator approach (Perigee System). International Continence Society, 35th Annual Meeting, 2005:171–2.
13. Gotze W, Melcher J. A new option in the treatment of pelvic organ prolapse –Perigee (Transobturator anterior prolapse repair system). International Continence Society, 35th Annual Meeting 2005.
14. Karlovsky ME, Kushner L, Baldani GH. Synthetic biomaterials for pelvic floor reconstruction. *Current Urol Reports* 2005;6:376–84.
15. Mage P. Interposition of the synthetic mesh by vaginal approach in the cure of genital prolapse. *Gynecol Obstet Biol Reprod* 1999;28:825.
16. de Tayrac R, Gervaise A, Chauveaud A et al. Tension-free polypropilene mesh for vaginal repair of anterior vaginal wall prolapse. *J Reprod Med* 2005;50:75–80.

Paper received: 14. 12. 2007.; *accepted:* 24. 01. 2008.

Address for correspondence: Prof. Slavko Orešković, MD, PhD, Department of Gynecology and Obstetrics, Univ. Med. School, Petrova 13, 10 000 Zagreb, Croatia.