Transvaginal Repair Using Acellular Collagen Biomesh for the Treatment of Anterior Prolapse

Sinharib Citgez, Oktay Demirkesen, Fatih Ozdemir, Fetullah Gevher, Cetin Demirdag, Bulent Onal, Bulent Cetinel

Department of Urology, University of Istanbul, Cerrahpasa Medical Faculty, Istanbul, Turkey.

Correspondence Author:
Sinharib Citgez, MD
Kartaltepe Mahaleesi, Yavuklular Sokak, Gul Apartmani, No:1/3 Bakirkoy, Istanbul, Turkey.

Tel: + 90 532 312 2377
Fax: + 90 212 571 3570
E-mail: drsinharib@yahoo.com

Received January 2013
Accepted December 2013

Purpose: To determine the results and satisfaction of the patients underwent transvaginal repair of cystocele in our clinic.

Materials and Methods: From January 2006 to October 2010, 15 patients with a mean age of 64 years (ranged 47-85 years) underwent transvaginal cystocele repair using acellular collagen biomesh. The patients were presented with vaginal mass in 10, dyspareunia and urge incontinence in 5 while 4 of them had both stress and urge incontinence. Grade 4 cystocele was determined in 2 patients, grade 3 in 9 and grade 2 in 4. Concomitant transobturator tape (TOT) was performed in 4 patients. Patient satisfactions were determined after the operation.

Results: The mean follow-up time was 23.5 (12-60) months. There was no postoperative complication in early follow- up period. Cystocele was recurrent in 1 patient. The success rate was 93.4%. Urinary incontinence was continued in 1 patient after TOT. Nearly all of the patients (14/15) were satisfied from the operation.

Conclusion: Transvaginal cystocele repair with using acellular collagen biomesh appears to be a safe and effective method. Further prospective and randomized controlled studies including large series of patients are needed.

Keywords: urinary bladder diseases; surgery; cystocele; vagina; treatment outcome; urinary incontinence; surgical mesh.

INTRODUCTION

Pelvic organ prolapse (POP) is accepted as the herniation of the pelvic organs from the vagina. International Continence Society (ICS) describes this condition as downward displacement of the reproductive organs during Valsalva maneuver.[1] POP is a condition that can affect women at any age. According to epidemiological studies, life-long risk in women to be operated due to prolapse or urinary incontinence is between 7% to 19%.[2,3] In a study from the USA, the number of women having POP is expected to increase by 46% in 2050.[4]

Treatment of POP aims to eliminate the symptoms, repair the anatomy, protect or improve the functions, prevent new problems related to the other compartments and to protect the quality of life in long term. Surgical treatment of POP can be made with methods performed through vaginal or abdominal routes. The studies demonstrated that vaginal route is preferred more for treatment of POP.[2,5,6] In fact, recurrence rates are high following anterior colporrhaphy performed especially because of anterior vaginal POP, and this rate is given as 40% in a recent randomized controlled trial.[7] Thus, use of synthetic or biological grafts can be argued in order to strengthen POP repair. In fact, International Consultation on Incontinence (ICI) emphasizes as a first level of evidence that the repairs carried out by vaginal route using synthetic polypropylene meshes yield more excellent anatomic outcomes in the first-year follow-ups than anterior colporrhaphy, while it reports an acceptable efficiency and lower risk of complications in the repairs alternatively performed with biological grafts.[8]

In this study, we investigated the success, complication rates and patients satisfaction in patients undergone cystocele repair by vaginal route using acellular collagen bio mesh.

MATERIALS AND METHODS

Between January 2006 and October 2010, 15 patients having anterior prolapse were investigated. Repair of anterior wall prolapse through vaginal route using acellular collagen bio mesh (PelviSoft BioMesh, CR Bard, Cranston, R.I., USA) was performed to all patients. Ten of the patients presented with a palpable mass and 5 with pain during sexual intercourse and urge urinary incontinence. The mean number of pregnancies was 4.5 (1-9), and the mean number of births was 2.8 (1-7) (Table 1). None of the patients had a history of prolapse surgery. Two of the patients had diabetes mellitus while no any other comorbidity was detected in any of the patients preoperatively. The grade of prolapse was preoperatively assessed according to Baden-Walker system and/or Pelvic Organ Prolapse Quantification System (POP-Q) classification.[1] Grade 4 cystocele was found in 2, grade 3 in 9 and grade 2 in 4 patients. Four of the patients complained of mixed (stress + urge) incontinence. These patients were asked to fill Turkish validated International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF).[9] Patients scheduled for concurrent surgery for stress urinary incontinence had undergone urodynamic study. Transobturator midurethral sling (Transobturator tape, TOT) was planned for patients who defined to have urodynamic stress urinary incontinence (USUI).

The operation was performed at lithotomy position under general anesthesia. All the patients were administered 1 g cefazolin preoperatively. Following insertion of the urethral catheter, an incision was made in the anterior vaginal wall from the level of the bladder neck towards to the vaginal apex. The incision was expanded to the sideways from inferior and superior, providing a horizontal 'H' shape (Figure). Thus, a wider area of dissection was obtained. The dissection plane was defined with the bright, white pubocervical fascia and expanded until infralevator obturator fascia was palpated. Two anchoring sutures were placed through the fascia as to be at 1 and 11 o'clock positions, and the other two sutures were inserted through the cardinal ligament as to be at 5 and 7 o'clock positions. In the meantime, acellular collagen biomesh of 4 × 7 cm in size was cropped and tailored to the size of the defect, and the sutures were crossed from the proper pore openings in the mesh and tied. After the mesh was inserted, excess of the vaginal wall was properly cut and the process was ended by closure of the anterior wall. In 4 patients who were found to have USUI, a separate suburethral and longitudinal incision was made, and TOT was properly placed. The urethral catheters were withdrawn immediately after or at the night of the operation.

Postoperative follow-up of the patients were carried out in the first, 3rd and 6th weeks of the operation and then annu-

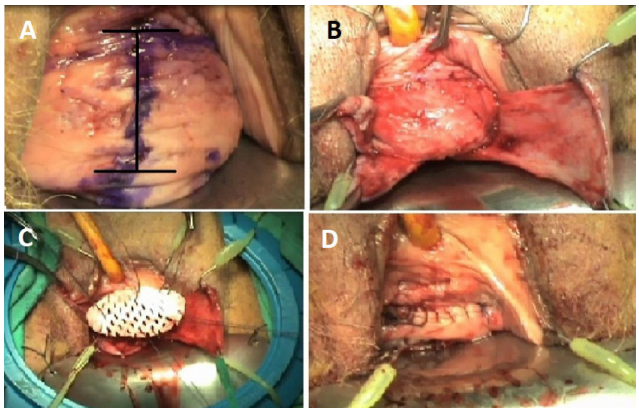

Figure 2. A) Type of incision, B) appearance after dissection, C) insertion of the prepared biomesh, and D) appearance after operation.

ally. The follow-up procedure was planned as questioning in terms of urinary incontinence (ICIQ-SF) and prolapse recurrence (palpable mass), full urine test, vaginal examination and determination of post void residual urine. In the follow-up, patients having not complaints of prolapse or those with anterior wall prolapse under grade 2 at the vaginal examination were considered as cure, while patients with complaints or those having a recurrence of grade 2 and above were considered as failed. Patient to be dry was accepted as success for the treatment of stress urinary incontinence. In addition, patient satisfaction was evaluated by asking them whether they would recommend this operation to a relative, and if they would want to be operated again if it is necessary, in order to learn their reviews for the operation.

RESULTS

Mean age of the patients was 64 years (ranged 47-85 years). Body mass index (BMI) was calculated as 26.5 (range, 24.2-28.4) for the patients. There was no any obese patient according to BMI while 5 of them were overweight. Mean operation time was 57.2 minutes (range, 30-75), while mean hospitalization stay was 18.4 hours (range, 12-36) (Table 2). There were no postoperative complications for the patients in early period. Mean follow up time was 23.5 months (range, 12-60). In one patient the palpable mass observed to persist. In this patient the examination revealed recurrence of grade 2 anterior prolapse. The patient did not want to be re-operated and was taken to follow-up. The success rate for repair of prolapse was found as 93.4%. None of the patients developed de novo dyspareunia or SUI. Two of the 4 patients who had urgency at the preoperative period were improved after the operation. De novo urgency was detected in 2 patients. A total of 4 patients, including those having urge urinary incontinence preoperatively and continued postoperatively, responded to anticholinergic therapy.

Combination treatment (prolapse repair + anti-incontinence surgery) was performed in 4 of our patients. Although decreasing, urinary incontinence was observed to continue in one of 4 patients in whom TOT was inserted and the rate of success for stress urinary incontinence was 75%. In patients with urinary incontinence, the mean preoperative and postoperative ICIQ-SF values were 14.33 (8-21) and 2.3 (0-11) respectively. Of 15 patients evaluated for satisfaction, 14 (93.4%) stated that they were completely well; they could be re-operated if necessary and would recommend the operation to their relatives. In one patient the palpable mass observed to persist and dissatisfaction was observed because of the failure and unnecessary anesthesia.

DISCUSSION

Rates of recurrence are reported between 3% and 70% following anterior colporrhaphy and between 5% and 50% after paravaginal repair by vaginal route in the treatment of anterior wall prolapse.[7,10-12] This is because the classical anterior colporrhaphy primarily focuses on central defects, while paravaginal repair targets lateral defects.[12] Since the central defects alone are rare,[13] the dissection should be expanded toward the lateral to provide adequate support both for lateral and central defects in all anterior prolapse repairs. By the technique and incision form we used and by expanding the dissection area toward the lateral, we aimed to realize an anterior wall repair supporting not only central but also lateral defects and to reduce the rates of recurrence. Besides the surgical method, use of support material is proposed in the literature in order to achieve a higher anatomic success compared to traditional anterior colporrhaphy.[8] Indeed, increased rates of anatomic success were demonstrated in the repair of central and lateral defects using additional support material.[14] Govier and colleagues also suggested a method similar to above mentioned using mesh.[15] Polypropylene

Table 1. Patients characteristics.

Number of patients	15
Mean age, years (range)	64 (47-85)
Body mass index (mean)	26.5 (24.2-28.4)
Underweight (< 18.5)	0
Normal weight (18.5-24.9)	10 (66.7%)
Overweight (25-29.9)	5 (33.3%)
Obesity (≥ 30)	0
Mean pregnancy, no. (range)	4.5 (1-9)
Mean delivery, no. (range)	2.8 (1-7)
Sexual activity, no. (%)	
Yes	9 (60.0)
No	6 (40.0)
Presentation of the patient	
Palpable mass	10 (66.7)
Dyspareunia, urinary incontinence	5 (33.3)
POP-Q classification (no.)	
Grade 2	4
Grade 3	9
Grade 4	2

Key: POP-Q, Pelvic Organ Prolapse Quantification.

type 1 synthetic meshes have priority as support material, while despite their low rate of success, biological grafts are also reported and can be preferred due to their lower risk of complications.[8,15]

In addition to repair of the anterior wall through vaginal route with synthetic meshes,[16,17] there are several studies in the literature about posterior wall,[18] vaginal stump[19] and total genital prolapse treatment.[20] However, as it is reported by ICI, there is no sufficient scientific evidence showing that support material in the posterior wall repair or use of any specific technique in apical wall repair through vaginal route is superior to native tissues.[8] In a study by Flood and colleagues, in the mean follow-up duration of 3.2 years following use of synthetic meshes for treatment of anterior wall prolapse, none of 142 patients developed recurrent prolapse and, only in 3 patients meshes had to be removed due to vaginal erosion.[21] In a prospective, randomized controlled trial with 161 women recurrence rates of anterior wall prolapse was found to be statistically significantly decreased with use of mesh.[22] In a study by Sand and colleagues, a higher rate of success was reported in the patients undergone repair of anterior wall prolapse using mesh compared to the traditional colporrhaphy methods.[22] In this study, rate of success was found as 75% in mesh group and 57% in the anterior colporrhaphy group. According to the Cochrane database regarding to the treatment of anterior wall prolapse, the anatomic failure rate is reported to be lower in the repair of anterior wall prolapse through vaginal route using mesh.[23,24]

Biomesh is another support material described in the literature and the rates of success using biomesh for the treatment of anterior wall prolapse are reported between 81%-93%.[25,26] ICI reports that, there is only one randomized controlled study with a high level of evidence demonstrating anterior repair using porcine dermis to be superior to traditional vaginal plication,[27] but although with low level of evidence, there are also several studies giving conflicting results, thus use of biomesh in anterior repair can be recommended at the level of C.[8] Although it is not recommended by ICS, high efficiency was found in a study with 35 patients undergone surgery for posterior wall prolapse surgery using acellular collagen biomesh.[28] In our study we also found the rate of success and patients satisfaction very high (93.4%) with acellular collagen biomesh we used for the repair of anterior wall prolapse through vaginal route. However, as mentioned earlier, since use of biological mesh is recommended by ICI at the level of C,[8] better designed studies with extensive series should be conducted in order to define its efficiency and to obtain higher levels of recommendations.[15]

On the other hand, it should be noted that the anatomic success is not always compatible with subjective results.[29] In fact, before the surgery to be performed using mesh, the patients should be informed in details about functional results such as sexual function, continence, detrusor over activity and about the operation. De novo dyspareunia was reported between 2% and 15% in patients undergone repair of the anterior wall with recently described transobturator four arms mesh which is inserted using trocar.[30-33] In this method, dyspareunia may be both due to the mesh,[34] and the tool used to insert the mesh.[35] On the other hand, a randomized controlled study comparing porcine dermis with standard repair anterior colporrhaphy without using graft reported that insertion of biomesh does not increase the risk for dyspareunia.[27] In another randomized, controlled study, synthetic

Table 2. Results and complications after surgery.

Mean follow up, month (range)	23.5 (12-60)
Mean operation time, min (range)	57.2 (30-75)
Mean hospitalization stay, hour (range)	18.4 (12-36)
Success rate, no. (%)	14/15 (93.4)
Complications, no. (%)	
Major (bleeding, organ injury)	0
de novo dyspareunia	0
de novo SUI	0
de novo urgency	2 (13.3)

Key: SUI, stress urinary incontinence.

polypropylene mesh Gynemesh PS (Ethicon, INC, Somerville, NJ,USA) and Pelvicol (C.R. Bard, Mol, Belgium) were compared, and sexual functions were found to be better in biomesh group, and this was attributed to propylene mesh to impair vaginal flexibility.[36] In accordance with the literature, in this study with biomesh, none of the sexually active patients developed dyspareunia.

Development of de novo SUI in anterior repairs through vaginal route using mesh is reported between 12% and 17% in the literature.[33,37,38] In a randomized controlled trial, this rate was stated as 12.3% following insertion of mesh using trocar, and it was reported to be statistically more frequent than anterior colporrhaphy.[37] In another randomized controlled study, no statistically significant difference was found between the mesh group and standard methods.[39] In our study, de novo SUI was not found in any patient. In addition, following the repairs with biological mesh, rate of detrusor overactivity was found as 17.4%, but this was not found statistically significant compared to the standard techniques.[36] In the present study, 13% of the patients developed complaints of de novo urgency, and responded to anticholinergic therapy.

In the reviews of Cochrane's database, conflicting data are mentioned about the prophylactic surgery for concurrent incontinence during the repair of anterior wall prolapse.[23,24] In our study, we simultaneously inserted TOT in 4 patients who was found to have USUI. None of these patients developed per- or postoperative additional complications. TOT was failed in one patient, although the patient was satisfied with the operation. The mean ICIQ-SF value was declined to 2.3 (0-11) postoperatively which was 14.33 (8-21) preoperatively. Use of mesh leads to additional complications requiring special treatment. The most common ones are mesh exposition or extrusion, and the complications related to the mesh shrinkage.[40] In fact, rates of vaginal exposition or extrusion may show an increase up to 11.9% according to the type of mesh used.[41] However, these types of complications are rare when using biological mesh because of the lower tissue rejection and less risk of infection.[27] Nevertheless, these complications should be considered in follow-up in the patients with complaints such as vaginal bleeding, vaginal discharge, vaginal or pelvic pain and dyspareunia. In this study, none of the patients developed such a biomesh specific complication. In addition, it should be remembered that despite they are prepared with aseptic techniques, all the allografts like biomeshes are under the risk for transmission of diseases such as human immunodeficiency virus (HIV) and hepatitis B.

There are several limitations to our study. One weakness of our study is that our data were collected retrospectively. Second, our series is small and not a long term study. Although it was not a randomized controlled study, this technique seems to be an alternative treatment in POP surgery. Further prospective, randomized and comparative studies with a high level of evidence are needed. In conclusion, in this study outcomes and complication rates seem to be acceptable in the anterior repair through vaginal route using acellular collagen biomesh.

CONFLICT OF INTEREST

None declared.

REFERENCES

1. Bump RC, Mattiason A, Bo K et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Am J Obstet Gynecol. 1996;175:10-17.
2. Olsen AL, Smith VJ, Bergstrom JO, Colling JC, Clark AL. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. Obstet Gynecol. 1997;89:501-6.
3. Smith FJ, Holman CD, Moorin RE, Tsokos N. Lifetime risk of undergoing surgery for pelvic organ prolapse. Obstet Gynecol. 2010;116:1096-1100.

4. Wu JM, Hundley AF, Fulton RG, Myers ER. Forecasting the prevalence of pelvic floor disorders in U.S. women: 2010 to 2050. Obstet Gynecol. 2009;114:1278-83.

5. Boyles SH, Weber AM, Meyn L. Procedures for pelvic Organ prolapse in the United States 1979-1997. Am J Obstet Gynecol. 2003;188:108-15.

6. Brown JS, Waetjen LE, Subak LL, Thom DH, Van den Eeden S, Vittinghoff E. Pelvic organ prolapse surgery in the United States, 1997. Am J Obstet Gynecol. 2002;186:712-6.

7. Nguyen J, Burchette RJ. Outcome after anterior vaginal prolapse repair: a randomized controlled trial. Obstet Gynecol. 2008;111:891-8.

8. Brubaker L. Surgery for pelvic organ prolapse. Committee 15. Incontinence. Editors: Paul Abrams, Linda Cardozo, Saad Khoury, Alan Wein. 4th International Consultation on Incontinence, Paris July 5-8, 2008.

9. Cetinel B, Ozkan B, Can G. The validation study of ICIQ-SF Turkish version. Turk J Urol. 2004;30:332-8.

10. Porges RF, Smilen SW. Long-term analysis of the surgical management of pelvic support defects. Am J Obstet Gynecol. 1994;171:1518-26.

11. Flood CG, Drutz HP, Waja L. Anterior colporrhaphy reinforced with Marlex mesh for the treatment of cystoceles. Int Urogynecol J Pelvic Floor Dysfunct. 1998;9:200-4.

12. Weber AM, Walters MD, Piedmonte MR, Ballard LA. Anterior colporrhaphy: a randomized trial of three surgical techniques. Am J Obstet Gynecol. 2001;185:1299-304.

13. Shull B, Baden W. A six-year experience with paravaginal defect repair for stress urinary incontinence. Am J Obstet Gynecol. 1989;160:1432-9.

14. De Ridder D. The use of biomaterials in reconstructive urology. Eur Urol. 2002;1 (Suppl):7-11.

15. Govier FE, Kobashi KC, Hsiao K. Use of synthetics and biomaterials in vaginal reconstructive surgery. Female Urology (Raz S and Rodriguez LV) Third edition. Philadelphia, Saunders; Ch59, 2008. p. 609-623.

16. Julian TM. The efficacy of Marlex mesh in the repair of severe, recurrent vaginal prolapse of the anterior midvaginal wall. Am J Obstet Gynecol. 1996;175:1472-5.

17. Salomon LJ, Detchev R, Barranger E, Cortez A, Callard P, Darai E. Treatment of anterior vaginal wall prolapse with porcine skin collagen implant by transobturator route: preliminary results. Eur Urol. 2004;45:219-25.

18. Kohli N, Miklos JR. Dermal graft-augmented rectocele repair. Int Urogynecol J Pelvic Floor Dysfunct. 2003;14:146-9.

19. Fox SD, Stanton SL. Vault prolapse and rectocele: assessment of repair using sacrocolpopexy with mesh interposition. BJOG. 2000;107:1371-5.

20. Nicita G. A new operation for genitourinary prolapse. J Urol. 1998;160:741-5.

21. Flood CG, Drutz HP, Waja L. Anterior colporrhaphy reinforced with Marlex mesh for the treatment of cystoceles. Int Urogynecol J Pelvic Floor Dysfunct. 1998;9:200-4.

22. Sand PK, Koduri S, Lobel RW, Winkler HA, Tomezsko J, Culligan PJ Goldberg R. Prospective randomized trial of polyglactin 910 mesh to prevent recurrence of cystoceles and rectoceles. Am J Obstet Gynecol. 2001;184:1357-62.

23. Maher C, Feiner B, Baessler K, Adams EJ, Hagen S, Glazener CM. Surgical management of pelvic organ prolapse in women. Cochrane Database Syst Rev. 2010;:CD004014.

24. Maher CM, Feiner B, Baessler K, Glazener CM. Surgical management of pelvic organ prolapse in women: the updated summary version Cochrane review. Int Urogynecol J. 2011;22:1445-57.

25. Leboeuf L, Miles RA, Kim SS, Gousse AE. Grade 4 cystocele repair using four-defect repair and porcine xenograft acellular matrix (Pelvicol): outcome measures using SEAPI. Urology. 2004;64:282-6.

26. Salomon LJ, Detchev R, Barranger E, Cortez A, Callard P, Darai E. Treatment of anterior vaginal wall prolapse with porcine skin collagen implant by the transobturator route: preliminary results. Eur Urol. 2004;45:219-25.

27. Meschia M, Pifarotti P, Bernasconi F, Magatti F, Riva D, Kocjancic E. Porcine skin collagen implants to prevent anterior vaginal wall prolapse recurrence: a multicenter, randomized study. J Urol. 2007;177:192-195.

28. Dell JR, O'Kelley KR. PelviSoft BioMesh augmentation of rectocele repair: the initial clinical experience in 35 patients. Int Urogynecol J Pelvic Floor Dysfunct. 2005;16:44-7.

29. Haylen BT, Sand PK, Swift SE, Maher C, Moran PA, Freeman RM. Freeman Transvaginal placement of surgical mesh for pelvic organ prolapse: more FDA concerns-positive reactions are possible. Int Urogynecol J. 2012;23:11-3.

30. Milani AL, Hinoul P, Gauld JM, Sikirica V, van Drie D, Cosson M; Prolift+M Investigators. Trocar-guided mesh repair of vaginal prolapse using partially absorbable mesh: 1 year outcomes. Am J Obstet Gynecol. 2011;204:74.e1-8.

31. Zyczynski HM, Carey MP, Smith AR, et al. One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device. Am J Obstet Gynecol. 2010;203:587.e1-8.

32. Moore RD, Beyer RD, Jacoby K, Freedman SJ, McCammon KA, Gambla MT. Prospective multicenter trial assessing type I, polypropylene mesh placed via transobturator route for the treatment of anterior vaginal prolapse with 2-year follow-up. Int Urogynecol J. 2010;21:545-552.

33. Jacquetin B, Fatton B, Rosenthal C, et al. Total transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse: a 3-year prospective followup study. Int Urogynecol J. 2010;21:1455-62.

34. Feiner B, Gietelink L, Maher C. Anterior vaginal mesh sacrospinous hysteropexy and posterior fascial plication for anterior compartment dominated uterovaginal prolapse. Int Urogynecol J. 2010;21:203-8.

35. Alcalay M, Cosson M, Livneh M, Lucot JP, Von Theobald P. Trocarless system for mesh attachment in pelvic organ prolapse repair–1-year evaluation. Int Urogynecol J. 2010;22:551-6.

36. Natale F, La Penna C, Padoa A, Agostini M, De Simone E, Cervigni M. A prospective, randomized, controlled study comparing Gynemesh, a synthetic mesh, and Pelvicol, a biologic graft, in the surgical treatment of recurrent cystocele. Int Urogynecol J Pelvic Floor Dysfunct. 2009;20:75-81.

37. Altman D, Vayrynen T, Engh ME, Axelsen S, Falconer C. Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse. N Engl J Med. 2011;364:1826-36.

38. Fayyad AM, North C, Reid FM, Smith AR. Prospective study of anterior transobturator mesh kit (prolift) for the management of recurrent anterior vaginal wall prolapse. Int Urogynecol J. 2010;22:157-63.

39. Hiltunen R, Nieminen K, Takala T, et al. Low-weight polypropylene mesh for anterior vaginal wall prolapse: a randomized controlled trial. Obstet Gynecol. 2007;110:455-62.

40. Chermansky CJ, Winters JC. Complications of vaginal mesh surgery. Curr Opin Urol. 2012;22:287-91.

41. Foon R, Smith P. The effectiveness and complications of graft materials used in vaginal prolapse surgery. Curr Opin Obstet Gynecol. 2009;21:424-7.