Int Urogynecol J (2012) 23:1391–1396
DOI 10.1007/s00192-012-1746-7

ORIGINAL ARTICLE

Beyond the complications: medium-term anatomical, sexual and functional outcomes following removal of trocar-guided transvaginal mesh. A retrospective cohort study

Stephen T. Jeffery · Andri Nieuwoudt

Received: 14 November 2011 / Accepted: 4 March 2012 / Published online: 20 April 2012

Abstract
Introduction and hypothesis The aims of this study were to assess the anatomical, sexual and functional outcomes of women undergoing surgical intervention for complications of the trocar-guided transvaginal mesh (TVM) procedure.
Methods This was a retrospective analysis of a clinical database of women who had developed a complication following a TVM procedure. This included dyspareunia, mesh erosion, urinary symptoms, mesh contraction and prolapse recurrence. Pre- and post-operatively, we assessed the women for prolapse, stress incontinence, urgency, defecatory difficulty, digitation, pain, dyspareunia and apareunia. We also recorded the Pelvic Organ Prolapse Quantification (POP-Q) score. The TVM was removed and a Biodesign graft was used in the majority of cases to prevent further prolapse. Follow-up was at 6 weeks, 6 months, 1 and 2 years.
Results In our cohort of 21 women, 18 required surgery for pain and/or dyspareunia; 20 women had reached the 6-week follow-up at the time of analysis. At 6 weeks, two women still had pain and required a second intervention. Fifteen women had reached a 6-month follow-up and only one woman had persistent pain requiring repeat surgery. Of the 15 women, 7 were sexually active and in 6 cases the dyspareunia had resolved completely with 1 woman retaining an element of pain at intercourse. Six women had been seen at 12 months and all four of the sexually active women had no dyspareunia. There were no symptoms relating to prolapse in any of the women at 6 weeks, 6, 12 or 24 months.
Conclusions We report satisfactory outcomes following removal of a complicated TVM kit.

Keywords TVM · Mesh kit complication · Prolapse · Vaginal pain · Dyspareunia · Prolift

S. T. Jeffery (✉)
Department of Obstetrics and Gynaecology,
Groote Schuur Hospital and University of Cape Town,
Anzio Road,
Cape Town 7595, South Africa
e-mail: stjeffery@gmail.com

A. Nieuwoudt
Zentrum Zorgsaam,
Smaragdboog 11,
4533 AZ, Terneuzen, The Netherlands
e-mail: nieuwoudt@gmail.com

Introduction

The last decade has seen the rapid development of techniques aimed at addressing pelvic organ prolapse in women. Most of these new procedures are based on the use polypropylene mesh products to reinforce the repair. Disillusionment with the outcomes of traditional native tissue repairs for prolapse has resulted in a rapid introduction of these procedures into routine clinical practice in many centres worldwide. The transobturator mesh kit procedures, including the Prolift, Perigee and Avaulta, have become an established option for prolapse surgery with many surgeons choosing to use these devices for both primary and secondary prolapse surgery. A recent randomized controlled trial (RCT) by Altman et al. showed improved anatomical and functional outcomes following an anterior transvaginal mesh (TVM) procedure compared to native tissue repair in women with anterior compartment prolapse [1].

Complications following surgical interventions are an unfortunate fact of life, and subsequent to the release of the mesh kits, the profile and impact of the complications of these devices have begun to emerge. A broad range of

adverse events have been described in association with the use of these products. A systematic review by Diwadkar et al. [2] showed that women in the mesh kit group had a higher re-operation rate than those who had a traditional operation or sacrocolpopexy. These re-interventions were due to complications including mesh erosion (5.8 %), pain (2.5 %) and dyspareunia (2.2 %). Marcus-Braun and von Theobald [3] describe 104 operations in 83 women who had a complication of previous mesh surgery. The indications for the re-interventions included erosion, infection, pain, granuloma, voiding problems and malposition. In their RCT, Altman et al. [1] also reported more complications in the group of women undergoing mesh repair. This included more bladder injury (3.5 %), pelvic pain (2.5 %) and mesh exposure (3.2 %).

Every pelvic floor surgeon will admit that there are unique challenges in managing the patient who has had previous surgery with a suboptimal outcome [2]. The surgical footprint makes the assessment of these women difficult and the redo surgery is always challenging due to tissue scarring and fibrosis. Success in addressing any concomitant prolapse is also not guaranteed with repeat surgery. This is arguably the most challenging of all types of prolapse surgery.

It has therefore become apparent that when we employ the use of mesh products, and the newer kits in particular, complications will occur. A number of publications are now emerging describing the techniques to address these problems when they develop [4–7]. This usually involves excision or release of the mesh. Reasonable short-term outcomes have been described [5]. There are presently very little data describing the medium- to long-term outcomes in these women, especially relating to the further development of prolapse and other ongoing pelvic floor symptoms.

The aims of this study were therefore to assess the anatomical, sexual and functional outcomes in a cohort of women undergoing repeat surgical intervention for complications associated with the insertion of the trocar-guided TVM kit.

Materials and methods

Twenty-one women underwent a re-intervention operation following the development of a complication of the TVM procedure. All of the TVM procedures had been performed in a district hospital in The Netherlands. The indications for re-intervention included dyspareunia, mesh erosion, urinary symptoms, mesh contraction and symptomatic prolapse recurrence. As part of the pre-operative workup we recorded the patient's symptoms including a history of prolapse, stress incontinence, urgency, defecatory difficulty and digitation. We also recorded whether the women were sexually active and if they had any symptoms of sexual dysfunction including dyspareunia and apareunia. This was done using an anamnestic method. We also recorded the pre-operative Pelvic Organ Prolapse Quantification (POP-Q) score.

A number of surgical interventions of variable combinations were performed on the cohort, depending on the indication and the anatomical findings. Since most of the problems were related to the anterior TVM device, this was removed in the majority of cases.

The main aim of the repeat procedure was to release the tension on the mesh-scar tissue complex, thus relieving the patient from her pain symptoms. The anterior vaginal wall skin was opened in the midline over the contracted mesh. The incision was usually about 1 cm in length over the border of the mesh proximally and distally. Utilizing a Lone Star Retractor System, the skin edges were put under traction, simplifying the dissection of the vaginal skin from the underlying scarred mesh (Fig. 1). This dissection was extended laterally as far as possible. By grabbing the retracted mesh with two small Kocher forceps in the distal midline, the mesh was then split from the proximal to distal ends. The two lateral portions of the mesh were then dissected loose from the underlying bladder wall, starting medially and working laterally—once again using the Lone Star System to apply traction and countertraction. This dissection was taken laterally until the lateral edge of the mesh was reached. By removing the central portion of the split mesh-fibrous tissue complex, the bulk of the mesh was removed successfully. If the two lateral mesh bands that pierced the obturator foramen were still centrally attached, this was divided with a pair of scissors, cutting them directly from medial to lateral under guidance of the index finger. Care was taken not to attempt removal of these two bands of mesh since the ureter can be part of this mesh-scar tissue complex.

Following removal of the mesh, we felt these women were at an increased risk for a recurrence and various procedures were performed to address this including re-

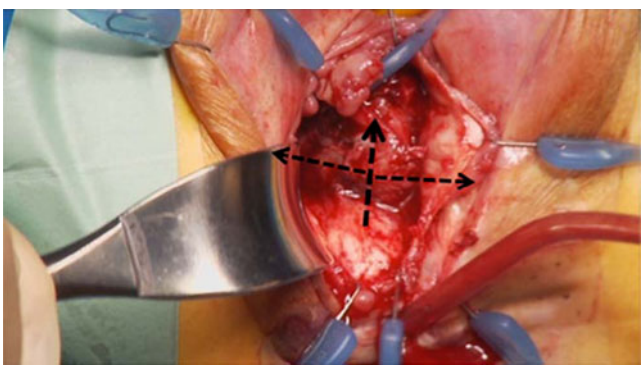

Fig. 1 Directions in which the mesh is being cut to release tension on the arms—the vaginal skin is dissected from the mesh

attachment of the vaginal apex to the top of the posterior TVM, insertion of a porcine subintestinal submucosal graft (Biodesign, Cook Medical) and vaginal hysterectomy.

When we employed the use of a xenograft, the two lateral bands of mesh/scar tissue were utilized as anchor points laterally. Maxon 0 stitches were placed into these, two on each side. If the cervix was still present, the inferior anchors included three Maxon stitches into the cervix. If the cervix was absent, two Maxon 0 stitches were placed into the uterosacral ligaments, one on each side, and centrally one stitch into the rectovaginal septum or transverse band of the posterior TVM if that had been placed previously. By placing a prepared Biodesign graft (10 × 7 cm) on the bladder base, these anchors were attached to the graft (Fig. 2).

After all the stitches were tied, stitch A was used on both sides to pull a fold of Biodesign graft laterally (this was done by re-catching the Biodesign directly medially, thus plicating it laterally when it is re-tied). The Biodesign graft was trimmed along the dotted line to fit the bladder base by cutting the superior edges where stitches B are due to be placed. A cystoscopy was always done at the end of the procedure.

Subjects were followed up at 6 weeks, 6 and 12 months for resolution or persistence of pre-operative symptoms, any new prolapse, stress incontinence, urgency and sexual symptoms. The examination and POP-Q were repeated at each visit.

The local hospital (Zentrum Zorgsaam, Terneuzen, The Netherlands) Research Ethics Committee gave approval for the performance of this study and publication of the results (ethics review number 07072011–1).

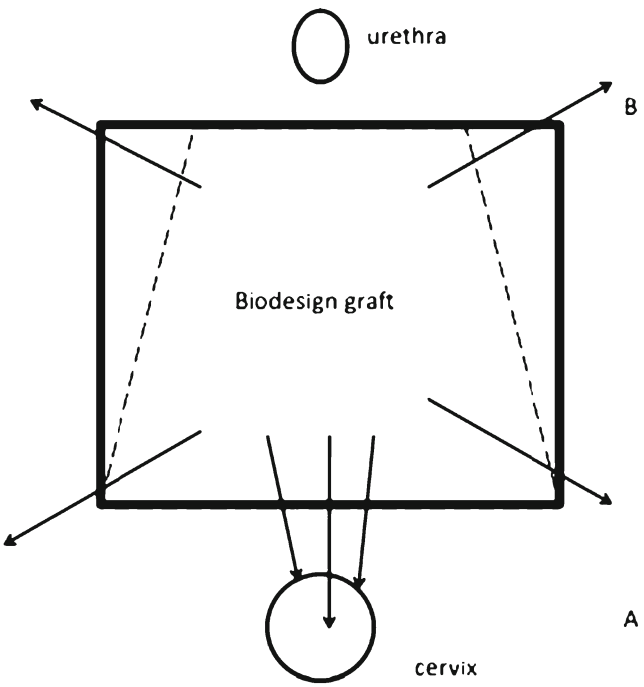

Fig. 2 Placement and attachment of the Biodesign graft

Results

Twenty-one women were included in our study. The mean age of the cohort was 61.7 years (SD 11.9, range 43–84). The mean interval between the primary and repeat surgery was 30 months (range 4–57, SD ±15.7). All of the women in our cohort had previously had an anterior trocar-guided TVM operation. Many of the subjects had also undergone additional procedures including posterior TVM, TVT-O and hysterectomy (Table 1). Of the 21 women, 18 (85 %) required surgery for pain or dyspareunia or both (Table 2). The remaining three required intervention for an erosion in one case, erosion and partner-related dyspareunia in another case and severe urinary urgency in the third case. Fourteen women who had been sexually active prior to the initial TVM procedure had developed sexual dysfunction, with twelve reporting dyspareunia and two reporting inability to have intercourse due to the surgery. Only five women had a mesh erosion. In addition to the issues relating to pain, nine women also had symptoms of prolapse.

The surgical re-intervention procedure included removal of the anterior TVM in 18 (85 %) of the 21 women (Table 3). Re-attachment of the vaginal apex to the top of the posterior TVM was done in 6 (29 %) and in 19 (90 %) a Biodesign graft was used to bolster the anterior compartment. Five (24 %) of the women had a vaginal hysterectomy. There were no intra-operative bladder or bowel injuries. Mean intra-operative blood loss was 128 ml (range 50–300, SD± 72.6).

The erosions in four cases were medial and thus directly related to the suture line. This mesh portion was excised and replaced with a Biodesign graft. In one case an erosion was lateral, away from the suture line. This patient had commenced coital activity 4 weeks post-operatively. In all cases the erosion was resolved following removal of the mesh.

Twenty women were seen at the 6-week follow-up (Table 4). Two still had pain and required a second

Table 1 Primary surgery

Procedure	*n*	%
Vagina top	1	4.8 %
Bolster	1	4.8 %
Anterior Prolift	21	100 %
Removal of Prolift	1	4.8 %
Posterior Prolift	16	76 %
TVT-O	3	14.3 %
Hysterectomy	5	23.8 %

Table 2 Summary of complications in the cohort

Complication	
Erosion	5 (24 %)
Dyspareunia	12 (57 %)
Apareunia	2 (9.5 %)
Prolapse	9 (43 %)
Pain	10 (48 %)
Pain or dyspareunia or both	18 (85 %)

intervention. One woman had a chronic granuloma due to a braided non-absorbable polyester suture that elicited pain on touch. This was removed in the office. The second patient had persistent pain due to tension in the remnants of the partially excised right arm of the previously removed anterior TVM. This was successfully relieved by partial removal of that arm in theatre. There were no additional cases of erosion. None of the women had commenced sexual activity.

Fifteen women have reached 6 months of follow-up. One woman had persistent pain requiring repeat surgery. This pain was due to tension on the right arm of her posterior TVM. The anterior TVM had been removed 6 months previously. The remaining tension was relieved successfully by bisecting the arm of the posterior TVM in theatre.

At 6 months 7 of the 15 women were sexually active and in 6 cases the dyspareunia had resolved completely with 1 woman retaining an element of pain at intercourse. Only six women have been seen for a 12-month assessment and all four of the sexually active women are completely free of dyspareunia. One woman required repeat surgery at 12 months for an infected mesh granuloma.

Five per cent of the women had stage II or more prolapse at 6 weeks and 13 % at 6 months (Table 5). Two of the six women who reached the 12-month follow-up had a stage II anterior compartment prolapse. There were, however, no symptoms relating to prolapse in any of the women at 6 weeks, 6, 12 or 24 months.

Discussion

In this study, we have demonstrated the challenges in obtaining satisfactory anatomical, sexual and functional outcomes in a small cohort of women presenting with a complication of a TVM kit. From our experience, the most distressing post-operative complications of mesh surgery are pain and dyspareunia. These problems occur in approximately 2–3 % of women undergoing a mesh kit procedure [2]. It is unfortunately impossible to avoid these complications. When a surgeon elects to use these devices it is essential that he or she has the skill to address these problems.

Table 3 Procedures that were performed at repeat intervention

Procedure	*n*	%
Anterior vaginal repair with Biodesign	19	90 %
Removal of anterior TVM	18	86 %
Posterior transvaginal mesh	1	4.8 %
Vaginal topplasty (apical repair)	6	29 %
Vaginal hysterectomy	5	24 %

In our cohort, all women had had an anterior TVM and this was removed in 18 cases. The TVM polypropylene mesh, with its proximal and distal obturator arms, gives extensive side-to-side pelvic floor support. Its monofilamentous, macroporous design allows rigid integration into the tissues. There is no doubt that following the use of this, and other mesh kit devices including the Perigee and Avaulta, that good anatomical success rates in excess of 85 % can be expected [8, 9]. This solid repair, however, makes any attempt at removal challenging. The mesh is often difficult to separate from the underlying tissues. There is also not an insignificant risk of bladder and bowel injury, especially in inexperienced hands. The mesh is often very close to the bladder and the surgeon needs to make sure that this is not injured. Adequate mobilization of the mesh from the underlying tissue is essential. When the indication for intervention is pain, as much of the mesh as possible should be removed [5]. The transobturator arms, in particular, are often very difficult to access surgically. When the indication for removal of the mesh is pain or dyspareunia, it is essential that the surgeon dissects as laterally as possible since it is the tension created by these arms that needs to be released. Prudence would suggest that these cases be referred to a high volume surgeon since he or she would have more experience with this type of surgery. Managing these problems is emotionally challenging for both the surgeon and the unfortunate women suffering from the complication. The data presented by our small cohort, however, suggest that there is hope for these women. By removing the TVM, we have shown satisfactory outcomes in the majority of our patients in our cohort. This should be considered in those patients who have had symptoms of pain following a mesh kit procedure.

When one considers the plethora of publications on surgical techniques to manage pelvic organ prolapse, a broad range of factors are used to determine the outcomes. Unfortunately, many studies have focussed on anatomical determinants to define success. Barber et al. make a very important point in a recent trial where they used a broad range of criteria to define surgical success [10]. Positive outcomes ranged from 18 to 98 %, depending on the criterion used to define success. This has been recently emphasized by the Cochrane collaboration [11]. This group found significantly better outcomes following the use of mesh for anterior repair but emphasized the concerning dearth of patient-centred outcomes in studies used.

Table 4 Pre- and post-operative signs and symptoms

Parameter	Pre-op (*n*=21)	6 weeks (*n*=20)	6 months (*n*=15)	12 months (*n*=6)	24 months (*n*=3)
Prolapse symptoms	9	0	0	0	0
Stress incontinence	3	1			
Urgency	1	2			
Sexually active	14	2	7	4	2
Dyspareunia	12	0	1	0	0
Apareunia	2	0	0	0	0
Pain		2	1		

Once the mesh has been removed, there remains a risk of recurrence of the prolapse. There are, unfortunately, very little data on the medium-term outcomes of the prolapse in this group of women. In our cohort, we felt that the addition of the Biodesign xenograft would provide additional support following the removal of the polypropylene graft.

Surgical technique is also an important determinant of outcomes and attention to the finer points will go a long way in preventing the development of complications. Adequate infiltration and a deep, full-thickness dissection are important in preventing erosion. The mesh should always lie flat without folds or kinking. The most important point in preventing pain and dyspareunia is to avoid any tension in the vagina. The mesh kits have the advantage above the traditional self-shaped mesh techniques in that they can be appropriately tensioned at the end following closure of the vaginal skin. A recent study showed much higher erosion rates following self-shaped mesh than the kits [12].

In one case the posterior TVM gave pain symptoms that persisted. This was due to tension on the one arm, and after releasing this tension the pain symptoms disappeared. The pain in all patients could be assessed clinically by direct touch. By putting strain on the palpable submucosal mesh, one could increase the pain sensation. This was only found on the anterior TVM, and not with the posterior TVM. By pre-operative vaginal pain mapping the procedure could be directed to the offending mesh. The anterior TVM, although claimed to be tension free, we believe, is often found to have some tension due to shrinkage and folding of the central piece of mesh, which places strain and tension on the arms attached to the side wall. This does not happen with the posterior TVM. Pain secondary to posterior TVM is probably due to the direct involvement of nerve bundles in the mesh.

Extrusion is often the most feared and cited as one of the major complications of this type of surgery. Only five women in our cohort had this problem. Most surgeons will agree that this is usually easily managed. We believe that the pain syndromes are the most important and that patients should be adequately counselled about this risk prior to proceeding with synthetic mesh kit surgery.

The US Food and Drug Administration has recently issued a document [13] highlighting the most important issues relating to the mesh used in prolapse surgery. This includes the lack of evidence to support improved outcomes, for posterior and apical prolapse in particular. More importantly, the risk of developing complications similar to those described in our paper is higher than previously thought.

A number of newer devices are now available including the Prosima [14], Pinnacle [5] and Elevate [5]. The fact that newer devices are launched so frequently reveals an underlying dissatisfaction with the current devices. The role of industry in driving the use of these products has been extensively debated [15, 16] and hopefully reconstructive pelvic floor surgeons are now coming to their senses.

The extent of complications following mesh kit surgery has only recently become apparent and every high volume surgeon has, no doubt, been involved in the removal of these devices. The significance of the pain syndromes and sexual dysfunction in many of these women means that the development of pelvic organ prolapse is a small price to pay for resolution of these symptoms. Nonetheless, there is very little evidence to guide us in the optimal approach to avert

Table 5 Pre- and post-operative POP-Q scores

Parameter	Pre-op (*n*=21)	6 weeks (*n*=20)	6 months (*n*=15)	12 months (*n*=6)	24 months (*n*=3
Aa > −1	6 (24 %)	0	0	0	0
Ba > −1	6 (24 %)	0	1 (6.7 %)	2 (33 %)	0
Ap > −1	2 (15 %)	1 (5 %)	1 (6.7 %)	1 (16 %)	0
Bp > −1	0	1 (5 %)	2 (13 %)	0	0
C > −1	5 (20 %)	0	0	0	0

prolapse recurring in this group of women. In our cohort, we elected to use the Biodesign xenograft (Cook Medical). A recent trial has shown the Biodesign graft to have superior outcomes to traditional surgery [17]. We have demonstrated good anatomical outcomes with this technique and we believe that this is the ideal setting to consider using a xenograft.

Our study has a significant weakness in that we failed to use a validated questionnaire to assess our patients pre- and post-operatively. de Boer et al. [18] have shown significant discrepancies between symptom reporting by patients in a questionnaire compared to face-to-face physician consultation. This may affect the quality of our data. Our cohort is also too small to make any useful conclusions regarding the outcomes from a perspective of prolapse recurrence.

Conclusion

Re-operation following prolapse surgery is always challenging. The surgeon has to contend with the increased adhesions and unclear tissue planes. In addition, the long-term outcomes of the surgery on the prolapse also need to be considered and addressed. In our small cohort of 21 women undergoing repeat surgery following a complicated TVM operation, we have demonstrated good anatomical and functional outcomes. Dyspareunia following mesh kit surgery is a distressing symptom which we feel can and should be addressed surgically. Although there are no data to guide us on the use of prophylactic xenograft insertion at the time of TVM removal, we have demonstrated satisfactory outcomes using this technique in this very small cohort.

We have demonstrated good anatomical, sexual and functional outcomes in our small cohort of women presenting with a complication of TVM. Since large numbers of these operations are being performed worldwide, further studies should focus on developing guidelines as to the management of the complications. Furthermore, we are in urgent need of data regarding the risk of prolapse recurrence following removal of the TVM and need for additional prophylactic interventions. It behoves every pelvic floor reconstructive surgeon to be familiar with the management strategies in women with complications of mesh kit surgery.

Acknowledgements Danette Nieuwoudt helped with data collection.

Conflicts of interest No funding was provided for this paper. Dr. Jeffery has received travel sponsorship from Johnson and Johnson, Boston Scientific, American Medical Systems, Cook and Bard. He has also received speakers fees and honoraria from Johnson and Johnson, Boston Scientific, American Medical Systems and Bard. He is a trainer for Johnson and Johnson, Boston Scientific and American Medical Systems. Dr. Nieuwoudt has received speakers fees and honoraria from Cook Medical and Gynecare (Johnson and Johnson)—all funds were paid into the account of his employer, Stichting Zorgsaam.

References

1. Altman D, Väyrynen T, Engh ME, Axelsen S, Falconer C, Nordic Transvaginal Mesh Group (2011) Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse. N Engl J Med 364 (19):1826–1836
2. Diwadkar GB, Barber MD, Feiner B, Maher C, Jelovsek JE (2009) Complication and reoperation rates after apical vaginal prolapse surgical repair: a systematic review. Obstet Gynecol 113(2 Pt 1):367–373
3. Marcus-Braun N, von Theobald P (2010) Mesh removal following transvaginal mesh placement: a case series of 104 operations. Int Urogynecol J 21(4):423–430
4. Feiner B, Jelovsek JE, Maher C (2009) Efficacy and safety of transvaginal mesh kits in the treatment of prolapse of the vaginal apex: a systematic review. BJOG 116(1):15–24
5. Muffly TM, Barber MD (2010) Insertion and removal of vaginal mesh for pelvic organ prolapse. Clin Obstet Gynecol 53(1):99–114
6. Feiner B, Maher C (2010) Vaginal mesh contraction: definition, clinical presentation, and management. Obstet Gynecol 115(2 Pt 1):325–330
7. Hurtado EA, Appell RA (2009) Management of complications arising from transvaginal mesh kit procedures: a tertiary referral center's experience. Int Urogynecol J Pelvic Floor Dysfunct 20 (1):11–17
8. Altman D, Väyrynen T, Engh ME, Axelsen S, Falconer C, Nordic Transvaginal Mesh Group (2008) Short-term outcome after transvaginal mesh repair of pelvic organ prolapse. Int Urogynecol J Pelvic Floor Dysfunct 19(6):787–793
9. Rane A, Kannan K, Barry C, Balakrishnan S, Lim Y, Corstiaans A (2008) Prospective study of the Perigee system for the management of cystocoeles–medium-term follow up. Aust N Z J Obstet Gynaecol 48(4):427–432
10. Barber MD, Brubaker L, Nygaard I, Wheeler TL 2nd, Schaffer J, Chen Z, Spino C, Pelvic Floor Disorders Network (2009) Defining success after surgery for pelvic organ prolapse. Obstet Gynecol 114(3):600–609
11. Maher C, Feiner B, Baessler K, Adams EJ, Hagen S, Glazener CM (2010) Surgical management of pelvic organ prolapse in women. Cochrane Database Syst Rev 4:CD004014
12. Finamore PS, Echols KT, Hunter K, Goldstein HB, Holzberg AS, Vakili B (2010) Risk factors for mesh erosion 3 months following vaginal reconstructive surgery using commercial kits vs. fashioned mesh-augmented vaginal repairs. Int Urogynecol J 21(3):285–291
13. US Food and Drug Administration. FDA Safety Communication: Update on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse. July 13, 2011
14. Zyczynski HM, Carey MP, Smith AR, Gauld JM, Robinson D, Sikirica V, Reisenauer C, Slack M, Prosima Study Investigators (2010) One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device. Am J Obstet Gynecol 203(6):587.e1–587.e8
15. Tincello DG (2009) The use of synthetic meshes in vaginal prolapse surgery. BJOG 116(1):1–2
16. Freeman RM, Lose G (2009) The great mesh debate. Int Urogynecol J Pelvic Floor Dysfunct 20(8):889–891
17. Feldner PC Jr, Castro RA, Cipolotti LA, Delroy CA, Sartori MG, Girão MJ (2010) Anterior vaginal wall prolapse: a randomized controlled trial of SIS graft versus traditional colporrhaphy. Int Urogynecol J 21(9):1057–1063
18. de Boer TA, Gietelink DA, Vierhout ME (2008) Discrepancies between physician interview and a patient self-assessment questionnaire after surgery for pelvic organ prolapse. Int Urogynecol J Pelvic Floor Dysfunct 19(10):1349–1352