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Anchorless implant for the treatment of advanced anterior and apical vaginal prolapse – Medium term follow up

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ABSTRACT

Objective: to evaluate the mid-term safety and efficacy of a surgical technique using an anchorless implant.
Study design: This is a prospective study. Women with symptomatic POP were recruited. The technique involved placement of an open trapezoid-shaped frame which retains a polypropylene mesh stretched within its parameter. No fixation techniques used. Demographic data and pre-operative quality of life (QoL) questionnaires were collected. Peri-operative data were documented. Patients were followed at 2, 6, 12, 24 and 36 months. Follow-up included repeated QoL questionnaires, Pelvic Organ Prolapse-Quantification (POP-Q) measurements and assessment for possible complications.
Results: Seventy women were recruited. Mean age was 63.1 years, mean parity was 4.6 deliveries. Mean pre-operative POP-Q were Ba = 3.1 (-1 to 6) cm and C = 0.4 (-8 to 6) cm. No intra-operative complications were observed. Surgical time averaged 24.7 min. Estimated blood loss averaged 155 cc. Mean follow up at last visit was 27.7 months. Two patients (2.8 %) underwent partial frame resection and two patients (2.8 %) underwent a TVT-O for de-novo stress urinary incontinence (SUI). At follow-up, the mean POP-Q were Ba= -2.8 (-3 to -1) cm and C = -6.8 (-10 to 1) cm. Two patients (2.8 %) had recurrent prolapse. One was symptomatic and received treatment. No mesh erosion or chronic pelvic pain were documented. Pelvic Function Distress Inventory (PFDI20) scores showed significant improvement. Thirty-eight (54 %) patients completed the Pelvic organ prolapse/Urinary Incontinence Sexual Questionnaire (PISQ12) showing no chronic dyspareunia.
Conclusion: The Self Retaining Support (SRS) implant provides 97 % subjective and 94.3 % objective cure. Two patients (2.8 %) had the implant's frame removed surgically. The SRS is a safe and effective treatment for pelvic organ prolapse.

Introduction

Since the FDA alerts on vaginal mesh complications were issued in 2008 and 2011 [1], surgeons reduced the use of vaginal meshes and reverted to native tissue repair (NTR) and sacrocolpopexy as the preferred approach for POP repair. Even after the success rate criteria were changed to include subjective outcome, the long-term success rate of NTR or sacrocolpopexy is still not optimal [2]. The use of vaginal mesh in Pelvic Organ Prolapse (POP) surgery has been shown to provide superior anatomical results when compared with native tissue repair, but has been associated with high complications rate, i.e. organ perforation, bleeding, mesh erosion, mesh contraction and pain [3]. Data on complications of vaginal mesh surgery have originated in studies on mesh implants which require anchoring to pelvic myofascial structures. Clinical evidence supports the assumption that the anchoring process and not the mesh itself may be responsible for such complications [4]. Therefore, in order to keep the benefits of vaginal meshes while minimizing complications the anchoring technique needs to be revised. Creating a replacement for the damaged pubo-cervical fascia (PCF) requires accurate imitation of the physiologic shape and attachments of this unique structure. This structure is stretched between the arcus-tendineus-fascia-pelvic (ATFP) on both sides of the pelvic wall, along the interior surface of the internal obturator muscles. The distal attachment is located at the inner aspect of the pubic bone. The new concept involves an anchorless placement of an implant which accurately imitates this physiologic support system. The implant (Self Retaining Support = SRS) consists of a flat, stretched, ultra-light polypropylene net, which serves as a scaffold for a neo PCF, thus providing adequate Level II support. The net is kept flat by a solid frame which extends to the level of the ischial spines and provides an additional

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level I support. The anatomical relations of the SRS have been examined in cadaver studies [5] and the preliminary experience with the SRS has been recently published [6]. The purpose of this study was to describe our midterm clinical experience using the SRS implant. As a primary aim, we evaluated midterm objective and subjective outcome following surgery with the SRS implant. The secondary aim was to estimate the rate and type of device-related complications.

Materials and methods

This prospective, multicenter, international study was approved by the local ethical committees in each medical center is Israel and Hungary. The study was performed for the evaluation of the efficacy and safety of the SRS developed and manufactured by Lyra Medical Ltd, Binyamina, Israel. The initial research protocol included 20 patients with one-year follow-up, which was extended to 36 months. Following the initial results, a second protocol was initiated which involved 50 additional patients. Study protocols were similar, and results were combined for the purpose of the current manuscript. Patients with anterior compartment prolapse stage 2 and above, with or without apical prolapse, were recruited from the women's outpatients' clinics in each medical center. Patients received detailed explanation of the risks involved in vaginal mesh implants. All participants signed an informed consent, translated into the local language. Patients with previous vaginal mesh surgery, POP-Q stage less than 2 or asymptomatic prolapse were excluded. Medical history data, POP-Q measurements and validated QoL questionnaires - PFDI-20 and PISQ-12 - were collected prior to surgery [7]. Surgery was performed by four experienced pelvic surgeons who had experience in vaginal implant techniques. The procedure starts with hydro-dissection of the space between the vaginal mucosa and the bladder. A longitudinal incision is made in the anterior vaginal wall and the mucosa is dissected laterally towards the ischial spines on both sides of the pelvis. The SRS implant (Fig. 1) is composed of an ultra-light, titanized polypropylene net (16 g/m^2), stretched and retained in place by a U-shaped flexible frame. The device is inserted between the bladder and the vaginal mucosa, with the lateral arms following the anatomy of the arcus-tendineus-fascia-pelvis (ATFP) (Fig. 2). The implant's frame is positioned symmetrically with its distal part under the edge of the pubic bone.. The cervix or the apex of the vaginal vault can be sutured to the center of the free edge of the net to ensure symmetrical location. For a detailed description of surgical technique, see previous publication [8]. MUS was added to the procedure based on documentation of urine leakage on vaginal exam, with or without prolapse reduction by the examiner's hand or documented in urodynamic study. Hysterectomy was added to the planned surgery if a pathology was documented on gynecologic ultrasound i.e. thickened endometrial echo, endometrial polyp or abnormal uterine bleeding. Peri-operative data included adverse events, length of the procedure and estimated blood loss. Patients were summoned for post-operative follow-up at 2 weeks and then at 2, 6, 12, 24 and 36 months. At each visit, patients were assessed for pelvic floor symptoms using a structured symptom questionnaire and a pelvic exam was carried out. A Urogynecologist performed the clinical follow up including POP-Q measurements performed in a semi fowler position on a gynecologic exam table. At each visit, patients filled the PFDI-20 and PISQ12 questionnaires. The PFDI20 quality of life questionnaire includes three domains: Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6), urine incontinence (UDI-6) and Colorectal-Anal Distress Inventory 8 (CRADI-8). Each question allows four answers graded 0-4. The mean value of all of the answered items within the corresponding domain (possible value 0–4) is multiply by 25 to obtain the domain score (range 0–100). Missing items are dealt with by using the mean from answered items only. PFSI-20 total Score is calculated by adding the scores from the 3 domains together to obtain the total score (range 0–300). The standard Minimally Clinically Important Difference (MCID) is 45 points for the total score and 15 points per domain. All adverse events were recorded, including re-operation and any intervention for the relief of pelvic floor dysfunction, including pessary treatment and pelvic floor rehabilitation.

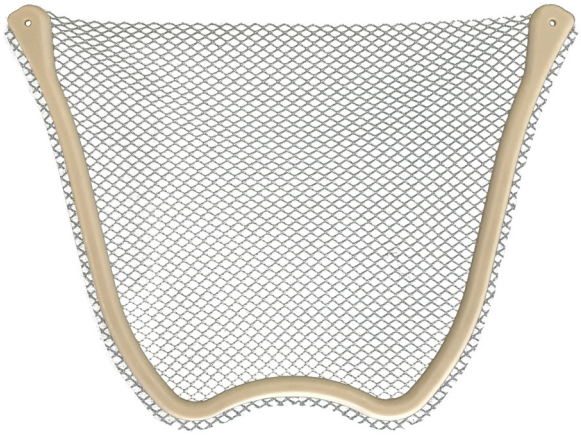

Fig. 1. The self-retaining support implant (SRS).

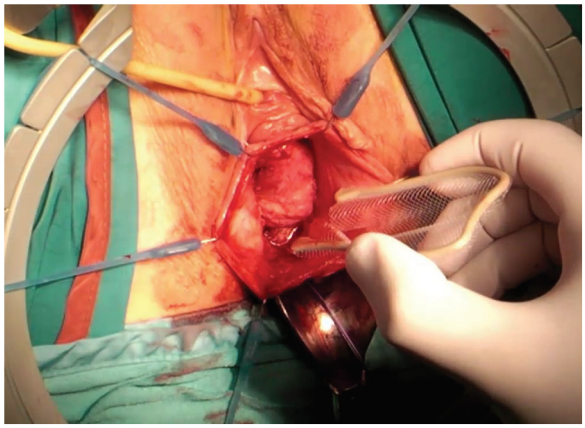

Fig. 2. Surgical insertion of the SRS.

Statistical analysis used Analysis of Variance (ANOVA) test where the null hypothesis is that all subgroup means are equal. Results of the two-way ANOVA on change of points Aa, Ba and C by subject and visit were analyzed, looking at P-Values of the term visit in the model to evaluate statistically significances. Pre and post-surgery POP-Q measurements were calculated using a non-parametric Wilcoxon signed ranks test.

Results

Seventy women were recruited in both studies. The first patient was enrolled in September 2014 and 19 out of 20 patients from the initial protocol completed their 36 months follow-up visits. The second protocol was initiated in March 2016. On August 30th, 2019, 27 (38.5 %) patients completed 36 months, 33 (47 %) patients completed 24 months and 10 patients (14 %) completed 12 months follow up. The overall mean follow-up was 27.7 months (11.4–41). One patient from the initial protocol refused to continue additional follow up after completion of the 12 month-follow-up visit. This patient reported no adverse events and no recurrent POP since her

last visit but declined additional vaginal examinations. Mean age was 63 (43–79) years and mean parity was 4.6 [1–16] deliveries. Six patients (8.6 %) had prior hysterectomy and 6 (8.6 %) patients had previous POP surgery. Mean BMI was 26.3 kg/m^2 (20.3–36.6). Twenty-eight (40 %) patients suffered from hypertension, 15 (21 %) patients had diabetes mellitus and 10 (14 %) were smokers. Mean POP-Q measurements prior to surgery were as follows: Aa = 2 cm (-1 to 3 cm), Ba = 3.1 cm (-1 to 6 cm) and C = 0.4 cm (-8 to 6 cm). Sixteen (23 %) patients had isolated anterior vaginal wall prolapse (point C <−1 cm). All patients underwent surgical repair using the SRS implant. Ten (14 %) patients underwent concomitant vaginal hysterectomy, 14 (20%) had a mid-urethral sling (MUS) and 15 (21 %) had posterior colporrhaphy. Surgical time for device implantation averaged 24.7 min (10−50 min). Estimated blood loss averaged 155 ml (25−500 ml). No intra-operative complications were observed. Post operatively one patient received transfusion with one unit of blood and two (2.8 %) patients experienced transient urinary retention. Eight months following the procedure one patient (1.4 %) presented with complaints of vaginal discharge and was diagnosed with frame erosion. Under local anesthesia the eroded part was resected. This was the only patient in whom a large sized frame was used, which possibly caused the adverse event. One patient was diagnosed with voiding dysfunction following complaints of prolonged voiding time at the 12-month follow-up visit. Post void residual measurements were found normal. We assumed pressure by the solid bridge might be the cause for voiding dysfunction and resected the sub urethral frame bridge in an ambulatory surgical procedure, without complications. At the 24-month-follow-up visit, the patient reported minimal improvement in voiding time and was recommended urethral dilation. Two patients (2.8 %) developed de-novo SUI and underwent a MUS procedure following a failed trial of pelvic floor muscle training. At the latest follow-up, mean POP-Q measurements were as follows: Aa= -2.9 (-3 to -1) cm, Ba= -2.8 (-3 to -1) cm and C = -7 (-10 to 1) cm. POP-Q staging of the anterior compartment at last follow up were: 57 (81.4 %) patients at grade 0, 9 (13 %) at grade 1, four (5.7 %) patients grade 2 and none at grade 3. (Table 1 summarizes the anatomical results at baseline and last follow up visit). All grade 2 patients had measurements of the leading edge above the hymen. Considering both grade 0 and grade 1, the anatomical success rate was 94.3 %.

Subjectively, based on the answers to question number 3 in the PFDI20 questionnaire (Usually have a bulge or something falling out that you can see or feel in your vaginal area), 97.2 % were cured. One patient had symptomatic apical recurrence with point C = 0 and opted for vaginal pessary treatment. A second patient with apical recurrence (C = 1 cm) was asymptomatic and did not require treatment. No mesh exposure was documented or chronic pelvic pain reported at follow up. One patient underwent repair of symptomatic rectocele six months following the SRS implant. No other repeat surgery for prolapse has been documented so far.

Table 1
POP-Q measurements at preoperative exam compare to postoperative follow up.

Variable	Baseline N = 70	At last follow up (average 27.7 mon.)
Anterior compartment		
Point Aa (range)	2.0 (-1 to 3) cm	−2.9 (-3 to -1) cm
Point Ba (range)	3.1 (-2 to 6) cm	−2.8 (-3 to -1) cm
Apical compartment		
Point C (range)	0.4 (-8 to 6) cm	−6.8 (-10 to 1) cm
Stage 0	0	57 (81.4 %)
Stage 1	0	9 (12.8 %)
Stage 2	7 (10 %)	4 (5.7 %)
Stage 3	51 (73 %)	0
Stage 4	12 (17 %)	0

A total of 68 patients answered the PFDI20 questionnaire at last follow up. The results showed a decrease of 59.1 points in the total score, 28.7 points in Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6) and 22.5 points in urine incontinence (UDI-6). These differences meet the MCID threshold. Results also showed a decrease of 7.9 points in the Colorectal-Anal Distress Inventory (CRAD-8), but we did not consider this decrease as clinically meaningful. Table 2 provide the details of the PFDI20 scores over the years. No deterioration was noted in the Colorectal-Anal Distress Inventory 8 (CRADI-8).

Thirty (42.8 %) patients completed the PISQ12 questionnaire at last follow up. Analysis of the PISQ12 scores revealed an increase of 5 points above baseline which implies no change in sexual function. No evidence of dyspareunia was documented (Table 2).

Posterior compartment POP-Q measurement were documented at each visit. Fifteen symptomatic patients had concomitant native tissue posterior colporrhaphy with resolution of their symptoms in all cases. At last follow up 21 (38 %) of untreated patients revealed second degree prolapse of the posterior compartment compared to 9 (16 %) pre-operatively. Only 3 patients had Bp measurements >0 at last follow up, out of which two were symptomatic (Table 3).

Discussion

This prospective, multicenter study on midterm outcome of the SRS implant shows a subjective improvement success rate of 97.2 % upon QoL questionnaire analysis, along with minor and manageable complications. No severe graft-related adverse events or chronic pain conditions were observed. These findings allow us to conclude that the SRS implant is a safe and effective surgical option for patients with symptomatic anterior and apical vaginal prolapse.

Vaginal POP repair using the SRS implant accurately imitates the physiologic support system: the SRS implant lateral arms are designed to replace the attachments of the PCF to the ATFP. The solid frame functions as the mesh-retaining system and allows the use of an ultra-light mesh (16 g/m^2). The device's shape and size eliminate the need for anchoring or fixation.

Based on the NIH criteria for optimal (leading prolapse at −3 cm) and Satisfactory (leading prolapse at −2 cm) outcome, the results of this study show 92 % anatomical success in a group of seventy patients at 24 months. A subgroup of twenty patients who completed 36 month-follow-up has experienced even better results. These midterm outcome data favorably compare with success rates of other transvaginal implants. At the same time, the low rate and severity of complications using the SRS implant technique found in this study indicates the procedure may be safer than previously studied vaginal mesh techniques.

The Cochrane report on vaginal mesh was based on four-corner fixation techniques [9], which reported an incidence of mesh exposure of 11.4 %, requiring mesh removal in 6.8 % of cases. Overall reoperation rate has been calculated to be 11 %. Other complications in those studies were voiding dysfunction in 9 % of patients and de novo OAB in 12 %. A more recent study from 2016, has reported the four-corner mesh implant techniques to yield a 74.4 % success rate at two years and a 13.5 % erosion rate [10]. In all the above parameters, the SRS implant has achieved better outcome so far.

In 2017, the Nordic Trans-vaginal Mesh (TVM) group reported on long term follow using a two-point fixation mesh - Uphold Lite® [11]. Anatomical success was documented in 94 % at the end of the first year but decreased to 78.8 % at 5 years. In their cohort, 19.7 % had undergone repeated pelvic surgery at the 5-year follow up. MUS amounted to 38.4 % of repeated surgeries while the remaining patients had prolapse-related operations. Among those patients,

Table 2
PFDI20 [N = 65] and PISQ12 scores at baseline vs. follow up visits.

Domains	Baseline	12m	24m	36m	last	Diff
POPDI-6	41.4	10.6	14.7	14.5	12.7	28.7*
CRAD-8	24.1	14.6	18.8	15.1	16.2	7.9
UDI-6	40.3	14.6	21.2	14.7	17.7	22.5*
Total PFDI20	105.8	39.7	54.7	44.3	46.6	59.1*
PISQ12	31.2 (N = 43)	35.4 (N = 32)	33 (N = 33)	36.7 (N = 7)	36.2	5

* = $P < 0.05$.

Table 3
Posterior wall measurement before and after surgery of untreated patients*.

	Pre-operative Bp (N = 55)	Post-operative Bp (N = 55)
Stage 0	24 (44 %)	23 (42 %)
Stage 1	20 (36 %)	11 (20 %)
Stage 2	9 (16 %)	21 (38 %)
Stage 3	2 (4 %)	0

Patients who did not have concomitant Posterior Colporrhaphy at the time of SRS implantation.

three had surgery for mesh removal secondary to chronic pain. In our study only 4 (5.7 %) patients had repeated surgery, 2 had MUS and 2 had partial resection of the frame for exposure and voiding dysfunction. No repeated surgery for recurrent prolapse was required, no mesh removal for pain or erosion was needed and no chronic pelvic pain documented.

Successful outcome for apical prolapse using large surface meshes has been reported to range between 87 % and 94 % [12–14]. The SRS implant can be considered as a large-surface mesh with a 95.8 % successful outcome.

The SRS technique can also be compared to open/laparoscopic sacrocolpopexy which resulted in an objective and subjective success rate ranging between 76.5 % and 100 % at midterm follow-up [15–17].

In a comparison study between native tissue and mesh implants the success rate for both groups was 51.16 % defining success at Ba<0) [10]. In our study the anatomical definition of success was Ba < −1 cm providing better results in comparison to both native tissue repairs or anchored mesh implants.

The use of pelvic implants have been associated with adverse events i.e. bleeding organ perforation, mesh erosion, contraction and chronic pain [3,9,18].

Although placement of the mesh in instructed to be in tension-free, flat, non-folded fashion [19], current securements techniques do not entirely prevent mesh contraction and folding, caused by dynamic pressures and scar accumulation over time [20]. Mesh folding, bunching and contraction may cause nerve entrapment and tension on the fixation points, which result in pain and dyspareunia [3]. Mesh fixation has been mentioned as a crucial parameter in the development of mesh-related chronic vaginal pain. Resection of the fixation points has been shown to result in reduction of the tension and pain resolution in 90 % of patients [19,21].

We anticipated the anchorless technique would reduce post-operative complications as well, as the solid frame keeps the mesh stretched so that bunching, crimping, mesh contraction and excessive tensioning of mesh arms are avoided.

POP-Q measurement of the posterior compartment revealed anatomical worsening in patients that were not treated surgically. Posterior colporrhaphy was performed only in women with posterior compartment complaints. Asymptomatic posterior compartment prolapse at any stage was not treated. It is known that repair of the anterior compartment can cause re-distribution of the intra-abdominal pressures which can impact weak areas i.e. untreated posterior compartment and cause worsening anatomical measurements. Such results should raise the question of performing concomitant posterior colporrhaphy even in asymptomatic posterior wall prolapse although only two patient complaint of posterior wall bulge at last follow up. We were unable to compare these results to other studies since there were no publications focusing on the impact of new vaginal mesh implant on the untreated compartment.

Chronic pain is considered one of the most concerning vaginal mesh complications and a common indication for re-operation. In some cases, removal of the mesh does not eliminate the pain [22]. Surgical techniques using non-fixation implants have been shown to cause less pelvic pain [23]. We have not observed chronic pelvic or vaginal pain in any of our patients so far. This finding possibly supports the initial assumption that bunching and folding of the mesh at the anchoring points carries a risk of nerve entrapment and pain. Those complications are avoided once the need to anchor the implant is eliminated and the net is kept flat by the solid frame during and after its positioning.

Rahkola-Soisalo et al. reported a 15.2 % re-operation risk at 5 years with most repeated surgeries done for mesh removal [11]. Other studies [24,25] reported between 8.9 % and 18 % reoperation rate at midterm follow-up. As regards to re-operation for apical failure, the reported rate in native tissue repair is 11.6 % [25]. Assuming that the only symptomatic apical failure, which is currently treated with a pessary, will undergo repeated POP surgery in the future, the potential re-operation rate for failure in the SRS group can be considered 1.4 %.

Using the PFDI-20 questionnaire, Rahkola-Soisalo et al. reported a 78.8 % improvement in all three domains [11]. Upon QoL questionnaire analysis, we found a 97.2 % improvement using the same PFDI-20 questionnaire in our study. No deterioration in QoL scores was observed over the years.

We couldn't reach a significant conclusion on the impact of the SRS procedure on sexual function. The issue of low compliance in assessing sexual function in our cohort is consistent with previous studies [11]. The important finding as for the PISQ-12, was the absence of de novo dyspareunia in our cohort.

Strengths of the study include the low rate of lost to follow-up and the length of follow-up reported. Limitations of the study include the absence of control group and the fact that approximately 80 % of follow up visits were performed by the surgeon.

Conclusions

Surgical reconstruction of anterior and apical vaginal compartments using the SRS implant provides high subjective and anatomical cure rate at 23–36 months with no intra operative or immediate post-operative complications. Two cases of partial implant removal (2.8 %) were described over the course of the follow up. In order to support the superiority of the anchor-less technique over other mesh fixation techniques these results need to be confirmed by a comparative protocol, larger sample size and longer follow-up.

Acknowledgement

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References

[1] http://www.fda.gov/MedicalDevice/Safety/AlertsandNotices/PublicHealthNOtifications/ucm061976.htmhttp://www.fda.gov/MedicalDevices/Safety/AlertsandNOtices/ucm262435.htm.
[2] Siddiqi NY, Grimes CL, Casiano ER, Abed HT, Jeppson PC, Olivera CK, et al. Mesh sacrocolpopexy compared with native tissue vaginal repair: a systematic review and meta-analysis. Obstet Gynecol 2015;125(January (1)):44–55.
[3] Altman D, Väyrynen T, Engh M, Axelsen S, Falconer C. Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse. N Engl J Med 2011;364:1826–36.
[4] Diwadkar Gouri B, Barber Matthew D, Feiner Benjamin, Maher Christopher, Eric Jelovsek J. Complication and reoperation rates after apical vaginal prolapse surgical repair a systematic review. Obstet Gynecol 2009;113 (February (2 Pt 1)):367–73.
[5] Cervigni M, Ercoli A, Levy G. Cadaver study of anchorless implant for the treatment of anterior and apical vaginal wall prolapse. Eur J Obstet Gynecol Reprod Biol 2016 Dec;23(210):173–6.
[6] Levy G, Padoa A, Fekete Z, Bartfai G, Pajor L, Cervigni M. Self-retaining support implant: an anchorless system for the treatment of pelvic organ prolapse-2-year follow-up. Int Urogynecol J 2018;29(May (5)):709–14.
[7] Lowenstein L, Levy G, Chen KO, Ginath S, Condrea A, Padoa A. Validation of hebrew versions of the pelvic floor distress inventory, pelvic organ Prolapse/Urinary incontinence sexual function questionnaire, and the urgency, severity and impact questionnaire. Female Pelvic Med Reconstr Surg 2012;18(6):329–31.
[8] https://www.youtube.com/watch?v=WT0V-WCeYkU.
[9] Maher C, Feiner B, Baessler K, Schmid C. Surgical management of pelvic organ prolapse in women. Cochrane Database Syst Rev 2013(April (4))CD004014, doi:http://dx.doi.org/10.1002/14651858.CD004014.pub5.
[10] Dias Marcia M, Castro Rodrigode A, Bortolini Maria Augusta T, Delroy Carlos A, Matins Paulo CF, Girao Manoel JBC, et al. Two years results of native tissue versus vaginal mesh repair in the treatment of anterior prolapse according to different success criteria: a randomized control trial. Neurourol Urodyn 2016;35:509–14.
[11] Rahkola-Soisalo P, Mikkola T, Altman D, Falconer C, for the Nordic TVM Group. Pelvic organ prolapse repair using the uphold vaginal support system: 5-Year follow-up. Female Pelvic Med Reconstr Surg 2017(December), doi:http://dx.doi.org/10.1097/SPV.0000000000000530 [Epub ahead of print].
[12] Heinonen P, Aaltonen R, Joronen K, Ala-Nissila S. Long term outcome after transvaginal mesh repair of pelvic organ prolapse. Int Urogynecol J Pelvic Floor Dysfunct 2016;27(July (7)):1069–74.
[13] Natale F, Constantini E, La Penna C, Illiano E, Balsamo R, Carbone A, et al. Trocar guided tran-vaginal mesh surgery for pelvic organ prolapse: effect on urinary continence and anatomical and functional outcomes. Aprospective observational study. Eur J Obstet Gynecol Reprod Biol 2017;210(March):29–34.
[14] Jacqentin B, Hinoul P, Gauld J, Fatton B, Rosenthal C, Clave H, et al. Total transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse: a 5-years prospective follow-up study. Int Urogynecolo J 2013;24(October (10)):1679–86.
[15] Nygaard I, Brubaker L, Zycynski HM, et al. Long-term outcomes following abdominal sacrocolpopexy for pelvic organ prolapse. JAMA 2013;309:2016–24.
[16] Constantini E, Mearini L, Lazzeri M, et al. Laparoscopic versus abdominal sacrocolpopexy: a randomized, controlled trial. J Urol 2016;196:159–65.
[17] Liang S, Zhu L, Song X, et al. Long term outcome of modified laparoscopic sacrocolpopexy for advanced pelvic organ prolapse: a 3 year prospective study. Menopause 2016;23:765–70.
[18] Maher C, Feiner B, Baessler K, Christmann-Schmid C, Haya N, Brown J. Surgery for women with anterior compartment prolapse. Cochrane Database Syst Rev 2016;11(November)CD004014.
[19] Margulies RU, Lewicky-Gaupp C, Fenner DE, McGuire EJ, Clemens JQ, Delancey JO. Complications requiring reoperation following vaginal mesh kit procedures for prolapse. Am J Obstet Gynecol 2008;199(December (6))678 e1-4.
[20] Lamblin G, Van-Nieuwenhuyse A, Chabert P, Lebail-Carval K, Moret S, Mellier G. A randomized controlled trial comparing anatomical and functional outcome between vaginal colposuspension and transvaginal mesh. Int Urogynecol J 2014;25(July (7)):961–70.
[21] Feiner B, Maher C. Vaginal mesh contraction: definition, clinical presentation, and management. Obstet Gynecol 2010;115(2 Pt 1):325–30.
[22] Mock S, Reynolds WS, Dmochowski RR. Trans-vaginal mesh revision: a comprehensive review on etiologies and management strategies with emphasis on postoperative pain outcomes. Low Urin Tract Symptoms 2014;6(May (2)):69–75.
[23] Sayer T, Lim J, Gauld JM, Hinoul P, Jones P, Franco N, et al. Medium-term clinical outcomes following surgical repair for vaginal prolapse with tension-free mesh and vaginal support device. Int Urogynecol J 2012;23(April (4)):487–93.
[24] De Tayrac R, Brouziyne M, Priou G, et al. Transvaginal repair of stage III-IV cystocele using a light weight mesh: safety and 36 months outcome. Int Urogynecol J 2015;26:1147–54.
[25] Eliber KS, Alperin M, Khan A, et al. Outcome of Vaginal prolapse surgery among female Medicare beneficiaries: the role of apical support. Obstet Gynecol 2013;122:981–7.