Research Article

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Outcomes of Single Incision Anchored Anterior Vaginal Mesh Repair for Recurrent Vaginal Prolapse

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Abstract

Objective: To report the safety and efficacy of single incision anchored anterior vaginal mesh repair for women with recurrent anterior vaginal prolapse.

Methods: Retrospective study of women with recurrent anterior vaginal prolapse, Stage 2 or beyond, who underwent single incision anchored vaginal mesh repair with Anterior Elevate (American Medical Systems, Minnetonka, USA) between June 2012 and October 2016. Pre-operatively, the Prolapse Quality-of-Life questionnaire (P-QOL) and Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire-12 (PISQ-12) were completed. Post-operatively, women completed the P-QOL, PISQ-12 and the global impression of improvement questionnaire (PGI-I). Preoperative POP-Q and post operative POP-Q examination at up to 24 months follow up were recorded. At average follow up of 36 months, participants were interviewed via telephone using questions from the P-QOL, PISQ and PGI-I.

Results: 45 women had single incision anterior vaginal mesh kit repair for recurrent prolapse. Postoperatively, 85% of women reported cure of their prolapse symptoms. At 24 months, 80.0% had POP-Q stage 0 or 1 in the anterior compartment, and 93.8% achieved anatomical cure of apical prolapse (point C above 0). During structured telephone interview at mean follow up of 36 months, on PGI-I, 70% reported feeling 'much better' or 'very much better'.

Conclusion: Vaginal surgery using single incision lightweight mesh kits can be an effective approach for women with recurrent anterior vaginal prolapse, resulting in subjective and objective cure rates of over 80% with reasonable safety profile up to 60 months postoperatively.

Keywords: Vaginal Prolapse, recurrent Prolapse, gynecologic surgical procedures/adverse effects, surgical mesh, vaginal mesh

Abbreviations: P-QOL: Prolapse Quality-of-Life; PISQ-12: Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire-12 (PISQ-12); PGI-I: Patient Global Impression of Improvement; POP: Pelvic Organ Prolapse; FDA: Food and Drug Administration; PDS: Polydioxanone; TVT: Tension free Vaginal Tape; POP-SS: Pelvic Organ Prolapse Symptom Score; EQ-5D: EuroQol 5 dimensions; SCD: Something Coming Down; RCT: Randomized Controlled Trial

Introduction

The introduction of vaginal meshes for pelvic floor reconstruction has generated considerable debate regarding safety and efficacy [1-3]. The initial rationale

for the use of vaginal mesh for prolapse repair relates to the reported high recurrence following traditional native tissue repair. Prolapse recurrence varies between 5%-40% depending on the definition of recurrence [4,5]. Although recurrent anatomical prolapse following

anterior vaginal repair could be common, only a minority of women appear to need repeat surgical intervention after non mesh anterior colporrhaphy [4,6,7].

Vaginal meshes were initially introduced to treat primary uterovaginal prolapse. The recent PROSPECT trial showed that using vaginal mesh for primary prolapse repair does not add additional benefit with increased complication rates such as vaginal mesh extrusion [6]. The role and safety of vaginal meshes in the treatment of recurrent prolapse, however, seems less clear.

In this study, we report the safety, medium term efficacy and complications of single incision anchored anterior vaginal mesh repair kit, Elevate PC, in the surgical treatment of women with *recurrent* anterior vaginal wall prolapse.

Materials and Methods

This is a retrospective study of 45 consecutive women with recurrent symptomatic anterior vaginal wall prolapse of Stage 2 or beyond who underwent single incision anchored anterior vaginal mesh repair with *Anterior Elevate* (American Medical Systems, Minnetonka, USA) between June 2012 and October 2016. Elevate is an InterPro®Lite™ monofilament polypropylene surgical mesh with low density of 26 g/m². The system for anterior and apical prolapse repair consists of mesh anatomically designed to cover the anterior area. They include fixing arms to allow accurate mesh placement and intra-operative tensioning, and apical and anterior needles to allow fixation of the mesh to the sacrospinous ligament and obturator internus muscle, respectively [8,9]. The apical portion of the mesh is adjustable to vaginal length prior to fixing [10].

200 women with recurrent prolapse were assessed. Options of management included expectant management, physiotherapy, use of a pessary or surgery. Surgical intervention was primarily decided depending on the degree of vaginal vault prolapse. In cases of co-existent vault prolapse, sacrocolpopexy was offered. For women with a well-supported vault, or for those who were unsuitable for abdominal surgery, single incision anterior vaginal mesh was offered.

The study was approved by the Interventional Procedures Governance Committee and the Institutional Review Board of our hospital, and all participants signed a consent form to participate in this study. Data from the last follow up are reported.

Figure 1: Summary flowchart of patient selection.

Pre-operatively, all women were assessed using the Prolapse Quality-of-Life questionnaire (P-QOL) [11], Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire-12 (PISQ-12) [12] and the Pelvic Organ Prolapse Quantification System (POP-Q) [13]. Preoperatively all women reported vaginal bulge as 'a lot' in the P-QOL questionnaire.

Post-operatively, they completed the P-QOL, PISQ-12 and the global impression of improvement questionnaire (PGI-I) [14] and were examined using the POP-Q system. Examination was carried out in lithotomy with an empty bladder at 3 months and yearly up to 24 months post operatively. Women were then interviewed using a structured telephone interview that included questions from the P-QOL, PISQ and PGI-I. The interview and data analysis were conducted by an independent clinician, JL, who was not involved in the surgery (Table 1).

The need for further surgery for prolapse and mesh related complications were reviewed. All women completed at least 24 months follow up in clinic. 40 women were available for telephone follow up and the interval ranged from 7 months to 60 months with an average of 36 months post-operative. The subjective outcomes reported in this study are from the latest telephone follow up interview.

Table 1: Structured telephone interview questions extracted from validated questionnaires.

	None	A little	Moderate	A lot
Are you aware of a lump/bulge coming down in your vagina?				
Heaviness/dragging				
Backache/Discomfort worse on standing				
	YES	NO	Additional comments	
Are you sexually active currently?				
	None	A little	Moderate	A lot
Do you experience pain with sex?				
Bulge in the way of sex				
Avoid intercourse due to bulge				
Negative emotional reactions				
	YES	NO	Additional comments	
Further surgery for mesh-related complications				
Further surgery for prolapse				

PGII	Very much worse	Much worse	A little worse	No change	A little better	Much better	Very much better
Compared to pre op, how would you rate your symptoms now?							

The primary outcome measure is the number of women with symptomatic cure of their bulge symptoms, defined as 'none' or 'a little' in the domain of vaginal bulge in the P-QOL questionnaire. Other prolapse symptoms are also reported. Secondary outcomes include patient global impression of improvement and anatomical position of the anterior vaginal wall (Point Aa and Point Ba) and apex (Point C) using POPQ.

The procedure was performed under general or spinal anesthesia in lithotomy position. After catheterization and positioning in Allen stirrups, a weighted vaginal speculum was inserted and the vaginal wall grasped with clamps from the bladder neck to an area of 3 cm from the vaginal apex in post-hysterectomy women, or 3 cm from the cervix in women with uterus in situ. Deep hydro dissection was then performed using 120 ml of Adrenaline diluted to 1:200,000 in 0.9% normal saline. The dissection was performed deep to the vaginal fascia. All surgeries were performed by the senior author (AF).

A vertical incision through the vaginal mucosa was then made, followed by dissection of the bladder from the fascia taking care to ensure this layer was maintained with the vaginal mucosa. Sharp and blunt dissection towards the pelvic sidewall was then performed and

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the sacrospinous ligament cleared from the rectum and surrounding fascia. The apical anchoring devices of the Elevate system were then introduced and fixed to the sacrospinous ligament at approximately two centimeters medial to the ischial spine.

The obturator fascia was digitally dissected and the caudal aspect of the mesh introduced into the obturator internus muscle bilaterally. The mesh was then fixed in a tension free manner to the bladder neck and vaginal apex using delayed absorbable sutures, polydioxanone (PDS). Cystoscopy was then performed to confirm bladder integrity, and the vaginal skin closed using continuous locking 1-vicryl suture. A vaginal pack and catheter were left overnight and routinely removed 24 hours later.

Statistical analyses

Pre- and post-operative data were compared using paired-samples *t*-test and Mc Nemars statistical test, and *P* values of ≤ 0.05 were considered significant.

Results

During the study period a total of 45 women had single incision anterior vaginal mesh kit repair for recurrent prolapse using anterior Elevate PC. 12 women (26.7%)

underwent concomitant procedures including posterior repair, urethral bulking agents and Tension free vaginal tape (TVT).

Demographics and characteristics are summarized in table 2.

Table 2: Patient demographics N=45.

Characteristics	Mean (range)
Age	63 (42-86)
Parity	2 (0-5)
Menopausal	42 (93.3%)
Previous hysterectomy	33 (73.3%)
Body Mass Index (BMI)	24 (22-39)
Prolapse Stage	Number (%)
Stage II	29 (64.4)
Stage III	12 (26.7)
Stage IV	4 (8.9)

The operative procedure, as described above, was successfully completed in all cases and the average operative time was 60 minutes (range 40-135 minutes) with average blood loss of 300 ml (100-1000 ml). 3 women required postoperative blood transfusion and one woman returned to theatre for drainage of a retropubic hematoma after anterior Elevate vaginal mesh repair. The average length of hospital stay was 48 hours. There was one case of intraoperative bladder injury and no cases of bowel injury. PGI-I responses are shown in table 3.

On assessing the quality of life domain in the P-QOL questionnaire post operatively, significant improvements were reported in all QOL domains apart from general health. Anatomically, at 24 months post operatively, 80.0% had POP-Q stage 0 or 1 in the anterior compartment (point Ba) and anatomical cure of apical prolapse (point C above 0) was achieved in 93.8% of women that had preoperative apical prolapse of Stage 2 and beyond.

Table 4 shows the changes in the quality of life domains of participants up to 2 years follow up and the change in POPQ examination at 2 years follow up

40 women were available for structured telephone interview. One woman died from unrelated illness after the 24 months follow up and 4 others could not be contacted. Postoperatively, a total of 85% (34/40) of participants reported cure of their prolapse symptoms; (defined as 'none' or 'a little' in the domain of vaginal bulge on P-QOL) and 82.5% (33/40) reported 'none' or 'a

little' when asked about heaviness symptoms or dragging feeling.

With regards to vaginal discomfort worse on standing, 77.5% (31/40) reported 'none' or 'a little' on P-QOL, and 72.5% (29/40) reported 'none' or 'a little' backache worse with vaginal discomfort.

At mean follow up of 36 months, on assessing patient global impression of improvement, PGI-I, 70% (28/40) reported feeling 'much better' or 'very much better'. 3 women reported feeling worse; one with bothersome urinary urgency and frequency symptoms, one with recurrent prolapse symptoms, and one with a combination of recurrent prolapse and urinary urgency symptoms. The participant with recurrent prolapse symptoms responded 'a little worse' on her PGI-I but declined further intervention. Both women with urinary symptoms underwent cystoscopy with no evidence of mesh extrusion into the urinary tract. One was found to have a urethral diverticulum and her symptoms of recurrent cystitis improved following excision.

When assessing sexual function, 18 out of 45 women (40.0%) were sexually active preoperatively and 16 out of 40 postoperatively (40.0%). At postoperative interview 15 of 16 (93.8%) women who were sexually active reported 'none' or 'a little' in response to the question 'vaginal bulge which gets in the way of sex'. One woman's response was 'a lot' to this question. The remainder of the group interviewed post operatively stated this question was 'not applicable' as they were not sexually active. Three women (7.5%) reported bulge symptoms as a cause of avoiding intercourse 'usually' or 'always' post operatively compared to 6 (13.3%) preoperatively.

Post operatively when the respondents were asked about experiencing negative emotional reactions such as fear, disgust, shame or guilt during sexual activity, whether they are sexually active or not, 6/40 (15.0%) answered as 'always' and stated this was the reason they were no longer sexually active. However, none of the women attributed this to prolapse symptoms. Causes included urinary incontinence symptoms (four women), dyspareunia (one) and non gynecological reasons (one).

Postoperatively, 75.0% (12/16) of those who were sexually active reported 'never' or 'seldom' in experiencing dyspareunia. 5 women (20.8%) had dyspareunia preoperatively that was cured following surgery. 3 women reported 'new onset' dyspareunia as 'always' after surgery.

Table 5 summarizes the prolapse and sexual function symptoms pre and post operatively

None of the women interviewed had further surgery for prolapse and none reported surgery for mesh related complications such as mesh extrusion, infection or vaginal discharge. One woman, who had chronic pelvic pain preoperatively, also experienced vaginal and pelvic pain postoperatively and as a consequence the mesh was removed at a different centre. The pain persisted and was treated with nerve stimulation therapy. One women had further surgery for excision of urethral diverticulum

36 months post operatively.

Discussion

Management of recurrent pelvic organ prolapse (POP) represents a challenge as the native tissues in this particular individual have failed twice in providing robust support for pelvic organs [7]. The use of mesh in this group has the theoretical advantage of providing additional support and reducing risk of prolapse recurrence [15,16]. There are few publications reporting the outcome of transvaginal mesh use for recurrent Prolapse [7]. In 2011 Fayyad reported on the safety and outcomes using

Table 3: PGI-I results at mean follow up of 36 months.

Patient global impression of improvement (PGI-I) N=40	Number (%)
Very much better (VMB)	10 (25)
Much better (MB)	18 (45)
A little better (ALB)	6 (15)
No change (NC)	3 (7.5)
A little worse (ALW)	1 (2.5)
Much worse (MW)	1 (2.5)
Very much worse (VMW)	1 (2.5)

	Preoperative P-QOL	Postoperative P-QOL	P value
General health	25.0 (6.3-33)	25.0 (6.3-43.7)	0.41
Prolapse impact	88.6 (66-100)	16.0 (0-33)	<0.001
Role limitations	50.0 (16-83)	8.5 (0-16)	<0.001
Physical limitations	50.0 (16-66)	12.5 (0-33)	<0.001
Social limitations	11.0 (0-66)	6.5 (0-16)	0.02
Personal relations	33.0 (0-100)	9.5 (0-16)	0.01
Emotions	60.0 (16-80)	6.0 (0-22)	0.004
Sleep	50 (16-83)	16 (0-33)	<0.001
Severity measures	50 (28.7-75)	12.5 (0-50)	0.002

Table 4: Change in quality of life domains up to 2 years follow up and POPQ examination at 2 years follow up.

	Preoperative Mean (range)	Postoperative Mean (range)	P Value (t test)
Point Aa	+2 (0 - +3)	-2.3 (-3 - +3)	<0.001
Point Ba	+4.0 (+1 - +6)	-2.3 (-3 - +4)	<0.001
Point C	-2.6 (-6 -+6)	-6.6 (-8 - -2)	<0.001
Point D	-3 (-8 - +2)	-7.6 (-8 - -3)	<0.001
Point Ap	-1.5 (-3 - +2)	-2.0 (-3 - -1)	0.54
Point Bp	-2.0 (-3 - +6)	-2.0 (-3 - -1)	0.32
Total vaginal length (TVL)	6.0 (5.5-8.0)	6.0 (5.5-8.0)	0.52

Table 5: Pre and post-operative prolapse and sexual function symptoms as described in structured telephone interview. N=40. Follow up period (7–60 months).

	Pre operatively	Post operatively	P Value
	Number (%) N=40	Number (%) N=40	
Vaginal Bulge (moderate/a lot)	40 (100)	6 (15.0)	<0.0001
Heaviness/Dragging (moderate/a lot)	40 (100)	6 (15.0)	<0.0001
Discomfort wore on standing (moderate/a lot)	32 (80)	9 (22.5)	<0.0001
Backache (moderate/a lot)	27 (67.5)	9 (22.5)	<0.0001
Backache worse with vaginal discomfort (moderate/a lot)	27 (67.5)	10 (25.0)	<0.0001
Avoid intercourse due to bulge (usually/always)	6 (15.0)	3 (7.5)	0.248
Negative emotional reactions during sex (usually/always)	13 (32.5)	6 (15.0)	0.023
Sexually active	18 (45.0)	16 (40.0)	0.480
Dyspareunia (usually/always)	6/18 (33.3)	4/16 (25.0)	
Bulge gets in the way of sex (moderate/a lot)	5/18 (27.8)	1/16 (6.3)	

anterior Prolift mesh, but since then second generation vaginal meshes have been introduced of lighter weight, single vaginal incision and with less complications reported [17].

However, mesh use within gynecology has become increasingly controversial, in 2011 the Food and Drug Administration (FDA) issued a warning about the high complication rates of meshes used for vaginal reconstruction and advised that all women undergoing vaginal prolapse repair with mesh should be followed up and the outcomes audited [18]. In 2018 NHS England and NHS Improvement advised the immediate implementation of a high vigilance restriction period [19] regarding vaginal mesh in the UK, and this is ongoing.

Given the range of mesh products available for use and concerns regarding safety, there have been calls for surgeons to report the outcomes achieved when using mesh-augmented prolapse repairs [20]. To our knowledge this is the first study that reports subjective outcomes of transvaginal mesh in women with recurrent anterior wall prolapse at mean follow up of 36 months.

Managing recurrent vaginal prolapse can be challenging and surgical options include the use of synthetic mesh or repeat native tissue repair. The PROSPECT trial evaluated the subjective and objective outcomes at two years for women undergoing repeat prolapse surgery with native tissue repair, mesh inlay or mesh kit [21]. Outcomes were assessed using the Pelvic Organ Prolapse Symptom Score (POP-SS) [22] and the EuroQol 5 dimensions (EQ-5D) [23]. Mean POP-SS score at two years was similar

for all groups and patient reported outcomes were not significantly different between each group.

Although the authors found no evidence of difference in terms of prolapse symptoms in each group, there was obvious advantage anatomically at 12 months in women that had a mesh kit compared to women with native tissue repair. None of the women who had mesh kit had POP-Q leading edge >0 compared to 16.7% in women with native tissue repair. In addition, there was a non-significant but obvious difference in the number of women feeling something coming down (SCD) between the two groups (36.4% mesh kit vs. 57.1% native tissue repair, $p=0.09$).

Within the trial, women that underwent concomitant uterine and vault suspension procedures in addition to the vaginal mesh, and women who had mesh inlay were included in the study as a third arm, which potentially diluted the numbers and made it difficult to reach conclusions. The authors concluded that the sample size was too small to be conclusive, and they therefore recommended studies to report results for primary and repeat prolapse surgery separately, so that more information can be identified for this group of women who are at higher risk of failure than after primary prolapse repair [21].

Fayyad et al. reported the outcomes of recurrent prolapse repair using the Prolift system and showed anatomical success rate, defined as stage 0 and 1 on POP Q post-operative assessment, to be around 60%. Vaginal mesh extrusion rate was 19%, and a significant

number of women reported new onset dyspareunia [7]. In contrast, in our study evaluating second generation mesh Elevate PC for recurrent anterior vaginal prolapse, we report more favourable outcomes including a higher cure rate both subjectively and objectively. These rates are comparable to those reported in other studies using Elevate PC mesh for anterior vaginal wall Prolapse [24,25]. The difference in outcomes between our study and the study of Prolift outcomes can be partly attributed to the mesh characteristics. The weight of the Prolift system is 42.7g/m² compared to 26g/m² for Elevate [26].

The Elevate PC prolapse repair system used in this study contains surgical mesh (IntePro® Lite) that is significantly less stiff than the alternative meshes, Ascend® (Caldera Medical, Agoura Hills, USA) and Gynemesh PS® (used in GynecareProlift® and GynecareProsima®, all Ethicon, Somerville, USA) [27]. In a study of 349 women undergoing mesh-augmented prolapse repair for anterior and/or posterior prolapse, use of IntePro Lite was associated with a 46% reduction in mesh exposure rate compared with a heavier weight mesh (50g/m²). Although this difference did not reach statistical significance, the authors suggested that it could be clinically important [17].

In this study we found the subjective cure rate of single incision mesh kit was 85% with objective cure rate of 80% in the mesh compartment. This study also shows that anchored single incision mesh improved apical support in almost 94% of women with concomitant apical prolapse. Therefore this technique can be considered to treat vaginal apical prolapse for women where abdominal approach with sacrocolpopexy may be considered more hazardous.

Our study found that the proportion of women sexually active preoperatively was small, 40% (18/45), but that the underlying reasons for this were multifactorial and often not solely due to prolapse. 32.5% of women reported negative emotional reactions during sexual activity as 'always', and stated it was the reason they were no longer sexually active, but none attributed this to prolapse symptoms. Furthermore, although the proportion of sexually active women preoperatively was small, the majority remained so post operatively. Of those who experienced dyspareunia preoperatively (6 of 18 women) the majority improved, with 5 women reporting cure of dyspareunia post operatively. Development of de novo symptoms was also recorded, and 3 women (25%) reported de novo dyspareunia. This is similar to previously reported in a prospective randomized controlled trial by

Carey [28] comparing vaginal repair augmented with prosima mesh vs. traditional native tissue repair. They reported a 27.8% de novo dyspareunia rate after mesh augmented repair and 41.7% after native tissue repair, however the values did not reach statistical significance (p=0.46).

The strengths of our study include the selection of women with recurrent anterior vaginal wall prolapse, as the anterior wall is the commonest site of prolapse recurrence [29] for which there is currently limited evidence-based guidance for management.

Other strengths include assessing subjective outcomes such as patient satisfaction and objective anatomical outcomes using POPQ assessment. The follow up outcomes were recorded by structured telephone interview by an independent observer (JL) and outcomes reported up to five years. These include subjective cure but also complications related to the mesh.

Safety concerns about the use of synthetic mesh in prolapse repairs, include mesh exposure and extrusion into the vagina, dyspareunia, chronic pain and infections [18]. In the UK, an estimated 15% of women undergoing mesh surgery for prolapse and urinary incontinence are thought to experience adverse events, though the Department of Health notes that the figures are difficult to interpret because a significant number of patients suffer problems prior to surgery [30]. At follow up interview, we recorded complications such as chronic pain, dyspareunia, mesh extrusion and mesh removal along with prolapse recurrence. To our knowledge these complications have not been reported in the literature before at this length of follow up. The findings of this study provide reassurance regarding the medium term efficacy and safety of using vaginal mesh for anterior wall prolapse recurrence.

Limitations of this study include the lack of a control group to compare the efficacy and safety of vaginal mesh repair with repeat native tissue repair, or women who did not have prolapse repair, and the small sample size.

Although Randomized Controlled Trials (RCTs) are considered the 'gold standard' [31], observational studies of patient reported outcomes still have a role to play in evidence-based medicine. Given the ongoing mesh controversy it may be considered unethical to conduct a randomized controlled trial including mesh kits for vaginal prolapse, thereby making observational studies

a valuable means by which to gather efficacy and safety evidence [32,33].

Additionally, large observational trials might better reflect the 'real clinical world' than an RCT performed in a homogenous subgroup of patients [33]. While RCT results may clearly demonstrate efficacy for a particular subgroup, they may lack external validity for the population likely to be undergoing treatment [32].

The intention to treat analysis often employed by RCTs can also affect validity of results. Therefore, it may be prudent to use systematic reviews combining results from RCTs and large observational studies to answer important clinical questions. Although the sample size was small in this study the results can add to the pool of information regarding vaginal mesh for recurrent prolapse, for which there is a currently a paucity of data.

Conclusion

This study shows that vaginal surgery using single incision lightweight mesh kits can be an effective approach for women with recurrent anterior vaginal prolapse, resulting in subjective and objective cure rates of over 80% with reasonable safety profile at mean follow up of 36 months.

Declarations

Ethics approval and consent to participate

The study was approved by the Interventional Procedures Governance Committee and the Institutional Review Board of the Luton and Dunstable University Hospital, UK, and all participants signed a consent form to participate in this study.

Consent for publication

All authors have given consent for publication

Availability of data and material

The datasets used and analyzed during the current study are available from the corresponding author on request

Competing interests

No competing interests

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Authors' contributions

JL: Conducted follow up interviews and data analysis. Drafted and edited manuscript.

AF: Designed study and obtained approval from Interventional Procedures Governance Committee. Supervised data analysis and review and editing of manuscript.

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