Anterior-Apical Mesh Repair System in an ambulatory setting

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Abstract

Aim: To examine use of Anterior –Apical mesh repair system for anterior prolapse ≥stage3 in an ambulatory setting .

Methods: This is a prospective case series of 111 women at our centre, who underwent an anterior and apical repair with mesh (graft augmented repair) over a consecutive 24 month period.

Results: We found a high objective (68.5%) and subjective (87.6%) success rate, with a mesh extrusion rate of only 3.8%. Most cases could be done in a day surgery setting (93.4%).

Conclusion: Anterior-Apical mesh repair system has the potential to be used in an ambulatory day surgery setting as demonstrated in our study.

Keywords: Cystocele, apical suspension, graft augmented repair.

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Introduction

Traditional anterior fascial repair of cystocele has reported failure rates in the range of 40–60% possibly owing to the fact these utilise previously weakened tissues [1]. Furthermore these repairs only result in the plication of tissues in the midline and do not sufficiently address lateral defects at the arcus tendineus fascia pelvis or apical level 1 support [1, 2].

A recent Cochrane review has shown that mesh use in the anterior compartment has a lower failure rate versus traditional repair [3,4]. First generation mesh kits like Perigee and Anterior Prolift resulted in robust support of the bladder, and initial studies have shown cure rates in the range of 87–96% [5–7]. These kits however, lacked proper level 1 support, which may have contributed to it apical failures. Furthermore, these operations necessitated groin incisions and 'blind' needle passes through the obturator foramina which served as conduits for the mesh arms, and presented a significant risk of vascular and visceral damage mainly in the hands of inexperienced surgeons [8, 9]. Other disadvantages were vaginal or pelvic pain from the mesh arms being pulled too tight, as well as high mesh extrusion rates up to 15% [10–12].

Abdominal sacralcolpopexy has long been described in contemporary literature to have the highest cure rates for vault prolapse and achieves good level 1 support. It is only recently though that so called "second generation" vaginal mesh augmentation procedures have also been utilised to achieve this type of support. Both procedures result in relatively tension free repairs, restore the anatomy and do not rely on the patients' stretched and weakened tissue to provide support.

The Anterior Elevate (TM) Device is a "second generation" mesh that has integrated apical (level 1) support in addition to providing level 2 support via a four point attachment through anchors in the obturator internus muscles and sacrospinous ligaments respectively. This is achieved through a single vaginal incision and does not require blind passes through the obturator foramen like its precursor PerigeeTM. We believe that the single incision access also reduces postoperative pain and has increased the feasibility of performing this procedure in a day surgery setting.

Material and methods

This study is a descriptive prospective case series of 111 women that underwent anterior repair with mesh (graft augmented repair) and vaginal apical suspension using the Anterior Elevate System by AMS (American Medical Systems, Minnetonka, MN, USA) over a consecutive 24 month period at our center. Comprehensive preoperative urogynecologic exams were completed including prolapse quantification utilizing the International Continence Society Pelvic Organ Prolapse Quantification (POPQ) staging system. Additional procedures performed pre-operatively included, urodynamics to rule out the presence of overt or occult stress urinary incontinence (SUI) and /or detrusor instability. Statistical analysis was done using the 'paired t' tests and the Mc Nemar test.

Inclusion criteria were patients with symptomatic anterior, primary or recurrent, prolapse ≥stage 3. In our practice, we avoid the use of the device in immuno-compromised patients and those with previous pelvic radiation. If patients had urodynamically proven SUI, they were also scheduled for a mid-urethral sling, but we did not perform any prophylactic slings .

Surgical technique:

A solution of local anaesthetic and adrenaline, approximately 30 ml, is injected into the anterior vaginal wall to facilitate hydrodissection. The bladder neck is then identified and an incision commenced below it. Full thickness vaginal wall dissection carries the dissection to the bladder serosal lining, laterally to the sacrospinous ligaments and the obturator internus muscles. The lateral tunnels to the sacrospinous ligament are created using gentle blunt dissection, keeping the pressure of the dissecting finger away from the bladder. The ischial spines are identified and the tissue overlying the ligament, 2 cm medial to the spine, is swept off. The tunnels to the obturator internus muscles are developed using sharp dissection taking care not to button-hole the vaginal fornices.. The sacrospinous anchors are then inserted about a finger's breadth medial to the ischial spines. 2/0 PDS sutures are taken below the bladder neck in the midline and to the vaginal vault or through the pericervical ring to attach the mesh to these structures. The mesh is then fed through the PDS suture

below the bladder neck and the obturator internus anchors gently inserted under the ischiopubic ramus into the muscle. The tail of the mesh is trimmed to the required dimensions and the sacrospinous anchors fed through the eyelets and eased in to place using the spatula provided. An intra-operative cystoscopy is performed to rule out bladder or urethral trauma. The mesh is locked into place with locking eyelets and a 2 layered closure done using 2/0 Vicryl. It is important to exercise great care to ensure that the mesh is not placed under tension. We avoid excising any vaginal skin and reserve vaginal trimming for only those cases where the skin overhangs the introitus after the prolapse is repositioned. If an incontinence or other prolapse procedure is deemed necessary these are achieved through separate colpotomy incisions.

A vaginal pack is placed for 1–2 hours and after removing this, patients will start with trial of void (TOV). Within the TOV, patients are allowed only 300 ml in the first 2 post-operative hours after which they are asked to void. If a patients voids 400 ml or more and the residual urine measures less than 100 ml, patients are deemed to have successfully passed the trial of void. If a patient doesn't pass the trial of void, another trial of void is attempted after 1–2 hours.

The patient is discharged the same day after a successful trial of void with antibiotics and analgesics. If more than 2 TOV's are unsuccessful, an indwelling catheter is placed overnight, the patient is discharged and reassessed the next day for a TOV. After discharge patients have direct access to an emergency number if they experience any problems. A designated nurse contacts all patients telephonically the next day to enquire about any ongoing problems and assess their post-op status utilising a visual analogue score for pain, bleeding and voiding.

Follow-up

Patients were evaluated in the office at 12 weeks, 6 months and 2 years. Prior to each appointment, standardized and validated Quality of life questionnaires like Incontinence Impact Questionnaire-Short form (IIQ-7) and the Urogenital Distress Inventory-Short form (UDI-6) were sent to each patient. At the appointment, ICS POP-Q staging was completed and patients were asked about "feeling or seeing a bulge", as a subjective assessment of prolapse. Furthermore subjective success rate was evaluated by satisfaction scores.

All patients were asked about complaints of urinary incontinence, urgency and frequency symptoms. Objective cure was defined as the midline anterior vaginal wall (points Aa and Ba) <1.0 cm inside the hymenal ring and the vaginal vault (apex) less than or equal to stage I.

Results

Between November 2009 and October 2011, 111 patients were eligible for an Anterior Elevate Procedure. Sixty-six (59,5%) had a stage 3 anterior wall prolapse, the remaining 45 (40.5%) had a stage 4 prolapse. Seventeen patients had a previous anterior vaginal wall repair of which three had a Perigee.

Table 1 shows the general characteristics of these 111 patients. No concomitant hysterectomies were performed (61 patients had uterus in situ at the time of anterior elevate). No patient had any other vault support besides the anterior elevate system.

Intra-operatively only one complication was defined. This was a bladder injury that was repaired at the same time and the mesh placed thereafter. Postoperatively 99 patients did not need a catheter (89.2%), 8 patients needed one for one day (7.2%) and only 4 patients (3.8%) had an indwelling catheter for more than a day with one patient needing it for a total of 8 days. Of all 111 patients, 94 (93.4%) could be treated in day surgery. The remainder needed overnight admission mainly for administrative reasons (long distance to travel, lack of local accommodation etc).

Table 1 General characteristics.

Age (years +/- SD)	62,8 +/- 9.2 (range 35-85)
Parity	2,9 +/- 1.2 (range 1-8)
Postmenopausal	N=108 (97.3%)
Previous hysterectomy	N=50 (45%)
Previous incontinence surgery	N=17 (15,3%)
Chron resp pathology	N= 27 (24.3%)
Smoking	N=11 (9.9%)
Prolapse stage 3	N= 66 (59.5%)
Prolapse stage 4	N= 45 (40.5%)

Patients were followed up postoperatively at 12 weeks ,six months and two years. Out of 111 patients, six (5.4%) were lost to follow up. In the 105 patients eligible for follow-up, few complications were noted in the postoperative period. Mesh exposure was found in 4 cases (3.8%), new onset symptoms urgency frequency in 3 cases (2.9%), new onset stress urinary incontinence in 2 cases (1.9%) and dyspareunia in 1 case (1.0%). Only one patient presented 6 months after surgery with pain in the left lateral vaginal fornix and was found to have a tight band in the track corresponding to the obturator internus anchor; this was divided and the patient had an uneventful recovery.

The anatomical pre-operative and postoperative results at the 6 month visit are shown in Table 2. The objective success rate, defined as Ba < -1, was 68.5% (P<0.001 Mc Nemar test). Postoperatively mean Ba value was -1.9 +/- 0.8, mean C -6.6 +/- 3.4, mean total vaginal length (TVL) was 8.3 +/- 3.5.

Table 2 Complications.

	Frequency	Percentage(n=105)
No complication	86	81.9
Dyspareunia	1	1
Mesh erosion	4	3.8
Prolapsed	1	1
SUI	1	1
Urge incontinence	1	1
Bowel dysfunction	2	1.9
Groin pain	1	1
Ileus	1	1
Suprapubic pain	3	2.9
UTI	4	3.8

Subjective success was defined as "absence of a lump sensation". "No lump sensation at all" was stated by 92 (87.6%) patients, 17 (16.2%) noticed some improvement and only 2 patients (1.9%) had more symptoms than before surgery. Furthermore subjective success rate was evaluated by satisfaction scores as shown in Table 3. The highest satisfaction score of 9–10 was achieved by 77 (73.3%) patients

Table 3 Pre-operative versus post-operative POP Q classification.

	Pre-operative	Post-operative	P Value (t-test)
Aa (+/-SD)	0.5 +/- 1.3	-2.0 +/- 0.8	<0.001
Ba (+/-SD)	1.2 +/- 1.4	-1.9 +/- 0.8	<0.001
C (+/-SD)	-4.1 +/- 3.4	-6.6 +/- 3.4	0.010
Ap (+/-SD)	-1.8 +/- 1.4	-2.6 +/- 0.9	0.008
Bp (+/-SD)	-1.6 +/- 1.5	-2.4 +/- 1.2	0.010
TVL (+/-SD)	8.1 +/- 2.0	8.3 +/- 3.5	0.683

Table 4 Postoperative satisfaction scores.

Very satisfied (9-10)	77 (73.3%)
Satisfied (6-8)	30 (28.6%)
Partially satisfied (3-5)	2 (1.9%)
Not satisfied (0-2)	2 (1.9%)

Discussion

In this study of the Anterior Elevate device in an ambulatory setting, we found a high rate of objective (68.5%) and subjective (87.6%) success, with a mesh extrusion rate of only 3.8%. Most cases could be done in a day surgery setting (93.4%) without the need of a catheter and a pack.

The Anterior Elevate was developed as an improvement over the existing first generation devices. The Mesh Delivery System allows for access via a single vaginal incision, avoids blind passes through the obturator foramen and provides good apical (level 1) in addition to level 2 support. Additionally the monofilament polypropylene mesh ,called 'Interprolite', is purportedly lighter.

Two earlier studies, by Moore et al [13] and Lukban et al [14], have shown high objective and subjective success rates of Anterior Elevate of up to 90%. In our study the objective success rate was slightly lower but this may well be caused by the difference in inclusion criteria. As earlier described, in our study only patients with a stage 3 or stage 4 prolapse were eligible for Anterior Elevate whilst in the two earlier published studies patients with a stage 2 prolapse were also included. As objective success is defined as Ba<-1, it is reasonable to assume that this condition is easier achieved if the pre-operative size of the prolapse is smaller. We think it is important though to set strict criteria for the use of mesh and only use it in cases with symptomatic large or recurrent prolapse.

In the earlier two published studies mesh extrusion rates varied between 0–6.5%. In this study, we used a deeper dissection plane together with a two layer closure technique, to minimize the chance of mesh extrusion. The combination of these may have lead to an extrusion rate as low as 3.8% in our study. With extrusion being one of the main complications of mesh repairs, it is very important that every possible effort be made to minimize the development of this condition.

One of the highlights of this study that distinguishes it from earlier studies is all procedures were done in a day surgery facility and most 93.4% were discharged the same day. Interestingly no patient had an indwelling catheter placed postoperatively and vaginal packing stayed in place for one to two hours only and was removed prior to TOV. In earlier published studies all patients received a catheter and vaginal pack for 24 hours. Most of our patients (82.9%) were able to void within a few hours and could leave the hospital the same day without a catheter. Performing this procedure in day surgery without using a bladder catheter or prolonged vaginal packing, reduces chance of developing infection, postoperative pain and discomfort.

The Anterior single incision mesh delivery system was developed in the aftermath of the USFDA notification in 2008 (16) in an attempt to reduce operative complications involving pelvic viscera and blood vessels. The most recent USFDA update has again drawn the mesh debate into the limelight (17). For that reason all our patients are given an information leaflet that discusses surgical and non-surgical options for prolapse and a list of questions that patients are encouraged to ask us before choosing mesh as a surgical option. Furthermore by employing strict selection criteria, good pre-operative counseling, a 24 hour phone number and standardized postoperative care, we ensured ambulatory day surgery for the vast majority of our patients. Finally we continually audit our practice both in-house and invite external reviewers from time to time.

We believe the Anterior Elevate device to be a viable alternative to native tissue repair for large and recurrent cystocele, with or without concurrent apical prolapse, and that it has the potential to be used in an ambulatory day surgery setting as demonstrated in our study.

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