51

Lukban J[1], VanDrie D[2], Roovers J[3], Moore R[4], Courtieu C[5], Mayne C[6]

1. *Eastern Virginia Medical School,* ***2.*** *Grand Rapids Women's Health, DBA Female Pelvic Medicine & Urogyn Inst of MI,* ***3.*** *Academic Medical Center, University of Amsterdam,* ***4.*** *Atlanta Urogynecology Associates and Atlanta Medical Research,* ***5.*** *CMC Beausoleli,* ***6.*** *Leicester General Hospital*

A PROSPECTIVE MULTI-CENTER CLINICAL TRIAL EVALUATING ELEVATE APICAL AND POSTERIOR IN THE TREATMENT OF PELVIC ORGAN PROLAPSE: TWO-YEAR FOLLOW-UP

Hypothesis / aims of study

To assess the safety and efficacy of the single-incision Elevate Apical and Posterior (EAP) (AMS, Minnetonka, MN, USA) in the treatment of patients with pelvic organ prolapse.

Study design, materials and methods

We conducted a prospective, multi-center trial of patients enrolled for primary posterior and/or apical mesh implant. Clinical sites included sixteen academic and community urogynecologic, urologic or gynecologic practices in the United States and Europe. Women with posterior vaginal prolapse (≥ Stage II) and/or apical (cuff or cervix) descent (≥ Stage II) were enrolled. Subjects received EAP with IntePro™ Lite (Type I polypropylene mesh) inserted transvaginally without trocars into the rectovaginal space, affixed without tension to the sacrospinous ligaments (SSL) using polypropylene anchors. Primary endpoint was the percent of subjects with Stage ≤ I ("cure") at follow-up. Secondary endpoints included, but were not limited to, procedure time, estimated blood loss, adverse events (AE's), postoperative pain (Wong-Baker Faces Pain Scale), quality of life (Pelvic Floor Distress Inventory, PFDI; Pelvic Floor Impact Questionnaire, PFIQ-7; Pelvic Organ Prolapse Urinary Incontinence Sexual Function Questionnaire, PISQ-12) and patient satisfaction. Subjects were seen postoperatively at 6 weeks, 3 months, 6 months, 1 year and 2 years. Descriptive statistics were employed as were a paired t-test or Wilcoxon signed-rank test for comparative values as appropriate. Statistical significance was defined by $P< 0.05$. Overall anatomic success by compartment was evaluated using the Last Failure Carried Forward (LFCF) method, which carried forward a patients' objective failure at previous visits if their 24 month results were missing. The LFCF analysis also considered subjects to be failures if they were re-operated for recurrent prolapse in the posterior or apical segments within 24 months from the initial implant.

Results

One-hundred thirty-nine women were implanted. At baseline, 134 (96.4%) patients presented with posterior vaginal prolapse ≥ Stage II and 42 (30.2%) had apical descent ≥ Stage II. Previous compartment specific surgery was recorded in 21 (15.1%) and 8 (5.8%) of those with posterior vaginal and apical prolapse, respectively. Mean age was 62.5 ± 11.6 years and mean BMI was 28.2 ± 6.5 kg/m^2. Forty-four (31.7%) patients had used vaginal estrogen cream for at least four weeks prior to surgery. Average procedure time was 45.8 ± 19.2 minutes. Mean EBL was 55.4 ± 45.7 cc, with no patient requiring transfusion. Hysterectomy was performed at the time of mesh placement in 20 (14.4%) subjects. Two-year follow-up data were available for 113 (81.3%) patients. Apical and posterior "cure" was seen in of 88.2% (30/34) and 91.5% (97/106) of subjects, respectively (Table 1). Of the 13 subjects who presented with anatomic failure, only 4 complained of bulge symptoms. Vaginal exposure of mesh was reported in 7.9% (11/139) of patients, with 3 of the extrusions requiring mesh revision in the operating room (OR). No device explants were performed. Median time to onset of extrusion was 140 days (range 19 – 807). Most common AE's (> 1%) included constipation (2.2%), pain or discomfort in the buttock (2.2%), hematoma (1.4%), vaginal infection (1.4%), UTI (1.4%), and superficial wound dehiscence without extrusion (1.4%). There were no self reported cases of dyspareunia. Mean Wong-Baker Pain scores showed significant improvement from 1.9 ± 2.3 at baseline to 0.6 ± 1.3 and 0.3 ± 0.9 at 6 weeks and 3 months, respectively. Significant improvement was seen in the PFDI and PFIQ-7 including all subscales between baseline and 24 months. Increase in mean PISQ-12 scores was recorded, however, improvement was not statistically significant. Of 37 patients who were sexually active at baseline, 15 (40.5%) reported dyspareunia (defined as "always", "usually" or "sometimes" on question 5 of the PISQ-12, "Do you feel pain during intercourse?"), with 7 (46.6%) showing improvement at 24 months. Additionally, 12 (18.5%) of 65 women who were not sexually active at baseline were sexually active at two-years. Patient satisfaction was such that 91.2% (103/113) felt that they were "some" or "a lot" improved and 88.5% (100/113) were "moderately", "very", or "extremely" satisfied. Overall, 92.0% (104/113) of subjects responded that they would recommend the procedure to a friend.

Table 1	Apical 24 month			Posterior 24 month		
Baseline Stage	N Patients	N Success	% Success	N Patients	N Success	% Success
2	15	14	93.3	71	67	94.4
3/4	19	16	84.2	35	30	85.7
Total	34	30	88.2	106	97	91.5

Interpretation of results

The use of Type I polypropylene mesh inserted through a single transvaginal incision secured bilaterally to the SSL provides good anatomic support to the posterior and apical compartments. Analysis of "cure" as defined by Stage ≤ I in addition to use of the LFCF method represents a conservative assessment of anatomic success. The majority of vaginal mesh exposures did not require revision in the OR.

Concluding message

The single-incision Elevate Apical and Posterior was shown to provide long term safety and effectiveness.

Specify source of funding or grant	**American Medical Systems funded the study.** **Drs. Lukbans, Beyer, Roovers, Moore, Courtieu & Mayne are consultants for AMS**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**clinicaltrials.gov NCT00638235**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Eastern Virginia Medical School IRB #06-05FB-0157**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**