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A PROSPECTIVE MULTICENTER STUDY EVALUATING ELEVATE™ APICAL AND POSTERIOR FOR TREATMENT OF POSTERIOR AND/OR APICAL VAGINAL WALL PROLAPSE: TWELVE-MONTH FOLLOW-UP

Hypothesis / aims of study

To assess the safety, efficacy, quality of life, and impact on sexual function of the Elevate Apical & Posterior system (Elevate A &P) with IntePro™ Lite (AMS, Minnetonka, MN, USA).

Study design, materials and methods:

In an ongoing, prospective, multi-center study involving 16 US and European urogynecologic, urologic, and gynecologic sites, women with posterior vaginal prolapse (≥ Stage II) and/or apical or uterine descent (≥ Stage II) received Elevate A&P with IntePro Lite (Type I polypropylene with a mesh density of 25.5 g/m^2). The system includes a 14 cm in length mesh with 2 proximal eyelets (9 cm apart) through which are passed ipsilateral sacrospinous ligament (SSL) anchored polypropylene arms (1.5 cm wide). Insertion of mesh was through a single vaginal incision into the rectovaginal space, affixed without tension to the SSL on either side. Demographic and peri-operative parameters were recorded. Primary endpoint was the percent of subjects with Stage ≤ I ("cure") at follow-up. Patients were seen postoperatively at 6 weeks, 3, 6 and 12 months and will be followed through 2 years. Assessment of anatomic durability was performed by a single practitioner at each clinical site employing the Pelvic Organ Prolapse – Quantification System (POP-Q) according to ICS guidelines. Outcomes also included peri-operative quality of life (QoL) questionnaire (Pelvic Floor Distress Inventory, PFDI-20; Pelvic Floor Impact Questionnaire, PFIQ-7; Pelvic Organ Prolapse Urinary Incontinence Sexual Function Questionnaire, PISQ-12) scores in addition to a postoperative patient satisfaction survey. Changes in QoL scores between baseline and 12 months were evaluated by a paired t-test or Wilcoxon signed rank test as appropriate. Overall anatomic success by compartment was evaluated using the Last Failure Carried Forward (LFCF) method, which carries forward a patients' objective failure at 6 months if their 12 month results are missing. The LFCF analysis also considers subjects to be failures if they were re-operated for recurrent prolapse in the posterior or apical segments within 12 months from the initial implant, regardless of their 6 month and 12 month test results.

Results

One-hundred thirty nine women were successfully implanted. Mean age was 62.5 years (range 34.5-84.9). Twelve-month follow-up data were available for 90.6% (126/139) of subjects. Of the 13 without follow-up, 8 missed their 12 month visit and 5 withdrew consent. At baseline, 96.4% of subjects presented with posterior vaginal prolapse, 47.5% had posterior enterocele, and 30.2% had apical or uterine descent. Average procedure time for Elevate A&P was 45.4 ± 18.6 minutes. Mean EBL was 56.2 ± 46.4 cc. A single intraoperative complication occurred in the form of injury to the rectum during initial dissection with no untoward sequelae. Anatomic "cure" was seen in 91.7% (110/120) and 89.2% (33/37) of subjects with posterior vaginal and apical prolapse, respectively. One patient receiving the device for posterior prolapse without an apical defect at baseline exhibited advanced cervical descent at follow-up. Vaginal exposure of mesh was reported in 6.5% (9/139) of subjects with no device explants. Additional device or procedure related adverse events (AEs) included constipation in 3 (2.2%), UTI in 3 (2.2%), urinary incontinence (persistent) in 3 (2.2%), urinary urgency in 3 (2.2%), vaginal infection in 2 (1.4%), buttock pain in 2 (1.4%), hematoma without transfusion in 2 (1.4%) and superficial wound dehiscence without extrusion in 2 (1.4%) subjects, with all other AEs at or below 1%. No significant postoperative pelvic pain was recorded with values of 0.6 ± 1.3 and 0.3 ± 0.9 at 6 weeks and 3 months, respectively, employing a (1 – 10) Wong-Baker pain scale. Significant improvement was seen in all QoL questionnaires at 12 months. Change in PFDI-20 and PFIQ-7 scores are presented in the table below.

QOL Measurements	Baseline Mean ± SD Score (n)	6-Month Mean ± SD Score (n)	P-value Signed Rank Test
PFDI Scales			
POPDI[1] General	47.9 ± 26.4 (126)	12.0 ± 19.4 (126)	< 0. 001*
POPDI Posterior	43.4 ± 32.6 (126)	18.4 ± 26.7 (126)	< 0.001
POPDI	122.0 ± 63.7 (126)	43.0 ± 52.5 (126)	< 0.001*
CRADI[2]	108.2 ± 71.7 (126)	49.6 ± 55.1 (126)	< 0.001
PFIQ Scales			
POPIQ[3]	19.5 ± 24.8 (121)	4.0 ± 13.8 (121)	< 0.001
CRAIQ[4]	18.2 ± 23.3 (120)	6.0 ± 15.6 (120)	< 0.001
PFIQ Score	65.6 ± 59.7 (120)	17.9 ± 39.9 (120)	< 0.001

* Paired t-Test
1 – Pelvic Organ Prolapse Distress Inventory
2 – Colorectal-Anal Distress Inventory
3 – Pelvic Organ Prolapse Impact Questionnaire
4 – Colorectal-Anal Impact Questionnaire

Forty eight subjects completed the PISQ-12 at both baseline and at 12 months. Mean score improved significantly from 34.1+ 6.1 to 36.5± 5.5 (P =0.004 Paired t-Test). The percentage of patients who reported dyspareunia (as per PISQ-12 question 5) at 1 year was 59% as compared to 61.4% at baseline. Five (9.6%) out of 52 subjects who were sexually active at baseline were no longer active at 12 months. Thirteen (18%) out of the 72 who were not active at baseline had become sexually active at follow-up. Regarding patient satisfaction, 96.8 % had "some" (23.0%) or "a lot" (73.8%) of improvement from before surgery; 95.9% were "moderately" (13.1%), "very" (42.6%) or "extremely" (40.2%) satisfied with their surgical outcome; and 98.4% would "recommend" the procedure to a friend.

Interpretation of results

The use of Type I polypropylene mesh in the posterior compartment secured bilaterally with two mesh arms affixed to the SSL provided good anatomic support to the posterior and apical compartments with short operative times, low peri-operative morbidity, and improved quality of life including sexual function. The system, employing a single vaginal incision, lightweight mesh, and self-fixating polypropylene anchors, was associated with infrequent leg pain and buttock discomfort, and offered a low incidence of extrusion. The LFCF represents a conservative assessment of anatomic success.

Concluding message

The Elevate A&P is safe and effective at 1 year with follow-up ongoing through 24 months.

Specify source of funding or grant	**Study was supported by American Medical Systems who initiated, executed and funded study**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**www.clinicaltrials.gov web site**
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	**1. Eastern Virginia Medical School IRB, VA USA 2. Mercy Hospital IRB, ME USA 3. Western Institutional Review Board (WIRB), USA 4. Amsterdam Medical Center EC, Netherlands 5.University Hospital of Leicester, UK 6.AFSSAPS EC#2009-A00336-51, France 7. Bayerische Landesärztekammer Ethikkommission- Munich, Germany 8. Landesärztekammer Rheinland-Pfalz Ethik-Kommission - Mainz, Germany**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**