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Stanford E[1], Moore R[2], Roovers J[3], Courtieu C[4], Lukban J[5], Bataller E[6], Liedl B[7], Sutherland S[8]
***1.*** *Delta County Memorial Hospital,* ***2.*** *Atlanta Urogynecology Associates and Atlanta Medical Research,* ***3.*** *Academic Medical Center University of Amsterdam,* ***4.*** *CMC Beausoieli,* ***5.*** *Eastern Virginia Medical School,* ***6.*** *Hospital General del Hospitalet,* ***7.*** *Pelvic Floor Center Munich,* ***8.*** *Metro Urology Clinical Research*

# ELEVATE ANTERIOR/APICAL: SAFETY AND EFFICACY IN SURGICAL TREATMENT OF PELVIC ORGAN PROLAPSE

Hypothesis / aims of study
To assess the safety and efficacy of the Elevate® Anterior and Apical (EAA) with IntePro® Lite™ support system (American medical Systems, Minnesota, USA) in the repair of pelvic organ prolapse (POP). Here we present 12-months post procedure data.

Study design, materials and methods
One hundred and forty-two women were enrolled at 16 investigational sites (10 U.S., 6 E.U.) of which 125 (88.0%) completed 12-months follow-up. Of the 17 subjects who did not complete the 12-months visit, 8 missed the visit; 4 were lost to follow up; 3 voluntarily withdrew consent; 1 had device removed and 1 died (unrelated to procedure). The primary outcome was treatment failure defined as ≥ Stage II POP-Q anytime during follow-up using the Last Failure Carried Forward (LFCF) method. The LFCF method carries forward a patients' objective failure at 6 months if their 12 month results were missing. And it also considers subjects to be failures if they were re-operated for recurrent prolapse in the anterior or apical segments within 12 months from the initial implant, regardless of their 6 month and 12 month test results. Subjects who had a concomitant Elevate Apical and Posterior system were excluded from the apical efficacy analysis. Secondary outcomes were quality of life (QOL) measures using Pelvic Organ Prolapse Urinary Incontinence Sexual Function Questionnaire (PISQ-12), Pelvic Floor Impact Questionnaire (PFIQ), and Pelvic Floor Distress Inventory (PFDI) questionnaires. Wilcoxon signed rank test was used to compare the POP-Q measurements between baseline and 12 month. The exact 95% confidence interval of the anatomic success rates was calculated using binomial method. Statistical significance was assessed at $P< 0.05$.

Results
Patient characteristics (mean± SD) were: age 63.9±9.8 yrs; weight 72.4±14.6 kgs; BMI 27.3±5.3 kg/m$^2$ ; gravidity 3±2; parity 3±1; menopausal 127 (89.4%); and prior hysterectomy 62 (43.7%). The anatomic success rate for the anterior compartment was 87.4% (95% CI 80.3%-92.6%) and for the apical compartment 95.9% (95% CI 88.5%-99.1%) as shown in Tables 1 and 2. Of the 17 subjects who presented with anatomic failure (16 anterior and 3 apical) only two complained of bulge symptoms and one subject had her device removed due to recurrence of cystocele. Related adverse events reported at >2% were mesh extrusion (8; 5.6%), urinary tract infection (8; 5.6%), Dyspareunia (6; 4.2%), transient buttock pain (5; 3.5%), de novo urinary stress incontinence (5; 3.5%); urinary retention (5; 3.5%), granuloma formation (3; 2.1%) and hematoma (3; 2.1%). All QOL scores were significantly improved from baseline ($p<0.001$). PISQ-12 score improved by a mean of 5.5±7.4, with 77.1% of the subjects who completed this questionnaire at baseline and at 12-months (n=48) reporting improvement concerning sexual function. Satisfaction scores revealed that 121 (96.8%) felt that they were some or a lot improved and 118 (94.4%) were moderately, very, or extremely satisfied.

Interpretation of results
Twelve month data shows that the Elevate anterior and apical support procedure completed through a single vaginal incision and no external needle passes is effective in treating both anterior and apical prolapse concomitantly with few complications. The data shows low mesh extrusion rates and high patient satisfaction. The EAA system appears to offer improvements over earlier generation mesh kits designed for anterior and apical vaginal prolapse treatment.

Concluding message
The EAA is safe and effective in supporting both the anterior and apical compartments.

| **Table 1** | Apical 12 month | | | Anterior 12 month | | |
|---|---|---|---|---|---|---|
| Baseline Stage | N Patients | N Success | % Success | N Patients | N Success | % Success |
| 2 | 41 | 39 | 95.1 | 35 | 31 | 88.6 |
| 3/4 | 32 | 31 | 96.9 | 92 | 80 | 87.0 |
| No de novo prolapse | | | | | | |

| **Table 2** | Baseline (n=125) | | 12 month (n=125) | | P-value (Wilcoxon) |
|---|---|---|---|---|---|
| POP-Q Point | Mean ± sd | 95% CI | Mean± sd | 95% CI | |
| Aa | 1.2±1.3 | (1.0, 1.4) | -2.3 ±0.9 | (-2.5, -2.2) | <0.001 |
| Ba | 2.6±1.9 | (2.2, 2.9) | -2.2±0.9 | (-2.4, -2.1) | <0.001 |
| C* | -0.5±3.6 | (-1.2, 0.2) | -7.1±1.8 | (-7.4, -6.8) | <0.001 |
| Total Vaginal Length | 8.5 ± 1.2 | (8.3, 8.8) | 8.6 ± 1.2 | (8.4, 8.8) | 0.822 |
| * n=112, subjects who had a concomitant Elevate Apical and Posterior were not included in the analysis | | | | | |

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| ***Specify source of funding or grant*** | **American Medical Systems (MN, USA) funded the clinical research** |
| ***Is this a clinical trial?*** | **Yes** |
| ***Is this study registered in a public clinical trials registry?*** | **Yes** |
| ***Specify Name of Public Registry, Registration Number*** | **clinicaltrial.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#06-05-FB-0157** |
| ***Was the Declaration of Helsinki followed?*** | **Yes** |
| ***Was informed consent obtained from the patients?*** | **Yes** |