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QUALITY OF LIFE ASSESSMENT TWO YEARS POST SURGICAL TREATMENT FOR PELVIC ORGAN PROLAPSE USING TRANSVAGINAL MESH

Hypothesis / aims of study
To assess the impact of the Elevate Anterior/Apical (EAA) on quality of life (QOL) at 24 months.

Study design, materials and methods
One hundred forty-two women with anterior vaginal prolapse and/or apical descent ≥ Stage II, were enrolled at 16 investigational sites (10 US, 6 EU). All received transvaginal polypropylene mesh insertion with no external needle passes anchored bilaterally to the sacrospinous ligaments and obturator foramen.
All patients' quality of life were assessed pre-operatively and at 6, 12 and 24-months post-procedure using 3 validated questionnaires: Pelvic Organ Prolapse Urinary Incontinence Sexual Function Questionnaire (PSIQ-12) for sexually active subjects, Pelvic Floor Impact Questionnaire (PFIQ-7), and Pelvic Floor Distress Inventory (PFDI). Baseline and 24-month results are presented along with number of subjects reporting improvement. Subcategory scores for the PFIQ-7 (urinary impact questionnaire, UIQ, and pelvic organ prolapse impact questionnaire, POPIQ) and PFDI (urinary distress impact, UDI; pelvic organ prolapse distress index anterior, POPDI Anterior; and pelvic organ prolapse distress inventory POPDI) at baseline and at 24 months are also presented. Tests used for statistical analysis were paired t-test and Wilcoxon signed rank test as appropriate. A p-value of <0.05 was considered significant.

Results
All QOL scores showed significant improvement from baseline through 24-months. Forty-five women who were sexually active at baseline completed the 24-month PISQ-12 and demonstrated significant improvement ($p=<0.001$). PFIQ-7 and PFDI scores for UIQ, POPIQ, UDI, POPDI Anterior, and POPDI were significantly improved at a p-value of <0.001.

Interpretation of results
The results of this study indicate the EAA pelvic prolapse procedure can improve QOL scores.

Concluding message
Analysis of the results from this study indicate that at 24 months, the EAA procedure is associated with improved QOL scores when compared to baseline when assessed using the PSIQ-12, PFIQ-7, and PFDI questionnaires.

Table 1: Questionnaire scores

Questionnaire	Baseline Mean ± SD (95% CI)	24- Month Mean ± SD (95% CI)	# of any improvement from baseline	P-value
PISQ-12	32.0 ± 8.4 (29.4, 34.5) (N = 45)	36.3 ± 6.1 (34.4, 38.1) (N = 45)	36 (80%)	<001[T]
PFIQ-7				
UIQ	25.9 ± 23.5 (21.7, 30.1) (N=124)	4.7 ± 12.5 (2.5, 6.9) (N = 124)	91 (73.4%)	<.001[S]
POPIQ	18.5 ± 23.9 (14.2, 22.7) (N = 123)	1.9 ± 7.2 (0.6, 3.1) (N = 123)	69 (56.1%)	<.001[S]
PFIQ-7 Total	54.8 ± 56.1 (44.7, 64.9) (N = 121)	9.3 ± 24.8 (4.9, 13.8) (N = 121)	101 (83.5)	<.001[S]
PFDI				
UDI	82.5 ± 50.6 (73.5, 91.5) (N = 124)	20.5 ± 25.0 (16.0, 24.9) (N = 124)	114 (91.9%)	<.001[S]
POPDI Anterior	33.2 ± 26.9 (28.4, 38.0) (N = 124)	9.4 ± 14.8 (6.8, 12.0) (N = 124)	93 (75.0%)	<.001[S]
POPDI	103.3 ± 59.1 (92.8, 113.8) (N = 124)	24.8 ± 32.3 (19.1, 30.6) (N = 124)	112 (90.3%)	<.001[S]
T P value from paired t-test; S P value from Wilcoxon signed rank test				

Disclosures
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2.Western Institutional Review Board
3.Northside Hospital IRB
4.Ethik Kommission Bayerischen Landesärztekammer
5.Medisch Ethische Commissie Academisch Medisch Centrum Universiteit van Amsterdam
6.Consorci Santari Integral
7.Leuven University Hospital
8.Allina Institutional Review Board Administrative Office
9.North Nottingham Research Ethics Committee **Helsinki:** Yes **Informed Consent:** Yes