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SYNTHETIC GRAFT AUGMENTATION IN VAGINAL PROLAPSE SURGERY: LONG-TERM OBJECTIVE AND SUBJECTIVE OUTCOMES

Hypothesis / aims of study
Long-term data on synthetic graft use in vaginal prolapse surgery are limited even though an increasing demand exists for more durable surgical treatment approaches for pelvic organ prolapse (POP) repair. Although currently off the market, many women received Prolift™ mesh augmentations and long-term post-operative outcome assessment is relevant and important. Our aim is to report long-term objective and subjective outcomes of women who have undergone transvaginal POP surgery with a synthetic graft augmentation using Prolift™ (Gynecare, Ethicon, Somerville, NJ, USA).

Study design, materials and methods
This is a retrospective observational study in women undergoing a vaginal POP surgery with Prolift™ between July 2006 and December 2008 at a major tertiary care center. Subjects returned validated questionnaires via mail including the Pelvic Floor Distress Inventory (PFDI-20), the Pelvic Floor Impact Questionnaire (PFIQ-7), the Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ), and the Patient Satisfaction Questionnaire (PSQ). Subjects were invited to undergo post-operative physical examination using the Pelvic Organ Prolapse Quantification (POP-Q) and vaginal pain/stricture assessment by a clinician not involved in the patients' care. Long-term post-operative findings were compared to baseline pre-surgical data. Demographic data were obtained by medical record reivew. Statistical analyses were performed using the Wilcoxon signed rank test, McNemar's test, and paired t-test as appropriate. P-values of ≤0.05 were considered statistically significant.

Results
208 eligible subjects provided baseline data; 70 completed postoperative questionnaires only, and 48/70 provided both postoperative examination and questionnaire assessment. Mean age was 60.3±9.3 years; mean follow-up interval 7.0±0.7 (range:5.8-8.1) years. The graft was inserted in the anterior wall in 47%, posterior wall in 33%, and total in 20% of identified subjects. Objectively, POP-Q measurements of Ba, Bp, C, TVL, GH, PB and overall POP stage significantly improved compared to baseline (all $p<0.0001$ except for PB, $p=0.006$, Table). Graft exposure was seen in 3/48 subjects examined (6.4%); all subjects with exposure had discontinued vaginal estrogen use after surgery and had significant vaginal atrophy noted on examination. Vaginal tenderness was noted in 4 (8.5%) within -3 cm, 5 (10.6%) at -3 to -6 cm, and 12 (25.5%) at <-6 cm, stricture was only seen in 1 (2.1%) at <-6 cm, measured from the hymen. Subjectively, the PFIQ (total, UIQ, POPIQ) and PFDI (total, UDI, POPDI) scores significantly improved (all $p<0.0005$), whereas no difference were noted in the Colorectal-Anal subscales (CRAIQ or CRADI) and PISQ scores at >5 years follow-up ($p=0.29$, 0.11, 0.14 respectively, Table). Satisfaction rates were 15.7% not satisfied at all, 35.7% somewhat satisfied, and 48.6% completely satisfied. Three of 70 subjects (4.3%) had undergone surgical revision.

Interpretation of results
Women undergoing transvaginal POP surgery using this synthetic graft continue to have positive outcomes in restoration of anatomy and improved symptom specific distress and impact on quality of life greater than 5 years post-surgical treatment. Relatively high patient satisfaction was noted. Revision and exposures rates remained low.

Concluding message
Although limited by the relatively low follow-up rate, this study provides the longest follow-up data assessing both subjective and objective outcomes in the current literature. Synthetic graft augmentation in transvaginal POP surgery can be a viable option with positive outcomes at long-term follow-up. Prospective randomized data is urgently needed to identify optimal candidates, location of insertion, and material type as well as safety and efficacy of synthetic graft use in transvaginal POP surgery.

Table: Long-Term Objective and Subjective Outcomes

Objective	Pre-op (n=48)	> 5 year follow-up (n=48)	Changes	p-value
POP-Q Stage, N (%)				<0.0001
1	3 (4.4)	22 (47.8)		
2	39 (42.0)	24 (52.2)		
3	31(44.9)	0 (0)		
4	6 (8.7)	0 (0)		
Overall. Mode (range)	3 (1-4)	2 (1-2)		
POP-Q, median				
Ba	1	-2	-3	<0.0001
Bp	0	-3	-3	<0.0001
C	-3	-7	-4	<0.0001
TVL	10	8	-2	<0.0001
GH	4.5	3	-1.5	<0.0001
PB	3	3.25	0.25	0.006
Subjective	Pre-op (n=70)	> 5 year follow-up (n=70)	Changes (±SD)	p-value
PFIQ	100.0±82.2	55.4±72.4	-44.6±9.8	<0.0001
UIQ	34.3±27.9	21.7±26.4	-12.6±1.5	0.0002
POPIQ	37.5±32.7	13.2±23.0	-24.3±9.7	<0.0001
CRAIQ	26.2±32.2	21.3±28.6	-4.9±3.6	0.29
PFDI	141.6±57.6	87.1±67.0	-54.5±9.4	<0.0001
UDI	47.7±24.4	34.1±28.4	-13.6±4.0	0.0005
POPDI	58.1±22.0	24.0±25.4	-34.1±3.5	<0.0001
CRADI	36.0±26.8	29.9±23.4	-6.06±3.3	0.11
PISQ	27.5±9.4	30.1±9.2	2.6±0.2	0.14

Disclosures
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