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THE OPTIMAL ANTERIOR REPAIR STUDY (OARS): A TRIPLE ARM RANDOMIZED DOUBLE BLINDED CLINICAL TRIAL OF STANDARD COLPORRAPHY VERSUS VAGINAL PARAVAGINAL REPAIR WITH PORCINE DERMIS GRAFT OR POLYPROPYLENE MESH

Hypothesis / aims of study
The high rate of recurrence after anterior vaginal wall prolapse repair is well described in the literature. Growing evidence suggests that the use of graft reinforced repairs may result in higher cure rates. However, the optimal graft material (xenograft versus synthetic) remains unclear. The objective of this study was to compare cure rates of traditional anterior colporrhaphy to graft augmented vaginal paravaginal repairs using porcine dermis or polypropylene mesh in a randomized double blinded clinical trial.

Study design, materials and methods
Institutional Review Board approval was obtained for this randomized, double blind clinical trial of women ≥ 18 years of age with a Pelvic Organ Prolapse Quantification (POP-Q) point Ba of ≥ 0. The study was performed at two clinical sites by 1 of 4 fellowship trained urogynecologists between July 2006 and September 2008. Subjects were randomly assigned to one of three treatment arms: 1) Standard anterior colporrhaphy (C) using midline plication with delayed absorbable suture. 2). Vaginal paravaginal repair using free-hand formed porcine dermis graft (Pelvicol™) (P) 3). Vaginal paravaginal repair using free formed polypropylene mesh (M). All graft material was secured to the arcus tendineus fascia pelvis using a Capio ™ device with permanent monofilament suture. Concomitant procedures including hysterectomy, colpopexy, posterior colporrhaphy and incontinence operations were performed at the surgeon's discretion.
Baseline characteristics were obtained including demographics, medical and surgical history, physical examination measures (including POP-Q measures) [1], and validated quality of life instruments. Outcomes were assessed at 6 weeks as well as at 6, 12 and 24 months post-operatively.
The primary outcome was anatomic success at a minimum of 2 year follow-up, defined as STAGE 0 OR 1 anterior vaginal wall prolapse. Symptomatic recurrence was defined as subjective complaint of "bulge" *and* the presence of stage 2 anterior prolapse. Secondary outcomes included quality of life (QOL) impact and degree of bother as measured using the Pelvic Floor Impact Questionnaire (PFIQ) and Pelvic Floor Distress Inventory (PFDI). Sexual function was assessed using Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PSIQ). Complications including peri-operative infection, blood loss, urinary retention as well as long term complications of graft erosion and re-operation were recorded. Power calculations were based on previously published data of anatomic cure rates of 50 and 85% between colporrhaphy and mesh respectively, assuming a two-tailed hypothesis test with 5% type I error and 80% power. Thirty-three subjects per treatment arm would be needed to detect at least a 35% difference in recurrent stage 2 or greater prolapse.
The proportion of subjects with anatomic success was compared across groups using chi-squared statistics. Median QOL scores were compared using Mann Whitney U test. Baseline clinical and demographic characteristics were compared using t-tests for continuous variables and chi-square or Fisher exact tests were used for categorical factors.

Results
A total of 99 subjects were enrolled, with thirty-two randomized to anterior colporrhaphy, 31 to porcine dermal graft, and 36 to polypropylene mesh. There was no difference in clinical or demographic characteristics between groups.
With 73% of data collection complete at the time of abstract submission, the cure rate was 43%, 52% and 85% in the anterior colporrhaphy, porcine dermis graft and polypropylene mesh groups respectively (Table 1). All three groups had a reduction in their prolapse and urinary symptom severity and degree of bother without significant differences between groups. The symptomatic recurrence rate of anterior wall prolapsed was 7% overall at 2 years: 3 in the colporrhaphy group (11.5%), 3 in porcine dermis group (12.5%) and 1 (3.6%) in the synthetic mesh group. There was no significant difference in the quality of life scores between groups. (Table 1) Graft erosion rates were 14% in the mesh group compared to 4% in the porcine group, only one of which required excision. No deaths or serious adverse events occurred. The two patients who elected to undergo re-operation for recurrent anterior wall prolapse were in the porcine dermis group.

Interpretation of results
In the present analysis of women randomized to 3 different approaches to anterior prolapse repair, mesh achieves superior anatomic outcomes in comparison with both traditional colporrhaphy and porcine graft. Although a slightly higher success rate was seen in the porcine group compared to the anterior colporrhaphy, this difference was not statistically significant, likely due to the fact that the study was not powered to assess this relationship.

Concluding message
Anterior repair with mesh augmentation offers higher anatomic cure rates than colporrhaphy alone.

Objective and Subjective Outcomes by Type of Intervention

	Colporrhaphy (C) Median (range) N = 23	**Porcine (P)** Median (range) N = 23	**Mesh (M)** Median (range) N = 27	**C vs. P** P value	**C vs. M** P value	**P vs. M** P value
Anatomic Success	10 (43%)	12 (52%)	25 (85%)	0.530	**0.005**	**0.02**

Change *POPDI	-33 (-87 to -8)	-38 (-100 to 8)	-35 (-100 to -8)	0.913	0.788	0.519
Change *UDI	-25 (-90 to -37)	-38 (-100 to 46)	-25 (-92 to 13)	0.961	0.903	0.846
Change *POPIQ	-14 (-85 to 0)	-29 (-95 to 3)	-31 (-100 to 0)	0.311	0.447	0.751
Change *UIQ	-21 (-85 to 10)	-29 (-91 to 38)	-21 (-100 to 0)	0.970	0.932	0.697
Change PSIQ	0 (-16 to 32)	1 (-24 to 11)	0 (-28 to 14)	0.135	0.397	0.123

*Symptom severity and degree of bother using prolapse and urinary subscales (0-100) of the PFDI and PFIQ.

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Institutional Review Board at Kaiser Permanente**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**