

COMPARISON OF SURGICAL OUTCOMES AFTER AUGMENTED ANTERIOR/APICAL REPAIR USING TWO DIFFERENT MATERIALS: DERMAL GRAFT AND POLYPROPYLENE MESH.

Hypothesis / aims of study

The aim of this study is to compare surgical outcomes after anterior repair and bilateral sacrospinous vaginal vault suspension augmented with two different materials: biologic (dermal allograft) and permanent synthetic (polypropylene mesh). The null hypothesis is that anatomical failure rates after anterior/apical repair using augmentation with dermal allograft and permanent polypropylene mesh are not significantly different.

Study design, materials and methods

This is a retrospective cohort study comparing post-hysterectomy women who underwent concomitant anterior repair and bilateral sacrospinous vaginal vault suspension augmented with either acellular cadaveric dermis or an apically suspended polypropylene mesh kit (Uphold™, Boston Scientific Corporation). All cases were recruited from a single urogynecology center after a review of all surgeries performed between January 1st, 2008, and July 7th, 2013. Standardized Pelvic Organ Prolapse Quantification System (POP-Q) was used pre- and postoperatively. The primary outcome variable was failure of the procedure, which was defined either as recurrence of apical (C) or anterior (Aa or Ba) prolapse ≥ 0 , or if patient needed retreatment (surgery or pessary). Secondary analyses were performed using POP-Q ≥ -1 as the anatomic threshold for failure. Secondary outcomes included length of surgery, blood loss, intraoperative and postoperative complications with specific focus on mesh erosion, exposure, and dyspareunia. All women with available postoperative POP-Q exams were included in the assessment of the primary outcome variable. All evaluable subjects were analyzed for secondary outcomes.

Results

Among women with prior hysterectomy, anterior repair and bilateral sacrospinous vaginal vault suspension was augmented with acellular cadaveric dermis in 56 cases (Biograft Group), and with apically suspended polypropylene mesh in 68 cases (Mesh Group). The mean clinical follow-up time was 519 \pm 456 days for Biograft Group and 415 \pm 294 days for Mesh Group [$p=0.6546$]. The mean POP-Q follow-up time was 376 \pm 371 days in Biograft Group and 325 \pm 225 days in Mesh Group [$p=0.692$]. The failure rate using ≥ 0 as an anatomic threshold was 8.3% in the Biograft Group (N=48) and 5.6% in the Mesh Group (N=54). This was not statistically different between groups [$p=0.593$]. The secondary analysis using ≥ -1 as a threshold for anatomical failure revealed a failure rate of 27.1% in the Biograft Group (N=48) and 18.5% in the Mesh Group (N=54), which was also not significantly different between the groups [0.302]. However, both groups showed significant improvement in anatomic improvement in their prolapse as measured at points Aa, Ba, and C (Table 1).

Table 1. Anatomical outcomes.

	Mesh Group			Biograft Group		
	Preop	Postop	p	Preop	Postop	p
Aa	1.06 \pm 1.5	-2.25 \pm 1.12	<.0001	0.78 \pm 1.7	-1.98 \pm 1.16	<.0001
Ba	1.80 \pm 2.05	-2.10 \pm 1.59	<.0001	1.34 \pm 2.21	-2.04 \pm 1.17	<.0001
C	-2.66 \pm 3.84	-7.84 \pm 2.84	<.0001	-3.12 \pm 4.13	-7.79 \pm 2.02	<.0001

Intraoperative blood loss was estimated to be significantly lower in the Mesh Group (86.5 \pm 64.9 ml), compared to the Biograft Group (136.9 \pm 39.0 ml) [$p=0.0001$]. However, postoperative reduction in haemoglobin was not significantly different between the two groups (-2.03 \pm 0.92 vs. -2.15 \pm 0.90 g/dL). Operating time was significantly shorter in the Mesh Group (93.99 \pm 35.55 min), compared to the Biograft Group (136.89 \pm 38.98 min) [<0.0001].

There were no erosions or exposures of dermal allograft in the Biograft Group, but there were 2 exposures of the polypropylene mesh into the vagina in the Mesh Group (2.9%). No significant difference in postoperative dyspareunia was observed between the two groups [$p=0.622$].

Interpretation of results

Analysis of the primary outcome variable revealed no significant difference for recurrences to the hymenal ring, but secondary analysis suggests a numerical difference between groups, that while not statistically different, may represent a type II error. Use of the polypropylene mesh led to shorter surgical times, but the reduction estimated blood loss is probably not significant in the absence of a significant difference in the postoperative haemoglobins. Use of the polypropylene mesh kit resulted in a relatively low vaginal exposure rate.

Concluding message

Use of the polypropylene mesh kit allowed us to perform anterior and apical suspensions faster with lower estimated blood loss at the expense of vaginal mesh exposures in 2.9% of cases, without any significant difference in anatomical outcomes.

Disclosures

Funding: None. **Clinical Trial:** Yes **Public Registry:** No **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Institutional Review Board **Helsinki:** Yes **Informed Consent:** No