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AVAULTA POLYPROPYLENE MESH FOR REPAIR OF RECURRENT PELVIC ORGAN PROLAPSE: A PROSPECTIVE FOLLOW UP STUDY OF OBJECTIVE AND SUBJECTIVE OUTCOMES

Hypothesis / aims of study

The lifetime risk of surgery for pelvic organ prolapse or urinary incontinence or both is 11.1% and in 29.2 %, a repeat surgery is required within 4 years. (1) Due to both patient and surgeon dissatisfaction with results from traditional colporrhaphies, vaginal implant meshes are being used increasingly. Currently, the type 1 low weight, polypropylene, monofilamentous, macro porous meshes are the synthetic meshes of choice. Despite the popularity of the vaginal mesh, the collective experience is still small. The largest transvaginal mesh series to date was retrospective and had a follow up of only 3 months and did not assess for subjective symptoms. (2) We carried out a prospective, subjective and objective follow up study with a minimum of 1 year follow up following insertion of a low weight polypropylene mesh for prolapse repair.

Study design, materials and methods

70 consecutive patients who consented for Avaulta mesh (Bard) repair were recruited into this prospective cohort study after informed consent. All these patients had symptomatic anterior and/or posterior vaginal wall prolapse + apical compartment prolapse. Preoperatively, using the International Continence Society standards, POPQ staging were performed by the operating surgeon with the patient exhibiting maximum Valsalva effort. Subjective symptoms were evaluated using Pelvic Floor Distress Inventory – Short Form 20 and quality of life symptoms were evaluated Pelvic Floor Impact Questionnaire – Short Form 7 both pre operatively and at least 1 year post surgery. Pelvic Floor Distress Inventory evaluated symptoms of prolapse, urinary symptoms and colorectal symptoms. Additional questions on the presence and reasons for dyspareunia were included. The mesh was placed using the standard manufacturer prescribed techniques.

Patients were followed up at the Urogynaecology clinic at 6 weeks and 1 year. Objective anatomical cure was defined as stage 0 or stage 1 POPQ. In patients who had been operated more than 1 year ago, they had the questionnaires redone to assess their symptoms at the time of writing this abstract and their final quality of life scores have been used to determine success of surgery in terms of subjective improvement. Statistical analysis was performed with SPSS statistical package 15.0 using the Paired t test and the non parametric Wilcoxon signed rank test to address any issues with normality of the data. $P < 0.05$ was considered significant.

Results

Mean age (± SD) was 62.2±9.55 years (range – 32 to 80), mean BMI (± SD) was 28.1± 4.01 (range – 21 to 39) and mean follow up (± SD) was 18.02 ± 5.71 months (range – 12 to 39). All patients except 1 (n=69/70) were menopausal. 4 patients were lost to subjective follow up.

65 patients (93%) had undergone previous surgery for prolapse or a hysterectomy. In 5 people, the decision to deploy the mesh was made as a traditional prolapse repair was deemed unsuitable due to the degree of prolapse (all had stage 4 and multicompartment prolapse). 54% (n= 38/70) had anterior compartment mesh, 17% (n = 12/70) had mesh deployed in the posterior compartment and 29% (n= 20/70) had mesh inserted in both compartments. Anatomical cure rate was 94% (n= 85/90 mesh insertions).

Table 1 pre operative and post operative POPQ staging.

	Anterior compartment		**Posterior compartment**	
	n = 58/70		n = 32/70	
	Pre-operative	Post-operative	Pre-operative	Post-operative
Stage 0		43(74.2%)		21(65.6%)
Stage 1		12(20.7%)		9(28.1%)
Stage 2	6(10.4%)	3(5.1%)	1(3.1%)	2(6.3%)
Stage 3	23(39.6%)		9(28.1%)	
Stage 4	29(50%)		22(68.8%)	

66 patients (94.2%) had completed subjective assessment questionnaires. We followed up their subjective symptoms at the time of writing this paper with view to noting any deterioration in the results of the subjective score. Here we present results for 34.3% (n=24/70) at 12 months, 35.7% (n=25/70) in their second year after treatment and 30% (n=21/70) in their third year after treatment. Only 2 patients of the 46 (4.3%) reported deterioration in the quality of life scores since the initial assessment at 12 months. Otherwise, the scores were similar.

Table 2 shows the pre and post operative scores of the PFDI and PFI questionnaires. The maximum scores are presented in brackets next to the variables. (UDI – Urinary Distress Inventory; CRADI – Colo Rectal Anal Distress Inventory; POPDI – Pelvic Organ Prolapse Distress Inventory; UIQ – Urinary Impact Questionnaire; CRAIQ – Colo Rectal Anal Impact Questionnaire; POPIQ – Pelvic Organ Prolapse Impact Questionnaire)

Symptoms	**PFDI**			**QOL**	**PFI**		
	Pre op	Post op	p		Pre op	Post op	p

Mean UDI (/28)	14.95	6.19	< 0. 001	Mean UIQ(/21)	8.97	2.00	< 0. 001
Mean CRADI(/32)	11.22	6.27	< 0. 001	Mean CRAIQ(/21)	5.73	1.37	< 0. 001
Mean POPDI(/20)	13.90	3.81	< 0.001	Mean POPIQ(/21)	8.83	1.81	< 0. 001

We found 60% (n=3/5) patients with POPQ $\geq$ 2 did not have subjective symptoms. On the other hand, 78% (n=7/9) with subjective symptoms did not have an anatomical failure that correlated with their symptoms
There was no visceral injury during surgery. 3 instances (3.3%; n=3/90 procedures) of vaginal mesh erosion were noted. In 1 patient, this was successfully treated conservatively with vaginal estrogen pessaries while 2 required trimming of mesh. No de novo dyspareunia was noted. 27% (n=19/ 70) developed de novo stress incontinence after surgery. Out of which 52.6% (n=10/19) were successfully treated with a subsequent sling surgery. The rest were treated conservatively with pelvic floor exercise.

Interpretation of results

Our results are comparable to previous studies: 86.6% cure with Prolift for post hysterectomy prolapse [3]; 95% cure with Prolift and Apogee in the West of Scotland study group. [2]
Though other studies have recorded a dyspareunia rate from 9% to 16.5%, the absence of de novo dyspareunia in our study can be explained by careful surgical techniques such as avoidance of excising excess vaginal tissue, trimming of the mesh when necessary to avoid bunching up of the mesh under the vagina and avoiding perineal muscle plication unless the introitus was very wide.
In the light of the finding of 27% de novo stress incontinence, we feel that all patients with recurrent/ multicompartment prolapses undergoing mesh insertion should be offered urodyanamic testing before surgery. This study proved that subjective prolapse symptoms are not necessarily supported by occurrence of POPQ $\geq$ 2 and vice versa. This observation underlies the importance of evaluation of subjective symptoms in assessing the severity of prolapse and success rates. When subjective symptoms are not assessed, the results are unlikely to be a true representation of patient well being and satisfaction after the surgery.

Concluding message

This study had success rates and complication rates that were in keeping with the polypropylene mesh literature to date. In this time of the great mesh debate, this study sets a precedent for all surgeons using the new generation meshes. We have reported the data on our first set of patients and intend to continue with our mesh register. Until long term follow up of at least 5 years becomes available, surgeons who choose to incorporate the mesh into their practice may consider using this for recurrent prolapses or primary repairs with a high risk of recurrence after a realistic discussion of bothersome outcomes with their patients.

References

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Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**