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SHORT-TERM SAFETY AND EFFICACY OF THE APOGEETM AND PERIGEETM MESH SYSTEMS FOR THE SURGICAL TREATMENT OF WOMEN WITH RECURRENT VAGINAL PROLAPSE.

Hypothesis / aims of study

A number of mesh systems have been introduced in recent years for pelvic floor repair. We sought to review the safety and efficacy of American Medical Systems (AMS) mesh systems in our patients, namely the AMS Apogee™ vault suspension system (used for the repair of the posterior vaginal compartment) and the Perigee™ trans-obturator anterior prolapse repair system (used for the repair of the anterior vaginal compartment).

Study design, materials and methods

All 27 patients in this review had previously undergone vaginal prolapse surgery and had been assessed as having prolapse greater than or equal to stage 2 under the POPQ scoring system (table 1). All except one of the patients had a previous hysterectomy either via vaginal or abdominal route. Patients were typically parous, with increased BMI, and over fifty years in age (table 1). Patients consented to this operation performed by one of two specialist Gynaecologists with a special interest in urogynaegology Mesh placement procedures were carried out according to American Medical Systems instructions in either a public or private hospital.(1)(2) Data for this review was collected from computerised and hand-written hospital and clinic records.

Table 1 Clinical and demographic details of the patient group

Age (yr) (mean, range)	64 (50-85)
Parity (median, range)	3 (0-7)
BMI (kg/m^2) (mean, range)	28.5 (23-36)
Previous repair (%) anterior wall posterior wall apical	**100%** 67% 50% 5%
POPQ scoring stage (median, range) anterior wall posterior wall apical	 3 (1-4) 2 (0-4) 3 (1-4)

Results

Out of the 27 procedures performed there were 8 Apogee™, 5 Perigee™ and 14 combined mesh placements. The operation duration for the individual meshes was similar at approximately 60 minutes, with a combined mesh placement taking an average of 87 minutes. Inpatient hospital stay was under 3 days for patients who had a single mesh placed and just over 3 days for those who had both meshes placed. A proportion of patients had concomitant procedures, such as an anterior vaginal wall repair or Monarc™ trans-obturator tape (table 2).

Table 2 Operation details, hospital stay and concomitant surgeries

Operation performed Apogee Perigee Both Apogee and Perigee	 8/27 5/27 14/27
Theatre time (minutes) (mean, range) Apogee Perigee Both	 53 (42-71) 62 (49-66) 87 (57-107)
Hospital stay (days) (mean, range) Apogee Perigee Both	 2.8 (2.3-4.3) 2.5 (2.3-3.3) 3.3 (2.3-6.3)
Concomitant surgeries Trans Obturator Tape repair (TOT) Anterior vaginal repair	 3/27 1/27

There were no significant intra-operative complications such as bladder, bowel or major blood vessel injury. There was a single case of vaginal bleeding on day 2; this was managed conservatively and did not require a return to theatre. By the time of the 6-week check two out of the 27 cases experienced mesh erosion. These were managed with a return to theatre and oversewing of the vaginal mucosa. However in one of these cases further erosion occurred and the Apogee mesh was subsequently removed with an alternative vault support procedure performed (sacrospinous fixation). Four patients experienced minor complications: groin discomfort, superficial infection of the vaginal mucosa, and two cases of minor urinary incontinence symptoms. One further patient still showed some degree of prolapse (scoring at POPQ stage 2), however she expressed satisfaction with the significant improvement over her pre-operative stage and symptoms.

Table 3 Intra- and post-operative complications and vaginal support

Intra-operative Complications	
Bladder perforation	0/27
Bowel perforation	0/27
Haemorrhage >500ml	0/27
Short term return to theatre <24 hours	0/27
Six Week Follow-Up	
Complications	
Minor discomfort	1/27
Superficial infection	1/27
Major infection	0/27
Minor urinary incontinence	2/27
Mesh erosion	2/27
Mesh failure and removal	1/27
Vaginal support	
POPQ stage 2	1/27
POPQ stage 0-1	25/27

Interpretation of results

The data presented here show no intra-operative and only one significant post-operative complication. Studies of such mesh products typically show vaginal support success rates of over 90%, with low erosion rates and other associated complications, when not combined with vaginal hysterectomy.

Concluding message

While there is as yet limited literature specifically evaluating American Medical System's Apogee™ and Perigee™ prolapse mesh repairs, this preliminary data appears to correspond well with the efficacy and safety of vaginal mesh products in general. Follow up at the 6-month mark and beyond will be important to identify developing erosion or failure, and to ascertain long-term efficacy.

References

(1) Apogee™ Vault Suspension System: Instructions for Use. American Medical Systems Inc., 2003.

(2) PerigreeTM System Transobturator anterior Prolapse Repair: Instructions for Use. American Medical Systems Inc., 2004.

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HUMAN SUBJECTS: This study did not need ethical approval because This was a review of hospital records and anonymity was preserved and did not follow the Declaration of Helsinki - with approval by the ethics committee - in the sense that This was a review of hospital records and anonymity was preserved Informed consent was obtained from the patients.