

A.M.I. PELVIC FLOOR REPAIR SYSTEM. A NOVEL 3 LEVEL APPROACH FOR FULL RECONSTRUCTION OF COMPLEX PELVIC FLOOR PROLAPSE.

Hypothesis / aims of study

The new A.M.I. transvaginal system (Agency for Medical Innovations) consists of 3 types of polypropilene meshes ("CR-mesh" for cystocele or rectocele, "E-mesh" for enterocele and "MPS mesh" that can be used as a multi-purpose sling); a suture instrument for attachment to sacrospinous ligament and tunnellers designed for lateral fixation, TVT and/or TOT procedures. These individually adjustable meshes and instruments can be used in various combinations to provide three levels of support (apical, lateral and distal). We report the outcome of this system in 31 patients over a mean follow up period of 10.5 months. Figures 1, 2 and 3 show positioning of the meshes for cystocele, rectocele and cysto-rectocele respectively.

Study design, materials and methods

41 CR meshes were implanted in 31 patients from August 2008 to date. 26 patients had cystocele grade III/IV, 21 had uterine prolapse and/or enterocele grade III-IV and 8 patients suffered rectocele grade III-IV. Patients main symptoms were stress urinary incontinence (16), abnormal bladder emptying (3), fecal incontinence (7) and obstructive defecation (4). All patients complained of prolapse sensation. Laparoscopic subtotal hysterectomy was performed when needed in order to preserve the cervix for apical fixation.

Results

The procedure took an average of 2 hours and 39 minutes and mean inpatient stay was 4.6 days. Stress urinary incontinence, abnormal bladder emptying, fecal incontinence and obstructive defecation were corrected in 87%, 100%, 85% and 75% of patients respectively. Intraoperative complications included bladder perforation (4); excessive bleeding (2) requiring intraoperative infra-umbilical laparotomy in 1 case; transvaginal tunneller perforation and repositioning in situ (5) and rectal perforation treated with primary suture and Martius' flap (1). None of them precluded from mesh insertion. Postoperative complications included transient urine retention (3); mesh infection treated conservatively (1); 5 reoperations secondary to recurrent uterine prolapse (2) -successfully treated with vaginal and laparoscopic hysterectomy followed by apical fixation using the multipurpose sling-, external erosion (3) and internal erosion (2). None of these complications had impact on clinical results following reoperation.

Interpretation of results

These results suggest that the A.M.I. system can be used for any complex pelvic floor prolapse, allowing for adjustment of the meshes to the prolapse to suit all pelvic shapes and configurations.

Concluding message

The adjustable A.M.I. system allows a three level approach for functional and anatomical reconstruction in complex pelvic floor prolapse. Although short-term results are promising, long-term data is required to determine the role of this new system in pelvic floor reconstruction.

Figure 1. Anterior vaginal wall repair.

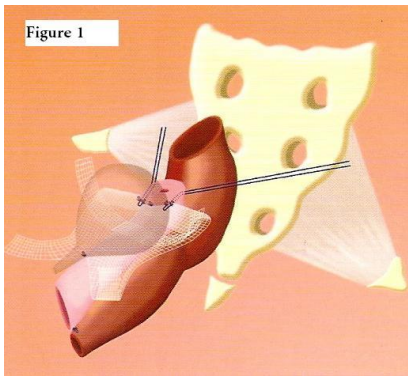


Figure 2. Posterior vaginal wall repair.

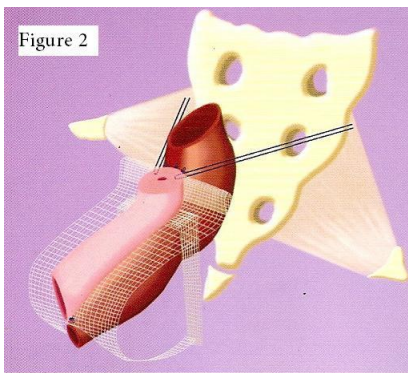
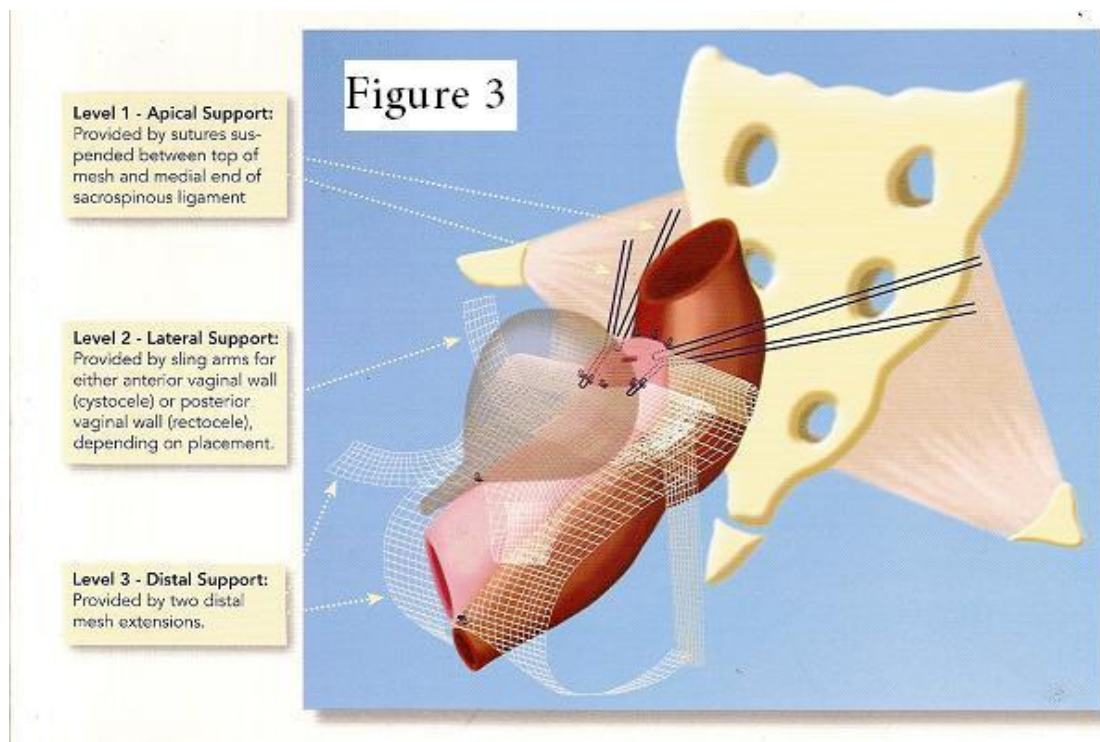


Figure 3. Full reconstruction. Anterior and posterior vaginal wall repair.



Specify source of funding or grant

The authors have no commercial relationship such as: consultancies, stock ownership or other equity interests, patents received and/or pending, or any commercial relationship which might be in any way considered related to the submitted work. There was no funding for this abstract.

Is this a clinical trial?

No

<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	No
<i>This study did not require ethics committee approval because</i>	This is a follow up study on patients after insertion of an approved mesh for use in the E.C.
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes