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MANAGEMENT AND OUTCOMES OF MAJOR COMPLICATIONS FROM COMMERCIAL MESH KITS FOR VAGINAL RECONSTRUCTION

Hypothesis / aims of study
Despite the limited efficacy and safety data, various commercially available vaginal mesh kits are being used for pelvic floor reconstruction procedures in increasing numbers. This has led to devastating complications which are often underreported and beyond the scope of management by some community surgeons. The aim of this study was to analyze the recent surge of mesh related complications which were referred to our tertiary center for presentation, management, and outcomes.

Study design, materials and methods
This was a retrospective evaluation of all consecutive cases of major complications resulting from pelvic floor reconstruction using commercial mesh kits that were referred to our institution from 2006 to 2008. We excluded patients who required only a simple transvaginal excision of mesh without major reconstruction.

Results
Seventeen patients underwent major surgical intervention for the treatment of mesh related complications. Mean age was 53 (range 36 – 83) with mean follow-up of 14 months (2 – 44). Five (29%) patients underwent concomitant transvaginal hysterectomy at the time of mesh reconstruction and 6 (35%) had prior hysterectomy. Seven (41%) patients presented within one week of surgery, 7 (41%) 1-3 months postoperative period, and 3 (18%) after one year. Mean time from original surgery to tertiary center referral was 20 months (1 – 120), and 14 (82%) patients underwent prior treatments before presenting to our institution. Twelve (71%) had multi-compartment vaginal reconstruction for prolapse and 5 (29%) had mid-urethral sling procedure. Most common presenting symptoms were persistent pain (71%) and infection (59%). Other complaints included dyspareunia (41%), de novo frequency and urgency (24%), recurrent incontinence and/or prolapse (29%), and fistula (18%). Operative findings included erosion into bladder (41%), urethra (18%), and rectum (6%); extensive vaginal extrusion of mesh with necrosis was noted in (47%). All patients required extensive transvaginal exploration to remove offending mesh, with 3 (18%) requiring concomitant transabdominal approach. Eight (47%) patients required flap reconstruction, 2 (12%) cystotomy for calculi extraction, and 4 (24%) extensive urethrolysis. The manufacturer of the original mesh kits could be identified in 7 (41%) cases. Additional surgery to correct prolapse and/or incontinence was performed in 8 (47%).

Interpretation of results
Most patients were managed conservatively by the primary surgeon prior to referral to tertiary center. Although the majority of patients presented with persistent pain and infection in the first three months, there was delayed time to definitive repair of 20 months. About half of the patients required flap augmented reconstruction and/or additional reconstructive surgery. Less than half of the patients had knowledge of the original mesh kit manufacturer to report to the MAUDE database.

Concluding message
Management of major complications from minimally invasive transvaginal mesh devices can be challenging to community surgeons and may require extensive transvaginal exploration and reconstruction by an experienced surgeon for optimal outcome. Limited peer-reviewed data on transvaginal mesh kits underscores the need for future well-conducted and adequately powered randomized control trials with longer follow-up and quality of life measurements. Patients should be carefully counselled on device related complications.

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Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Internal Review Board of UCLA**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**