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ANTERIOR REPAIR WITH MESH GRAFT VIA TRANSOBTURATOR APPROACH:WITH OR WITHOUT PRIOR REPAIR

Hypothesis / aims of study To compare outcomes of subjects with primary versus recurrent cystocele undergoing anterior repair with mesh placed via a transobturator route

Study design, materials and methods: In an ongoing, prospective, multi-center trial, 111 women underwent repair of anterior vaginal wall prolapse (> Stage II) with an anterior wall mesh via the Perigee Transobturator System (AMS, Minnetonka, MN, USA) with Intepro, a macroporous Type I polypropylene mesh . Twenty five (25) patients had previous anterior repair (PAR) with recurrent cystocele and 86 had no previous repair (NPAR). At the time of implant, the cystocele was not reduced nor repaired under the mesh. Additional reconstructive and incontinence procedures were completed, as indicated. Concomitant hysterectomy was excluded. Follow-up is ongoing at 6 weeks, 3-, 6-, 12-, and 24 months. Continuous measurements were compared using the two sample t-test for difference of means. Frequency measurements were compared by Fisher's exact test or Chi-Square test.

Results: There was no significant difference in demographics (age, bmi, gravidity, parity), but prior hysterectomy was significantly more common in NPAR ($p < 0.0001$). Two intra-operative complications occurred in NPAR—hematoma and bladder perforation. Mean follow up is 16.9± 7.9 months. 12 month visit anterior staging success rates (< Stage I) were similar (PAR: 95.2%; NPAR: 88.7%, $p = 0.6785$). Subjects experiencing complications do not differ significantly ($p > 0.05$). There were no statistical differences in estimated blood loss, operative time, intra-operative or post-operative adverse events. 11 extrusions were seen (9.9%) and were marginally different between treatment groups (PAR: 20 %; NPAR: 7.0%, $p = 0.0551$). PAR extrusions were treated conservatively more often than NPAR extrusions ($p = 0.0351$).

Interpretation of results: Subjects with recurrent cystocele are generally thought to be at a higher risk of complications and failure. This study involving the Perigee System demonstrates a similar risk of PAR and NPAR at a medium duration of follow up.

Concluding message: The Perigee System to treat anterior wall prolapse with a mesh graft via transobturator approach seems to be a safe and effective treatment in patients that have either primary or recurrent cystocele after traditional repair.

Specify source of funding or grant	**American Medical Systems**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Northside Hospital IRB, Atlanta GA**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**