Evaluation of a transvaginal mesh delivery system for the correction of pelvic organ prolapse: subjective and objective findings at least 1 year after surgery

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OBJECTIVE: We sought to track objective and subjective outcomes ≥1 year after transvaginal mesh system to correct prolapse.

STUDY DESIGN: This was a retrospective cohort study of 120 women who received a transvaginal mesh procedure (Avaulta Solo, CR Bard Inc, Covington, GA). Outcomes were pelvic organ prolapse quantification values; Pelvic Floor Distress Inventory, Short Form 20/Pelvic Floor Impact Questionnaire, Short Form 7 scores; and a surgical satisfaction survey. "Surgical failure" was defined as pelvic organ prolapse quantification point >0, and/or any reports of vaginal bulge.

RESULTS: Of 120 patients, 116 (97%) were followed up for a mean of 14.4 months (range, 12–30). In all, 74 patients had only anterior mesh, 21 only posterior mesh, and 21 both meshes. Surgical cure rate was 81%. Surgical failure was more common if preoperative point C ≥+2 (35% vs 16%; $P = .04$). Mesh erosion and de novo pain occurred in 11.7% and 3.3%, respectively. Pelvic Floor Distress Inventory, Short Form 20/Pelvic Floor Impact Questionnaire, Short Form 7 scores improved ($P < .01$).

CONCLUSION: Objective and subjective improvements occurred at ≥1 year, yet failure rates were high when preoperative point C was ≥+2.

Key words: Avaulta, prolapse, vaginal mesh

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In 2001, the Posterior IVS Tunneller (Tyco Healthcare LP, Norwalk, CT) became available in the United States as the first transvaginal mesh delivery system approved by the Food and Drug Administration (FDA) for the correction of pelvic organ prolapse. That device was intended to provide the surgeon with an easily reproducible, safe, and effective method to correct pelvic organ prolapse. A wide array of transvaginal mesh delivery systems soon followed in the marketplace. Although each of these devices was designed to improve on previously released products, none of them were subjected to clinical trials prior to their release.[1] Instead, each mesh kit received FDA approval through the 510(k) process.[2] Therefore, any clinical information regarding any of these devices has been derived from postmarket clinical studies. Interestingly, postmarket publications regarding the original mesh kit (the Posterior IVS Tunneller) pointed to poor results, complications, and the need for independent postmarket research studies about each and every similar new device.[3] Ideally, such studies would be randomized clinical trials with each patient followed up for a minimum of 12 months.[4,5] However few companies fund such level-1 studies once their devices have made it through the 510(k) process. In the absence of level-1 data, each new device should at the very least be scrutinized via properly designed single-arm retrospective studies. Our main objective, then, was to provide such information for a particular mesh delivery system.

The Avaulta Solo polypropylene mesh delivery system (CR Bard Inc, Covington, GA) was released into the United States in November 2005, and our group began using this device for selected patients in 2006. Since no other peer-reviewed publications exist regarding this device, our objective was to report subjective and objective outcomes at ≥12 months following placement of the Avaulta Solo vaginal mesh delivery system.

Materials and Methods

This was a retrospective cohort study of the first 120 patients who underwent placement of Avaulta Solo synthetic vaginal mesh system from January 2006 through April 2008 through the Division of Urogynecology and Reconstructive Pelvic Surgery at Atlantic Health. Atlantic Health is a tertiary care system comprised of 2 hospitals in northern New Jersey. The senior authors (P.J.C. and A.S.) performed all of the surgeries. The study group included all patients who underwent any vaginal prolapse repair incorporating the anterior, posterior, or combined Avaulta Solo systems during

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the above-mentioned time period. The Atlantic Health Institutional Review Board approved this protocol (#R07-09-016), which was posted on the World Wide Web site www.clinicaltrials.gov (identifier #NCT00774215). Prior to their 1 year objective and subjective postoperative assessments, all study patients signed the informed consent document generated by our institutional review board.

Our study group resulted from an obvious selection bias. During the study period at our center we tended to perform the Avaulta Solo procedure for patients who had ≥1 of the following characteristics: (1) were generally in the older age range; (2) had a rather specific isolated support defect; and/or (3) had significant medical comorbidities. At our center, patients who did not fall into ≥1 of these categories tended to be offered robotic assisted laparoscopic sacrocolpopexy. During the study period, we performed very few prolapse repairs that did not involve placement of some type of graft material.

Preoperatively, all patients had a comprehensive gynecologic examination including the pelvic organ prolapse quantification (POP-Q) system.[6] Shortly after the beginning of the study period, we began asking all of our new patients to complete the validated short forms of the Pelvic Floor Distress Inventory, Short Form 20 (PFDI-20) and the Pelvic Floor Impact Questionnaire, Short Form 7 (PFIQ-7). Despite the absence of these preoperative data among the first few patients in the cohort, we decided to use these instruments to assess the subjective outcomes for this study. Both the PFDI-20 and PFIQ-7 are scored from 0-300, with a higher score indicating worse symptoms.[7] The PFDI-20 consists of 3 subscales: the Pelvic Organ Prolapse Distress Inventory-6 (POPDI-6), the Colorectal-anal Distress Inventory-8, and the Urogenital Distress Inventory-6. The PFIQ-7 also consists of 3 subscales: the Urinary Impact Questionnaire-7, the Colorectal-anal Impact Questionnaire-7, and the Pelvic Organ Prolapse Impact Questionnaire-7. The answer to question 3 of the POPDI-6 that asks "Do you have a bulge or something falling out that you can see or feel in the vaginal area?" was also used independently as the subjective part of our definition of "surgical cure." Regardless of objective POP-Q scores, women who answered this question affirmatively were classified as surgical failures.

At the attending surgeons' discretion, concomitant vaginal hysterectomies were performed for a portion of the study group. When a vaginal hysterectomy was performed, the vaginal apex was supported via bilateral high uterosacral ligament suspension sutures using a previously described technique.[8] If the correction of urinary stress incontinence was necessary as determined via symptom profiles and multichannel urodynamic testing, a retropubic midurethral sling was performed–always through a vaginal incision made separate from the Avaulta Solo incision. All patients received a single dose of preoperative prophylactic intravenous antibiotics and no routine follow-up antibiotics. The default preoperative antibiotic choice was cefazolin, or combination of gentamicin and clindamycin for those patients who reported penicillin allergies.

All patients received general anesthesia, and were positioned in a modified dorsal lithotomy position. A dilute vasopressin solution was injected beneath the full thickness of the vaginal epithelium to develop either the vesicovaginal or rectovaginal spaces as needed. To place the anterior Avaulta Solo device, a vertical midline incision through the full thickness of the vaginal epithelium was made at the most dependent aspect of the protruding anterior vaginal wall. The endopelvic connective tissue was sharply separated from the vaginal epithelium–first to the pubic ramus and then down to the level of the ischial spines. An anterior colporrhaphy was then performed using a delayed absorbable suture in an interrupted technique.

Bilateral small groin incisions were made at the most superior and inferior aspects of the medial border of the obturator foramen. The Avaulta Solo trocars were then sequentially passed through these incisions, with the superior incisions serving as the site for the distal mesh arms, and the inferior incisions for the proximal arms. Care was taken to place the proximal arms of the mesh through the obturator internus muscles approximately 1 cm above the ischial spines.

The mesh was loosely positioned by gently pulling on each arm, and then tacked down to the anterior colporrhaphy in the midline using delayed absorbable sutures. Cystoscopy was performed to make sure that no lower urinary tract injuries had occurred. At most, a minimal amount of vaginal epithelium was trimmed–with the goal simply being to freshen up these edges. The vaginal epithelium was then closed in a running fashion before the final tensioning of the mesh was performed. The final adjustment of mesh tension was performed such that the apex and anterior vaginal walls were supported in a neutral position and mesh arms were not under any tension.

For placement of the posterior Avaulta Solo devices, a similar hydrodissection was performed followed by a vertical incision through the full thickness of the vaginal epithelium–with care taken to enter the true rectovaginal space. Bilateral stab incisions were made in the buttocks 3 cm lateral to and 3 cm distal from the anus. Trocars were passed through these stab incisions horizontally into the ischiorectal fossa under finger guidance. The trocars were placed through the levator muscles just lateral to the rectum and just medial to the ischial spines, and the superior mesh arms were then set into place. The same buttocks incisions were used for the distal trocar passes. These passes were also performed via finger guidance–allowing the surgeon to pass the trocar from the buttocks to the perineal body bilaterally. The distal landmark for trocar placement was the junction between the bulbocavernosus and transverse perineal muscles. The mesh was then positioned and tacked down in the midline via delayed absorbable sutures. After each posterior needle pass (and before the mesh was actually pulled into place) a digital rectal examination was performed to make sure that no penetration of the rectum had occurred. A final rectal examination was performed to verify that no mesh was palpable in the