

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

Patrick J. Culligan, MD; Paul M. Littman, DO; Charbel G. Salamon, MD; Jennifer L. Priestley, PhD; Amir Shariati, MD, MS

**OBJECTIVE:** We sought to track objective and subjective outcomes  $\geq 1$  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  $\geq +2$  (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  $\geq 1$  year, yet failure rates were high when preoperative point C was  $\geq +2$ .

**Key words:** Avaulta, prolapse, vaginal mesh

Cite this article as: Culligan PJ, Littman PM, Salamon CG, et al. Evaluation of a transvaginal mesh delivery system for the correction of pelvic organ prolapse: subjective and objective findings at least 1 year after surgery. *Am J Obstet Gynecol* 2010;203:506.e1-6.

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

From the Division of Urogynecology and Reconstructive Pelvic Surgery, Atlantic Health, Morristown and Summit, NJ (Drs Culligan, Littman, Salamon, and Shariati), and the Department of Mathematics and Statistics, Kennesaw State University, Kennesaw, GA (Dr Priestly).

Presented at the 36th Annual Scientific Meeting of the Society of Gynecologic Surgeons, Tucson, AZ, April 12–14, 2010.

Received Jan. 12, 2010; revised May 22, 2010; accepted July 20, 2010.

Reprints: Patrick J. Culligan, MD, Division of Urogynecology and Reconstructive Pelvic Surgery, Atlantic Health, 95 Madison Ave., Suite 204, Morristown, NJ 07962. [patrick.culligan@atlanticealth.org](mailto:patrick.culligan@atlanticealth.org).

Self-funded by the Atlantic Health Division of Urogynecology.

Trial registration: [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Identifier #NCT00774215.

0002-9378/\$36.00

© 2010 Mosby, Inc. All rights reserved. doi: 10.1016/j.ajog.2010.07.020

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.<sup>1</sup> Instead, each mesh kit received FDA approval through the 510(k) process.<sup>2</sup> 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.<sup>3</sup> Ideally, such studies would be randomized clinical trials with each patient followed up for a minimum of 12 months.<sup>4,5</sup> 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 in-

formation 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  $\geq 12$  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

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](http://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  $\geq 1$  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  $\geq 1$  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.<sup>6</sup> 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.<sup>7</sup> 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.<sup>8</sup> 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

rectum and that no tension could be felt along the mesh arms. For patients in whom both the anterior and posterior devices were placed, the worst compartment was repaired first. In other words, the leading edge of the given prolapse was dealt with as the first step of the combined anterior/posterior cases. If a suburethral sling was required, it was performed through a separate vaginal incision. A Foley catheter and vaginal pack were left in place until the morning after surgery. All patients underwent a voiding trial the day after surgery. In general, patients who received only the anterior procedure had no measurable posterior compartment prolapse symptoms or relaxation.

During the study period (July 2007) the product manufacturer introduced a second-generation Avaulta Solo that was very similar to the first-generation product except for an improvement in the trocar design. Because we believed that the new trocar design was intuitively superior to that of the first-generation product, we exclusively used the second-generation Avaulta Solo once it was available. It just so happened that this second-generation product was used on exactly one half of the patients in our study group. It should also be noted that our group never tried the sister product, called the Avaulta Plus Biosynthetic Support System, which was released at the same time. That product differs from the Avaulta Solo in that it has a porous acellular sheet of cross-linked porcine collagen affixed to the polypropylene mesh.

Each patient was evaluated  $\geq 1$  year postoperatively. At that time, the PFDI-20 and PFIQ-7 were completed for all patients. We also administered a validated surgical satisfaction questionnaire.<sup>9</sup> All patients also underwent a gynecologic examination including the POP-Q assessment—performed by a physician other than the original operating surgeon. In addition to POP-Q assessments, these examinations also focused on identifying mesh erosion and mesh-related vaginal/pelvic pain.

Surgical cure at  $\geq 12$  months was defined by considering subjective and objective findings simultaneously. A patient with any POP-Q point  $> 0$  or any reports of a vaginal bulge on the PFDI-20

was considered a surgical failure. We classified the rest of the patients as having had surgical cure. Secondary outcomes included the rates of mesh erosion and new-onset vaginal or pelvic pain. Lastly, anatomic success and complication rates between the 2 generations of the Avaulta Solo were compared. A given patient was classified as having a mesh erosion if any amount of any visible or palpable mesh material was discovered by physical examination at any postoperative point.

Statistical analysis was performed using software (SAS 9.1; SAS Institute Inc, Cary, NC). Preoperative and postoperative POP-Q points and questionnaire values were compared using paired *t* tests. Comparisons between proportions were done using  $\chi^2$  tests. Values between independent groups were compared using 2-sample independent *t* tests.

## RESULTS

Of the 120 patients identified, 116 (97%) signed consent and returned for subjective and objective evaluation at  $\geq 12$  months following surgery. The mean follow-up interval was 14.4 months (range, 12–30). The mean age of our population was  $64.7 \pm 10.7$  years; the mean body mass index (BMI) was  $26.4 \pm 5.0$ . Of the 116 patients, 20 (17%) had a BMI  $\geq 30$ , 9 (8%) were current smokers, and 107 (92%) were Caucasian. The median preoperative POP-Q stage was 3 (range, 2–4).

Of the 116 patients, 74 underwent only anterior Avaulta Solo placement, 21 underwent only posterior Avaulta Solo placement, and 21 underwent the combined anterior/posterior procedure. We performed 25 concomitant vaginal hysterectomies and 61 concomitant retro-pubic midurethral slings. There were no bladder perforations (either from the anterior Avaulta Solo trocar placement or from our retropubic sling placement), bowel perforations, or any other intraoperative complications. No patients required blood transfusion. The estimated blood loss was  $125.0 \pm 79.7$  and  $68.3 \pm 34.7$  mL for those with and without a concomitant vaginal hysterectomy ( $P = .05$ ). We discharged 105 (90.5%) pa-

**TABLE 1**  
**POP-Q values (n = 116)**

POP-Q point	Preoperative	$\geq 12$ mo postoperative
Aa	1 (–3 to 3)	–2 (–3 to 3)
Ba	1 (–3 to 9)	–2 (–3 to 5)
C	–4 (–10 to 10)	–7 (–10 to 5)
D	–5 (–11 to 8)	–8 (–10 to 5)
Ap	–1 (–3 to 3)	–2.5 (–3 to 3)
Bp	–1 (–3 to 9)	–2 (–3 to 3)
TVL	9.5 (6–11.5)	9 (6–11.5)
GH	3 (1–8)	3 (1–5)
PB	2 (1–6.5)	2.5 (1.5–4)
Stage	3 (1–4)	1 (0–3)

GH, genital hiatus; PB, perineal body; POP-Q, pelvic organ prolapse quantification; TVL, total vaginal length. Data represented as median (range).

Culligan. Long-term results of a transvaginal mesh system. *Am J Obstet Gynecol* 2010.

tients from the hospital in  $< 24$  hours. Eight (7%) patients were discharged between 24 and 47 hours, and 3 (2.5%) between 48 and 72 hours. All patients who stayed in the hospital  $> 24$  hours had received concomitant hysterectomy. There were no significant demographic differences between those patients having surgery with the first- or second-generation Avaulta Solo systems.

Objective preoperative and postoperative POP-Q measurements are presented in Table 1, and subjective measures are presented in Table 2. Surgical cure (using our definition) was achieved in 81% (94/116) of the overall group. For patients who received just the anterior mesh, just the posterior mesh, and both meshes, the surgical cure rates were 78% (58/74 patients), 90% (19/21), and 81% (16/21), respectively. The surgical success rates for the first- and second-generation Avaulta Solo were 78% and 84%, respectively ( $P = .34$ ). Obesity did not appear to influence our success rates. The success rate for those with a BMI  $< 30$  was 79% (73/92), compared to 87% (20/23) for those with a BMI  $\geq 30$  ( $P = .41$ ).

The severity of apical prolapse did appear to influence our results. The failure rate among patients with a preoperative point C  $\geq +2$  was 35% (7/20) compared

**TABLE 2**  
**Subjective questionnaire scores**

Questionnaire	Preoperative (n = 85)	Postoperative (n = 116)	Change (n = 85) P < .01	95% CI	P value
PFDI-20	113.3 ± 68.4	38.1 ± 40.9	-77.9	-93.7 to 62.2	< .01
POPDI-6	44.1 ± 26.7	11.0 ± 15.3	-34.3	-40.4 to 28.3	
CRADI-8	26.8 ± 24.2	11.1 ± 15.7	-16.7	-21.9 to 11.4	
UDI-7	42.1 ± 30.9	16.0 ± 18.4	-26.5	-33.8 to 19.1	
PFIQ-7	84.0 ± 84.0	24.4 ± 43.9	-61.5	-79.6 to 43.3	< .01
POPIQ-7	31.5 ± 33.0	6.7 ± 17.6	-26.0	-33.7 to 18.3	
CRAIQ-7	22.0 ± 32.9	7.8 ± 18.1	-15.3	-21.7 to -8.9	
UIQ-7	32.1 ± 34.3	9.8 ± 17.3	-22.0	-29.7 to 14.3	

CI, confidence interval; CRADI-8, Colorectal-anal Distress Inventory-8; CRAIQ-7, Colorectal-anal Impact Questionnaire-7; PFDI-20, Pelvic Floor Distress Inventory, Short Form 20; PFIQ-7, Pelvic Floor Impact Questionnaire, Short Form 7; POPDI-6, Pelvic Organ Prolapse Distress Inventory-6; POPIQ-7, Pelvic Organ Prolapse Impact Questionnaire-7; UDI-6, Urogenital Distress Inventory-6; UIQ-7, Urinary Impact Questionnaire-7.

Data represented as mean ± SD.

Culligan. Long-term results of a transvaginal mesh system. *Am J Obstet Gynecol* 2010.

to a failure rate of 16% in the remainder of the group ( $P = .04$ ). In each of these cases, the failures occurred at both the point C and the Ba point.

Of the 22 patients classified as surgical failures, 11 had a recurrence in the same anatomic compartment in which the mesh had been placed. Six patients had a recurrence within the opposite compartment of mesh placement, and 5 simply reported feeling a bulge on subjective assessment despite having no postoperative POP-Q measurements  $>0$ . Twelve patients with a recurrence decided to undergo a subsequent prolapse operation. Three patients with surgical failure opted for use of a pessary, and the remaining 7 patients simply decided to “live with it.” Of note, none of the 5 patients who were classified as surgical failures based solely on subjective findings decided to seek any further prolapse treatments.

Patients who experienced surgical failure reported significantly smaller improvements on the PFDI-20, POPDI-6, and PFIQ-7 than those who were cured. When considering only patients with failure, the PFDI-20 improved by just  $30.7 \pm 88.3$  points ( $P = .05$ ), the POPDI-6 by just  $11.2 \pm 34.2$  points ( $P = .02$ ), and the PFIQ-7 by just  $11.8 \pm 84.6$  points ( $P = .04$ ), respectively. No significant differences were noted on any of the other subscales.

Mesh erosion into the vagina occurred in 14 of 120 patients (11.7%). Of those,

just 2 patients had noticed any symptoms related to the mesh erosion. One patient reported vaginal discharge, and the other reported that the husband was scratched by the mesh during intercourse. Of the 14 mesh erosions, 2 spontaneously resolved, 9 resolved with vaginal estrogen and/or in-office excision, and 3 were excised in the operating room during surgery for another indication. No reoperations were required strictly for mesh erosion, and there were no cases of mesh erosion into adjacent viscera. There were 4 patients (3%) who experienced de novo mesh-related pain requiring surgical revision. The 3 mesh erosions that were excised in the operating room occurred among these 4 patients. There were no significant differences in mesh-related complications between the first- and second-generation systems. Patients who experienced mesh erosions reported improvements of  $87.3 \pm 52.9$  and  $81.3 \pm 96.3$  points on the PFDI-20 and the PFIQ-7, respectively, a finding not significantly different when compared to scores reported by patients without a mesh erosion ( $P = .63$ ,  $P = .55$ ). The erosion rates among patients with or without concomitant vaginal hysterectomy were 16% (4/25) and 10% (10/95), respectively ( $P = .45$ ).

Of the 116 patients, 95 (82%) reported that they were satisfied or highly satisfied with their results, and 102 (88%) reported that they would recommend the

surgery to a friend. Eleven of 14 (79%) patients with a mesh erosion were satisfied with their surgical results, a finding that was not different from those without a mesh erosion ( $P = .73$ ). However, only 2 of 5 (40%) patients with persistent postoperative pain were satisfied, a finding that was significantly different than those without pain ( $P = .01$ ).

## COMMENT

Our results indicated that the Avaulta Solo device provided successful treatment for isolated anterior or posterior vaginal wall defects; however, it did not optimally treat patients with severe apical defects in which the POP-Q point C was  $\geq +2$ . Our surgical success rate of 81% lies within the reported range of success for other similar systems.<sup>10-14</sup>

Our definition of surgical success was unique from other studies because it was based on simultaneous consideration of both objective and subjective outcome measures. Traditionally, success after prolapse surgery has been defined based on the recommendations of Weber et al.<sup>15</sup> Those authors somewhat arbitrarily defined an unsatisfactory anatomic outcome after prolapse surgery as any vaginal point bulging to within 1 cm of the hymen. However, since those original recommendations were made other researchers found that a majority of asymptomatic women with no history of

pelvic organ prolapse treatment would not meet this definition.<sup>16</sup> Several other researchers have reported that women do not usually report prolapse symptoms until some aspect of their anatomy bulges beyond the introitus.<sup>17-20</sup> Furthermore, a recent study by Barber et al<sup>21</sup> called for definitions of surgical success similar to the one we used.

Some may question our decision to include patients in the surgical failure group who experienced postoperative prolapse in an anatomic compartment where mesh had not been placed. For instance, a patient who had mesh placed in the anterior compartment was considered a failure if she subsequently developed a recurrence in the posterior compartment. Our rationale behind this decision was that the goal of surgery was to improve the quality of life of each patient, and therefore a recurrence in any vaginal compartment would not be viewed as a success by the patient. Such a situation occurred in 6 of the 22 documented failures.

The mean postoperative PFDI-20 and PFIQ-7 scores (along with their subscales) were all statistically significantly improved from the preoperative scores. The minimum clinically important difference represents the smallest change in a subjective score associated with a clinically meaningful change in quality of life. The published within-treatment minimum clinically important difference for the summary score of the PFDI-20 is 45 points (15%) and 36 points (12%) for the PFIQ-7.<sup>7</sup> In our study, the mean changes were appreciably larger: 78 points for the PFDI-20 and 61.5 points for the PFIQ-7.

Not surprisingly, those patients who experienced a recurrence or those with persistent de novo postoperative pain reported much less improvement than those patients who were successfully treated—facts that point to the validity of our definition of surgical cure. Our definition was further validated by the fact that the very same 81% of patients classified as surgical cures also reported satisfaction with their operation.

Our erosion rate of 11.7% was similar to other publications regarding transvaginal mesh placement.<sup>5-8,22-26</sup> Fur-

thermore, mesh erosion did not predispose to pain or recurrence, and was treated rather easily. Therefore, the mesh erosion we witnessed might be considered more of a nuisance for patients than a serious adverse event.

While de novo postoperative pain was not a frequent occurrence, each case was considerably more than merely a nuisance. All 4 patients who experienced mesh-related pain required surgical intervention. Fortunately, in each of these cases the pain was relieved by simply cutting out a small portion of  $\geq 1$  arms of the mesh. Such good fortune may not always follow mesh-related pain.

Strengths of this study include the relatively large cohort size and 97% follow-up rate at  $\geq 1$  year as well as our standardized surgical technique. Weaknesses of our study include those typically associated with retrospective projects. We created a selection bias by choosing the Avaulta Solo procedure for patients who were generally in the older age range within our practice and/or those who had significant medical comorbidities. Another weakness of our study group was the lack of subjective scores within the first 31 patients in the cohort. Further, some may argue that our overall success rate of 81% is not significantly different than previously reported success rates for nonmesh-based prolapse repairs.

Certainly, one must also consider the cost of the Avaulta Solo device within the context of prolapse repairs in general. We did not perform a formal cost-effectiveness analysis as a part of this study. The anterior and posterior Avaulta Solo devices each cost approximately \$1400-\$1600, and on the surface these costs may seem to be purely add-ons. Yet there are at least 2 ways to look at the issue of device costs. On one hand it could be argued that our overall success rate may not have warranted the extra expense of using the devices—given what we may have been able to achieve without the addition of any mesh material. On the other hand, by using the devices, we were able to achieve acceptable success rates while maintaining relatively short operating times and low morbidity within a patient population that was arguably at risk for perioperative complications. If

a formal cost analysis is done in the future, the decreased costs associated with shorter operative times and hospital stays should be considered as well.

Notwithstanding these limitations, our study suggests that the Avaulta Solo procedure provides satisfactory subjective and objective results in patients who demonstrate pelvic organ prolapse without a severe apical component. ■

## REFERENCES

1. Littman PM, Culligan PJ. The rapid evolution of vaginal mesh delivery systems for the correction of pelvic organ prolapse, part I: clinical data. *Female Patient* 2009;34:32-8.
2. Nygaard I. What does "FDA approved" mean for medical devices? *Obstet Gynecol* 2008; 111:4-6.
3. Baessler K, Maher C. Severe mesh complications following intravaginal slingplasty. *Obstet Gynecol* 2006;107:423-4.
4. Culligan PJ, Murphy M, Blackwell L, Hammons G, Graham C, Heit MH. Long-term success of abdominal sacral colpopexy using synthetic mesh. *Am J Obstet Gynecol* 2002; 187:1473-82.
5. Shull BL, Bachofen C, Coates KW, Kuehl TJ. A transvaginal approach to repair of apical and other associated sites of pelvic organ prolapse with uterosacral ligaments. *Am J Obstet Gynecol* 2000;183:1365-74.
6. Bump R, Mattiasson A, Bo K, Brubaker L, DeLancey J, Klarskov P. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. *Am J Obstet Gynecol* 1996;175:10-7.
7. Barber MD, Walter MS, Bump RC. Short forms for two condition-specific quality of life questionnaires for women with pelvic floor disorders (PFDI-20 and PFIQ-7). *Am J Obstet Gynecol* 2005;193:103-13.
8. Culligan PJ, Miklos JR, Murphy M, et al. The tensile strength of uterosacral ligament sutures: a comparison of vaginal and laparoscopic techniques. *Obstet Gynecol* 2003;101:500-3.
9. Murphy M, Sternschuss G, Haff R, van Raalte H, Saltz S, Lucente V. Quality of life and surgical satisfaction after vaginal reconstructive vs obliterative surgery for the treatment of advanced pelvic organ prolapse. *Am J Obstet Gynecol* 2008;198:573.e1-7.
10. Abdel-Fattah M, Ramsay I, West of Scotland Study Group. Retrospective multicenter study of the new minimally invasive mesh repair devices for pelvic organ prolapse. *BJOG* 2008;115:22-30.
11. Nguyen JN, Burchette RJ. Outcome after anterior vaginal prolapse repair; a randomized controlled trial. *Obstet Gynecol* 2008;111: 891-8.
12. Gauruder-Burmester A, Koutouzidou P, Rohne J, Gronewold M, Tunn R. Follow-up after polypropylene mesh repair of anterior and pos-

terior compartments in patients with recurrent prolapse. *Int Urogynecol J* 2007;18:1059-64.

**13.** Elmér C, Altman D, Ellström E, Axelsen S, Väyrynen T, Falconer C, for the Nordic Transvaginal Mesh Group. Trocar-guided transvaginal mesh repair of pelvic organ prolapse. *Obstet Gynecol* 2009;113:117-26.

**14.** Van Raalte HM, Lucente VR, Molden SM, Haff R, Murphy M. One-year anatomic and quality-of-life outcomes after the Prolift procedure for treatment of posthysterectomy prolapse. *Am J Obstet Gynecol* 2008;199:694.e1-6.

**15.** Weber AM, Abrams P, Brubaker L, et al. The standardization of terminology for researchers in female pelvic floor disorders. *Int Urogynecol J* 2001;12:178-86.

**16.** Swift S, Woodman P, O'Boyle A, et al. Pelvic organ support study (POSST): the distribution, clinical definition, and epidemiologic condition of pelvic organ support defects. *Am J Obstet Gynecol* 2005;192:795-806.

**17.** Swift SE, Tate SB, Nicholas J. Correlation of symptoms with degree of pelvic organ support

in a general population of women: what is pelvic organ prolapse? *Am J Obstet Gynecol* 2003;189:372-9.

**18.** Bradley CS, Nygaard IE. Vaginal wall descensus and pelvic floor symptoms in older women. *Obstet Gynecol* 2005;106:759-66.

**19.** Ellerkmann RM, Cundiff GW, Melick CF, Nihira MA, Leffler K, Bent AE. Correlation of symptoms with location and severity of pelvic organ prolapse. *Am J Obstet Gynecol* 2001;185:1332-7.

**20.** Tan JS, Lukacz ES, Menefee SA, Powell CR, Nager CW. Predictive value of prolapse symptoms: a large database study. *Int Urogynecol J* 2005;16:203-9.

**21.** Barber MD, Brubaker L, Nygaard I, et al. Defining success after surgery for pelvic organ prolapse. *Obstet Gynecol* 2009;114:600-9.

**22.** Reisenauer C, Kirschniak A, Drews U, Wallwiener D. Anatomical conditions for pelvic floor reconstruction with polypropylene implant and its application for the treatment of vaginal prolapse. *Eur J Obstet Gynecol Reprod Biol* 2007;131:214-25.

**23.** Lucioni A, Rapp DE, Gong EM, Reynolds WS, Fedunok PA, Bales GT. The surgical technique and early postoperative complications of the Gynecare Prolift pelvic floor repair system. *Can J Urol* 2008;15:4004-8.

**24.** Pacquee S, Palit G, Jacquemyn Y. Complications and patient satisfaction after transobturator anterior and/or posterior tension-free vaginal polypropylene mesh for pelvic organ prolapse. *Acta Obstet Gynecol Scand* 2008;87:972-4.

**25.** Hinoul P, Ombelet WU, Burger MP, Roovers JP. A prospective study to evaluate the anatomic and functional outcome of a transobturator mesh system (prolift anterior) for symptomatic cystocele repair. *J Minim Invasive Gynecol* 2008;15:615-20.

**26.** Baessler K, Hewson AD, Tunn R, Schuessler B, Maher CF. Severe mesh complications following intravaginal slingplasty. *Obstet Gynecol* 2005;106:713-6.