

A Prospective Multi-Center Clinical Trial Evaluating the Apogee System for the Treatment of Posterior Vaginal Wall and Apical Prolapse

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Industry Support: Yes (Industry-initiated, full sponsorship)

Objective: To evaluate the efficacy and safety of the Apogee® System (AMS, Minnetonka, MN) in pelvic organ prolapse repair.

Background: In an ongoing, prospective, multi-center study involving 13 US sites, women with posterior vaginal prolapse (>Stage II) and/or apical descent (>Stage II) were enrolled for primary posterior mesh implant. All sites received IRB approval prior to inclusion.

Methods: Each patient underwent placement of an apical polypropylene strip with a 5 x 14 cm (approximate) cape of polypropylene mesh (Apogee with IntePro[™],[€]) or porcine dermis (Apogee with InteXen® LP) employing a bilateral transgluteal approach. Primary endpoint was the percent of patients with Stage < I ("cure") at follow-up, with clinical evaluations performed by an unblinded practitioner. Secondary endpoints included, but were not limited to, procedure time, estimated blood loss, device-related complications, quality of life (PFDI and PFIQ- 7), and patient satisfaction (Patient Satisfaction Survey). Patients were seen postoperatively at 6 weeks, 3 months, 6 months and 12 months, and will be followed prospectively through 2 years. **Results:** Two-hundred women underwent the procedure with a mean follow-up of 8.6 months (range 0.4 - 14.7). Baseline demographics included a mean age of 60.8 years (range 33 - 90), mean BMI of 28.5 (range 18.0 - 53.1), and mean parity of 3.1 (range 0 - 9). The majority were postmenopausal (88.3%). Just less than half (49.2%) were on estrogen replacement therapy for at least 4 weeks prior to surgery. At baseline, 96.4% of patients presented with posterior vaginal prolapse, 52.5% had posterior enterocele, and 25.8% had apical or uterine descent. Hysterectomy was performed at the time of Apogee placement in 48 (24.0%) patients. Additional reconstructive procedures were performed as indicated with the exception of concomitant repairs in the same vaginal segment. Poly-

propylene (PP) was used in 174 (87%) patients and 26 (13%) received porcine dermis (PD). Average procedure time for Apogee only was 45.8 + 20.8 minutes. Mean EBL was 69.7 + 63 cc and no patient required transfusion. No intra-operative complications were attributed to the Apogee trocars including trauma to the rectum or the bowel. Six and twelve month follow-up data were available on 169 (84.5%) and 90 (48.0%) patients, respectively. Objective posterior wall cure rates at 6 and 12 months were 92.8% and 92.2% (91.4% and 90.6% for PP; 100% and 100% for PD), with apical cure rates of 97.0% and 93.3% (96.5% and 92.0% for PP; 100% and 100% for PD). Extrusions (vaginal exposure of mesh) were seen in 14 (7.0%) PP patients, with none reported in those receiving PD. Six (3.0%) patients with extrusion required revision in the operating room while the remaining patients were treated conservatively (local estrogen and/or trimming in the office) or observed. With respect to extrusion sites, mesh exposure occurred along the midline incision in 42.8%, distal vagina in 57.1%, and at the apex in 14.3%. One (0.5%) erosion (mesh into viscus) was reported involving the anterior rectum, 2 cm proximal to the anal verge. Detected 13 months postoperatively on routine fecal occult blood testing, the site was managed surgically by trimming a 3-4 mm corner of visible polypropylene mesh and closing the defect in two layers. No anatomic or functional compromise was incurred following correction. Other device-related complications occurred at or below 1 %, with the following complications reported by number of patients: infection of the apical incision in 1 (0.5%), buttock discomfort in 1 (0.5%), perineal discomfort in 2 (1.0%), vaginal discomfort in 1 (0.5%), dyspareunia in 2 (1.0%), hematoma in 1 (0.5%), and rectal pain in 1 (0.5%). QOL questionnaires (PFDI, PFIQ- 7) showed improvement, with percent improvements of 69.4% and 69.0% for the mean PFIQ summary score; and 68.9% and 72.0% for the mean PFIQ-7 summary score. Regarding patient satisfaction, 99.4% and 98.9% of patients had an overall feeling of "a lot" (83.4% and 85.1%) or "some" (16.0% and 13.8%) improvement"; 88.1 % and 86.2% were "very" (34.3% and 36.2%) or "extremely" (53.8% and 50.0%) satisfied; and 97.0% and 95.7% would recommend the procedure to a friend at 6 and 12-months, respectively.

Conclusions: The Apogee System appears to be effective in the treatment of patients with posterior vaginal wall and/or apical prolapse, with good anatomic durability through 6 and 12 months. The risks and benefits of employing mesh in the posterior compartment should be thoughtfully considered. Follow-up through 24 months is ongoing.

