The surgical technique and early postoperative complications of the Gynecare Prolift pelvic floor repair system

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Introduction: *The Gynecare Prolift pelvic floor repair system (GPS) comprises a synthetic mesh placed via a transvaginal, transobturator approach. We present our technique focusing on the safety and feasibility of the GPS.*
Materials and methods: *GPS candidates are evaluated in the office with a full history, physical examination, urinalysis and when appropriate, urodynamic evaluation. Patients were offered total vaginal vault prolapse repair or isolated anterior repair dependent of site of defect. Follow-up comprised a full history, physical examination, and global assessment of subjective satisfaction (2 and 6 weeks, 6 months postoperative). Concentration was placed on intraoperative and short-term postoperative complications and assessment of prolapse recurrence.*
Results: *GPS prolapse repair has been used in 12 patients for anterior or total vault prolapse. Mean postoperative follow-up time is 42 weeks. There were no major perioperative complications. De novo enterocele development was seen in one patient without any other incidence of recurrence. No incidence of mesh erosion or sexual dysfunction has been observed.*
Conclusions: *The GPS is a safe and reproducible system for use in transvaginal repairs of vaginal vault prolapse. Long-term studies are needed to evaluate repair durability and for potential complications.*

Key Words: outcomes, prolapse, surgical technique, complications, mesh, transobturator

Introduction

The treatment of genital prolapse is often difficult and there exist a variety of approaches to prolapse repair. The vaginal approach offers decreased hospital stay, convalescence, and cost.[1] However, recurrence rates remain problematic, especially in the treatment of apical vault prolapse.[2] For this reason, abdominal sacrocolpopexy is advocated by some physicians to more effectively treat apical prolapse. Concurrently, the use of nonabsorbable mesh has become more common in an attempt to decrease overall recurrence rates. While commonly used for repair of anterior defects, only a limited experience is reported using transvaginal mesh placement in the treatment of apical descent.[3]

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The Gynecare Prolift pelvic floor repair system (GPS) is a polypropylene mesh system developed for the transvaginal repair of vaginal vault prolapse. This system is deployed in a transobturator approach using a trocar system. The goal of this report is to describe our technique for repair using the GPS system and focus on its safety and feasibility.

Methods

Since August 2005, all patients with cystocele or total vaginal vault prolapse were considered as candidates to undergo repair using the GPS. Patients are evaluated in the office with a full history, physical examination, and urinalysis. The degree of prolapse was evaluated using the Baden-Walker grading system.[4] Urodynamic evaluation was performed when the etiology of the urinary incontinence remained unclear. Depending on site of prolapse, patients are offered total vaginal vault prolapse repair or isolated anterior repair. Our protocol is to place a midurethral sling after GPS repair in patients with either moderate or severe stress urinary incontinence (SUI). SUI is stratified as mild (less than one pad/day), moderate (2-3 pads/day), and severe (greater than 3 pads/day).

Surgical technique

Patients receive bowel preparation with clear liquid diet and Fleet Phospho-soda (Fleet Laboratory, Lynchburg, Virginia) the day prior to surgery. Standard perioperative antibiotics using ASHP guidelines[5] and general anesthesia are generally preferred. Following positioning (extended dorsal lithotomy), a complete pelvic examination is performed to confirm the site of prolapse. A 16F Foley catheter is placed to drain the bladder.

Attention is then focused on identification and marking of the anatomical landmarks for placement of the surgical passers. The first landmark is the obturator foramen. Two anterior passers will be placed through each obturator foramen. One passer enters via the superior medial aspect of the obturator foramen to hold the distal and mid-urethral portion of the mesh (anterior superior passer). The second passer travels through the inferior medial aspect of the foramen and holds the proximal arms of the mesh (anterior inferior passer). Accordingly, the skin is marked to identify the passer insertion sites, Figure 1.

Following infiltration with 1% lidocaine with epinephrine, a vertical incision is made in the anterior vaginal epithelium over the prolapse. Development of vaginal flaps is performed in a standard fashion using sharp and blunt dissection and continued proximally until the inferior pubic ramus is readily palpable. The previously marked skin sites are incised and surgical passer placement is begun. Under manual guidance, the anterior superior passer is advanced through the superior medial aspect of the obturator foramen and out the pubic ramus.

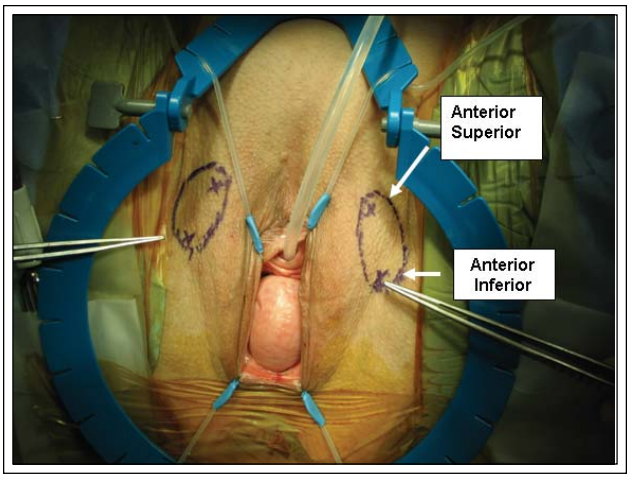

Figure 1. Landmarks for trocar placement. The landmarks for the obturator foramen (oval marking) and trocar insertion sites (anterior superior, anterior inferior) are shown.

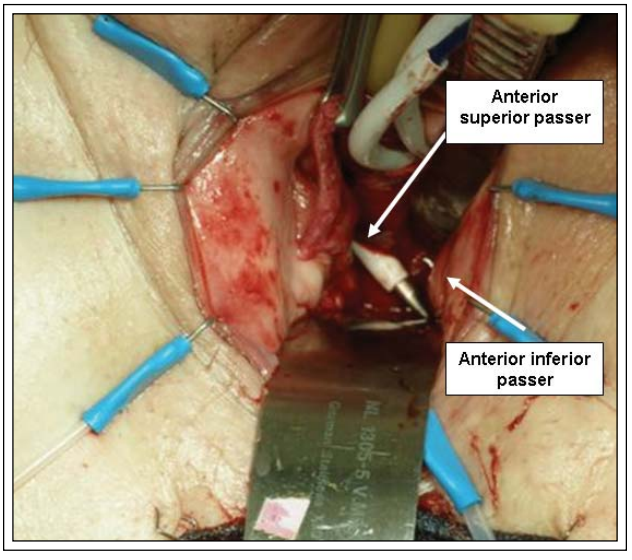

Figure 2. Placement of the GPS passers. The anterior passers are placed with aid of a trocar through the superior medial and inferior medial aspect of the obturator foramen. As seen, the anterior inferior passer exits into the vaginal vault more proximal than the anterior superior passer.

Subsequently, the anterior inferior passer is placed in a similar manner, both inferior and proximal with respect to the previously placed passer, Figure 2. Placement of the anterior passers is repeated on the opposite side. Following passer placement, advancing strings are placed through the passers and secured.

In the treatment of total vault prolapse in patients posthysterectomy the posterior dissection is now performed. A posterior vaginal wall incision is performed, with care taken to leave a mucosal bridge between the anterior and posterior vaginal incisions, Figure 3. The vaginal epithelium is then dissected from the rectocele in standard fashion using sharp and blunt dissection. Posterior passer entrance sites are marked and incised approximately 4 cm lateral and 2 cm inferior to the anus. Manual guidance is used to palpate the ischiorectal fossa and the passer insertion begun. Passer advancement is performed in a plane parallel to the rectum, extending up to the levator ani complex near the posterior iliac spine. The passer placement is again repeated on the opposite side and the advancing strings are inserted though the passers.

Attention is now focused on mesh placement. The mesh is first passed below the mucosal bridge that separates the anterior and posterior vaginal mucosa. The previously placed advancing strings are hooked to the respective mesh arms, which are pulled though each of the six passers. This maneuver brings the mesh in place, at which point the mesh is checked to ensure that twisting has not occurred. The mesh is deployed into position by pulling out the passers. Both the anterior and posterior aspects of the mesh are anchored using 2-0 vicryl suture. Cystourethroscopy is performed to rule out urethral or bladder injury. Significant excess vaginal epithelium is trimmed with care taken to leave enough epithelium for a tension-free closure. The vaginal epithelium is closed with 3-0 vicryl suture. The arms of the mesh are cut below skin level and skin incisions closed with Dermabond (Ethicon, Somerville, NJ). In cases of moderate to severe SUI placement of a transvaginal tape is performed. Care is taken to place the tape mesh at least 1 cm-2 cm distal to the anterior portion of the GPS.

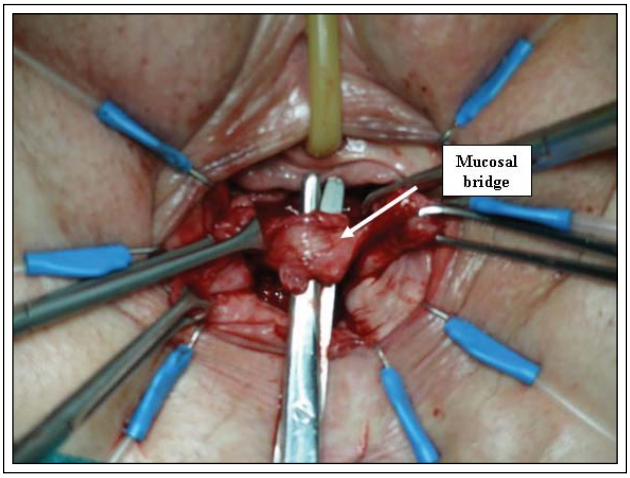

Figure 3. Mucosal bridge. A 2 cm mucosal bridge is left between the posterior and anterior vaginal dissections. The mesh is passed under the mucosal bridge.

In our experience, patients may be discharged home immediately after surgery or admitted for overnight observation. The Foley catheter is maintained overnight. Duration of antibiotic prophylaxis after transvaginal surgery with placement of prosthetic material has not been established. Given the amount of mesh used during this procedure, all patients receive 5 days of cephalexin (or ciprofloxacin for patients allergic to penicillin) for prophylactic antibiotic coverage. Outpatient follow-up is performed at 2 and 6 weeks following surgery, at which point a full history, physical exam, urinalysis, and PVR are obtained. Patients are instructed to avoid heavy lifting or sexual intercourse until 6-week follow-up.

Results

Since August 2005, a total of 12 vaginal vault prolapse repairs have been performed using the GPS. Table 1 details the patient characteristics, operative characteristics, and short-term outcomes using GPS repair. For the anterior GPS (five total patients, one and four patients had Grade 2 and 3 prolapse, respectively. Patients undergoing total GPS had at least Grade 3 cystocele, enterocele, or rectocele, alone or in combination. Of the 12 patients, seven underwent a total vaginal vault prolapse repair while five only had an anterior vaginal repair. As per our protocol, two of five patients with moderate SUI underwent mid-urethral sling placement, while the anterior GPS mesh positioning alone was performed in the remaining three patients with minimal SUI.

No intraoperative or major postoperative complications have been observed with 42 week follow-up. One patient was diagnosed with a vaginal yeast infection seven days after surgery and was treated with one dose of oral Diflucan and one patient had an *Echerichia coli* urinary tract infection diagnosed 4 weeks after surgery and treated with 3 days of antibiotics. One patient who underwent total vaginal vault prolapse repair returned to clinic 6 weeks after the procedure complaining of minor pelvic pressure. Pelvic exam revealed a Grade 1 posterior enterocele.

TABLE 1. **University of Chicago experience: GPS repair of vaginal vault prolapse**

Patient characteristics	
Age (years) (mean,range)	67 (52-78)
Body mass index (kg/m^2, range)	28 (24-34)
Previous hysterectomy (patients,%)	8 (67)
Stress urinary incontinence (patients,%)	5 (42)
Post-void residual (ml) (mean(pre-op)	55
Operative characteristics	
Operative time (min) (mean, range)	118 (56-198)
Estimate blood loss (ml) (mean, range)	141 (25-300)
Hospital stay (days) (mean, range)	0.58 (0-2)
Anterior GPS (patients)	5
Total vault GPS (patients)	7
Outcomes	
Post-void residual (ml) (mean, range)	37 (4-83)
Urinary retention (patients)	0
Complications, major (patients)	0
Complications, minor (patients)	2*
Prolapse recurrence	0**

*Urinary tract infection
**One patient presented with de novo enterocele following total vault GPS

Discussion

A variety of techniques exist for the transvaginal repair of a vault prolapse. These procedures share the common principle of reconstructing the pelvic floor to provide adequate support to the pelvic organs. Despite the reported success of these repairs, the variety of available techniques makes it difficult to both uniformly assess patient outcomes and to identify a standard approach for repair. Concurrently, the use of synthetic mesh placement to reinforce prolapse repair has become increasingly popular, owing to the often disappointing results seen without such reinforcement.[6]

Numerous reports have described the successful use of mesh in the treatment of anterior vault defects.[7] More recently, mesh reinforcement has been utilized in the treatment of a larger spectrum of vault defects.[1,3,8] Shah et al reported the treatment of 29 patients with apical vault prolapse with sacrospinous fixation using mesh.[3] In addition, 79% and 45% of patients underwent site specific repair of anterior and posterior defects, respectively. At 2 year follow-up, a 7% genital prolapse recurrence rate was observed. Farnsworth reported the successful use of posterior intravaginal slingplasty (infracoccygeal sacropexy) in the treatment of vault prolapse.[9] Of note, this repair utilized a tunneler device to achieve posterior mesh insertion between the perineum and vaginal vault and entailed repair via the ischiorectal fossa.

Concurrently, a large experience has been reported using the transobturator approach in the treatment of stress urinary incontinence, with multiple experiences demonstrate that transobturator placement of suburethral mesh is associated with excellent success rates and minimal complications.[10-14] More recently, the transobturator route has been used to surgically approach both anterior and apical vault prolapse. David-Montefiore et al reported a cure rate of 94% using the transobturator placement of a porcine skin collagen implant for vault prolapse.[1]

Similar to the above techniques, the GPS is also placed via a transobturator approach. Unique to the GPS is the ability to treat all sites of vault prolapse and to provide a reproducible technique that may be used by a greater number of urologists. Previous studies report the use of a transvaginal repair of either isolated anterior or posterior defects with mesh.[1,3,7,8] The GPS allows the surgeon the flexibility to repair either isolated anterior or posterior, as well as total pelvic floor prolapse using mesh placed via a transobturator approach. Further, the surgeon is able to obtain reproducible results given that the mesh is placed in a very similar manner with standard points of fixation.

Certainly, significant caution must be undertaken in the description of a novel technique. Foremost, no intermediate or long-term data is available regarding efficacy and safety of the GPS system. Additionally, further investigation is needed to better define selection criteria for and optimal type of concomitant anti-incontinence procedures. Given the large amount of mesh used in this repair, erosion rates must remain a concern. Using polypropylene mesh for total pelvic reconstruction via a vaginal approach, Shah et al observed no incidence of mesh erosion with 2 year follow-up. Nonetheless, data investigating this potential concern is needed. Subjective outcome assessment using validated questionnaires is not presented in our study. This evaluation is needed if engaging in a larger cohort of patients and definitive conclusions must be reserved until such data is accrued. Finally, no literature is available using such a repair in a sexually active patient population. Theoretically, the deployment of such a large mesh, with resultant scarring, may have deleterious effects on both vault size and compliance. None of our sexually active patients to data have reported dyspareunia, however, more data is needed in a greater number of patients.

Conclusion

Our results suggest that the GPS is a safe and feasible technique for the transvaginal repair of vault prolapse. Our results suggest that the GPS can be performed without major intraoperative complications. Early postoperative complications occurred in two of our twelve patients and were minor. Additional study is needed and continued surveillance of patients will assess intermediate and long-term efficacy and complication rates. □

References

1. David-Montefiore M, Barrander E, Dubernard G et al. Treatment of genital prolapse by hammock using porcine skin collagen implant (Pelvicol). *Urology* 2005;66:1314-1318.
2. Olsen AL, Smith VJ, Bergstrom JO et al. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. *Obstet Gynecol* 1997;89:501-506.
3. Shah D, Paul EM, Rastinehad AR et al. Short-term outcome analysis of total pelvic reconstruction with mesh: the vaginal approach. *J Urol* 2004;171:261-263.
4. Baden WF, Walker TA. Genesis of the vaginal profile: a correlated classification of vaginal relaxation. *Clinical Obstet Gynecol* 1972;15:1048-1054.
5. American Society of Health-System Pharmacists. ASHP therapeutic guidelines on antimicrobial prophylaxis in surgery. *Am J Health Syst Pharm* 1998;56:1839-1888.
6. Comiter CV, Vasavada SP, Raz S. Transvaginal colposuspension: technique and results. *Urology* 1999;54:819-822.
7. de Tayrac R, Gervaise A, Chauveaud A et al. Tension-free polypropylene mesh for repair of anterior vaginal wall prolapse. *J Reprod Med* 2005;50:75-80.
8. Rutman MP, Deng DY, Rodriguez LV et al. Repair of vaginal vault prolapse and pelvic floor relaxation using polypropylene mesh. *Neurourol Urodyn* 2005;24:654-658.
9. Farnsworth BN. Posterior intravaginal slingplasty (infracoccygeal sacropexy) for severe posthysterectomy vaginal vault prolapse-a preliminary report on efficacy and safety. *Int Urogynecol J* 2002;13:4-8.
10. Waltregny D, Reul O, Mathantu B et al. Inside out transobturator vaginal tape for the treatment of female stress urinary incontinence: interim results of a prospective study after a 1-year minimum follow-up. *J Urol* 2006;175(6):2191-2195.
11. Bonnet R, Waltregny D, Reul O et al. Transobturator vaginal tape inside out for the surgical treatment of female stress urinary incontinence: anatomical considerations. *J Urol* 2005;173:1223-1228.
12. Delorme E. Transobturator urethral suspension: mini-invasive procedure in the treatment of stress urinary incontinence in women. *Prog Urol* 2001;11:1306-1313.
13. de Leval J, Waltregny D. New surgical technique for treatment of stress urinary incontinence TVT-obturator: new development and results. *Surg Technol Int* 2005;14:212-221.
14. Bracq A, Fourmarier M, Boutemy F et al. Urodynamic changes after transobturator suburethral tape. *Prog Urol* 2006;16:62-66.