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Two-Year Outcomes After Vaginal Prolapse Reconstruction With Mesh Pelvic Floor Repair System

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Abstract

Objective—The aim of this study was to assess anatomical and functional outcomes 2 years after prolapse repair using vaginal mesh repair system.

Methods—Women enrolled in a 12-month observational study of outcomes after transvaginal mesh-augmented prolapse repair were invited to participate in an extended follow-up. Subjects completed questionnaires assessing pelvic symptoms, quality of life, global satisfaction, and a pelvic examination for anatomical support and mesh complications.

Results—Of 118 eligible women, 85 enrolled, 82 provided subjective data at 24 months, and pelvic examination/Pelvic Organ Prolapse Quantification data are available from 79 women. Total, anterior, and posterior Prolift kits were used in 47 (55%), 25 (29%), and 13 (15%), respectively. At baseline, most of the women had stage III prolapse (75%), with the anterior compartment constituting the leading edge in 71% of subjects. At 24 months, Pelvic Organ Prolapse Quantification measures were significantly improved from baseline in all compartments, with 51 (65%) stage 0/I, 25 (31%) stage II, 3 (4%) and stage III ($P < 0.001$), as were quality of life scores ($P < 0.001$), with the exception of sexual function. Symptomatic prolapse was reported by 7 (8.5%) women, of which 4 demonstrated prolapse in the nonoperated compartment. Three subjects (4%) reported persistent pelvic pain. The 2-year mesh exposure incidence was at least 13% (11/85). The proportion reporting dyspareunia was 28.9% (13/45) and was unchanged from baseline. The median global satisfaction was 9.3 (range 2.0–10.0).

Conclusions—Anatomical support, symptom relief, and satisfaction are high 24 months after mesh-augmented vaginal prolapse repair, although mesh exposure and new onset prolapse of the nonoperated compartment are not uncommon.

Keywords

vaginal mesh; pelvic organ prolapse; anatomical outcomes; functional outcomes

The goals of surgical reconstruction include restoration of normal anatomy with improvement in bladder, bowel, and sexual function, ultimately leading to improvement in quality of women's lives. Mesh-augmented vaginal suspension, predominantly performed transabdominally, has demonstrated superior durability when compared with transvaginal plication techniques,^{1,2} but the morbidity associated with a laparotomy or prolonged laparoscopy precludes its broad use in women with substantial medical comorbidities or relative contraindications. In 2004, the Food and Drug Administration approved the first commercially available polypropylene mesh "system" for transvaginal repair of uterovaginal and/or vaginal prolapse. Since then, numerous manufacturers developed kits with various anchoring mechanisms and mesh characteristics. All were marketed as a means to provide women with the durability attributed to mesh reinforcement with the lower invasiveness of a vaginal route of surgery. Short-term anatomical success rates have been favorably reported at 94%,³ with demonstrated benefit in the anterior compartment by several studies.^{4,5} These kits were rapidly adopted by pelvic surgeons despite a scarcity of published outcomes and a full characterization of the risk/benefit profile. The Food and Drug Administration noted that approximately 3 of 4 prolapse repairs using mesh were done as transvaginal procedures in 2010. The agency recently advised on an increase in reported adverse outcomes to their database, highlighting the need for more detailed and extended outcomes assessed with validated measures, by investigators with surgical experience beyond their learning curve.

We have previously reported on the adoption of the Prolift system (Gynecare/Ethicon, Somerville, NJ) in a university training program that included the development of an institutional database of objective and subjective clinical outcomes.⁶ Recruitment of this cohort into an extended follow-up study provides us with an opportunity to describe midrange functional and anatomical effects of transvaginal system. We report clinical outcomes, including postoperative anatomical support, pelvic symptoms, quality of life, sexual function, satisfaction, and frequency of adverse events during the 2 years after reconstructive pelvic surgery using the Prolift systems.

MATERIALS AND METHODS

In 2006, the institutional review board at the University of Pittsburgh approved a prospective observational study of clinical outcomes in women undergoing mesh-augmented transvaginal prolapse surgery using Prolift systems at Magee-Womens Hospital. Every patient planning a transvaginal mesh-augmented prolapse repair with a Prolift system was approached for participation. In 2008, we obtained institutional review board approval for an extended follow-up to 2 years postoperatively. Women participating in the original 12-month study were approached for enrollment into the extended follow-up study at their 12-month in-person visit.

The decision to undergo a transvaginal mesh-augmented repair was mutually made by the patient and her surgeon after preoperative counselling and preceded participation in the

study. At initiation of the index study, our practice offered women seeking surgical reconstruction of prolapse, procedures via an abdominal or vaginal approach. The recommendation for a mesh-augmented repair was individualized by the surgeon. All consented subjects completed a pelvic examination and questionnaire panel at baseline and 6 and 12 months postoperatively, assessing objective and subjective outcomes. In addition, clinical charts were audited for visits incurred due to adverse events. The extended follow-up study collected the full complement of data at 24 months after surgery. Data collected from the pelvic examination included visible or palpable evidence of mesh exposure, pain on palpation, vaginal stenosis/strictures, and assessment of uterine and vaginal support as measured by the International Continence Society Pelvic Organ Prolapse Quantification (POPQ) examination.⁷ Subjective outcomes of pelvic symptoms, quality of life, and sexual function were assessed using the condition-specific validated Pelvic Floor Distress Inventory (PFDI), Pelvic Floor Impact Questionnaire (PFIQ), and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ) questionnaires. The PFDI assesses the presence of symptoms and the associated distress in women with pelvic floor disorders and has 3 scales, including Urinary Distress Inventory (UDI, 28 items, 300 possible points), Colo-Rectal-Anal Distress Inventory (CRADI, 17 items, 400 possible points), and Pelvic Organ Prolapse Distress Inventory (POPDI, 16 items, 300 possible points). The UDI queries obstructive and irritative voiding symptoms and the presence of stress incontinence. The CRADI surveys gastrointestinal symptoms of constipation, fecal incontinence, pain, irritation, and rectal prolapse. The POPDI assesses the presence of general, anterior, and posterior prolapse symptoms. Each item includes a measure of bother [not at all (1) to quite a bit (4)]. Lower scores indicate lesser degree of bother. Subjects also completed PFIQ, a measure of functional impact on life. The PFIQ's 3 scales, include the Urinary Impact Questionnaire (UIQ), Colo-Rectal-Anal Impact Questionnaire (CRAIQ), and Pelvic Organ Prolapse Impact Questionnaire (POPIQ). Each containing 31 items and 400 possible points. Lower scores indicate lesser negative impact of pelvic floor dysfunction on a woman's life.⁸ The PISQ measure of sexual function for women with pelvic floor disorders surveys sexual desire, ability to be aroused, satisfaction, pain, the impact of urinary and fecal incontinence, prolapse, and partner dysfunction on the sexual experience. Scores range from 0 to 125, with higher scores indicating better sexual function.⁹ Global satisfaction with the procedure was assessed using a visual analog scale from 0 to 10, with the boundaries of *very unsatisfied* and *very satisfied*, respectively. Subjects were also asked if they would recommend the procedure to a friend as a secondary assessment of satisfaction.

Each surgeon was proficient in related procedures such as sacrospinous ligament colpopexy and transobturator midurethral slings before attending an extramural surgical preceptorship. The total and posterior Prolift procedures were performed according to the manufacturer's instructions.¹⁰ Early in the adoption of the procedure, the insertion technique for the anterior Prolift was modified for women with anterior and apical support defects who the surgeon determined did not require mesh reinforcement of the posterior vaginal wall. This previously described modification involved anchoring the bisected central apical tab of the anterior mesh to the sacrospinous ligaments bilaterally for additional apical support with the end result of 6 anchoring points for the anterior mesh.⁶ The above modification was used in all women who underwent anterior Prolift in this series. We felt that this was an important

component of our anterior vaginal wall suspension since previous studies have demonstrated that loss of apical support significantly contributed to the presentation of anterior vaginal wall prolapse.¹¹ All women received antibiotic and mechanical deep venous thrombosis prophylaxis and intraoperative cystourethroscopy. Patients were discharged from the operating room with 2-in. plain gauze vaginal packing and a transurethral Foley catheter, both of which were removed 24 hours after surgery. A retrograde fill voiding trial was performed after packing removal to determine if the patient needed assisted bladder drainage with a Foley catheter or self-catheterization on discharge. Treatment of preoperative stress urinary incontinence by concurrent or by staged approach was not standardized. The presence of preoperative stress urinary incontinence was, however, recorded.

Vaginal caliber at the introitus (genital hiatus at rest), mid vagina, and the apex was assessed to evaluate for vaginal narrowing and stricture formation by the examiners spreading their fingers until vaginal walls were touched without pushing on the walls. Medical history, surgical data, and perioperative complications were extracted from office and hospital records. To reduce potential biases, all postoperative POPQ examinations and evaluations for mesh exposures were performed by clinicians other than the primary surgeon.

Results are presented as mean (SD) or median (range) for continuous variables and as frequency and percentages for categorical variables. For participants who did not respond to some of the items on the PFDI and PFIQ questionnaires, subscale scores were computed from the mean of the answered items within the subscale, and the denominators were adjusted accordingly.⁸ Paired Student *t* tests were used to analyze preoperative versus postoperative POPQ measurements and PFDI, PFIQ, and PISQ questionnaire scores. Wilcoxon signed rank test was used to assess differences between preoperative and postoperative stage of prolapse. Differences in the 2-year satisfaction scores between women who experienced mesh exposure and those who did not were evaluated using the Mann-Whitney *U* test. Differences in enrollment characteristics between women who consented to the 2-year study and those who did not were evaluated using Student *t*, Mann-Whitney *U*, and Fisher exact tests, where appropriate. All statistical analyses were considered significant at the level of 0.05.

RESULTS

Of the 126 women who enrolled into the index study, 3 withdrew before surgery (2 elected native tissue repair, 1 sacrocolpopexy), and 5 withdrew after surgery with Prolift because of relocation and difficulty with keeping appointments. Of the remaining 118 subjects who presented for their 1-year visit, 85 (72%) provided written consent for the extended follow-up study. The median follow-up was 25.9 (range, 19.8–33.8) months, with subjective data available for 82 of 85 and POPQ measurements for 79 of 85 women. Baseline demographic and clinical characteristics of women who consented to extended follow-up are summarized in Table 1. There were no differences in demographic or clinical characteristics between subjects who did and did not consent for the 24-month study ($P > 0.05$, data not shown). Most women had stage III prolapse (75%) at baseline, with the anterior compartment constituting the leading edge in 71% of subjects. Total Prolift was performed in 47 (55%), anterior Prolift with apical modification in 25 (29%), and posterior Prolift in 13 (15%).

Concomitant vaginal hysterectomy (TVH) was performed in 9 women and midurethral sling in 16 women. Other concomitant procedures included 11 perineorrhaphies and 4 salpingo-oophorectomies. General and regional anesthesia was equally used.

At 24 months, POPQ measurements of the anterior, apical, and posterior compartments were all significantly improved from baseline, as were quality of life scores, with the exception of sexual function, which did not differ from baseline (Table 2). Sixty-seven women (84.8%) were stage 0/I at the vaginal apex, defined as TVL - point C less than or equal to 2 cm. The mean (SD) descent of the apex with Valsalva was 1.2 (1.3) cm. Prolapse to or beyond the hymen occurred in 16 (20%) of 79 women of which 10 were in treated and 6 were in untreated compartments. To assess the natural history of support of the mesh-augmented compartments, we analyzed the lowest presenting point (POPQ points Ba and Bp) of the anterior and posterior vaginal walls. The POPQ data were available in 68 (94.4%) of 72 subjects with mesh placed in the anterior compartment (total or anterior Prolift with apical modification) and 56 (93.3%) of 60 women with mesh in the posterior compartment (total or posterior Prolift). Two years after surgery, mesh-augmented anterior compartments were found to be above the hymen (point Ba -0.5 cm) in 63 (93%) of 68 women. Similarly, mesh-augmented posterior compartments were above the hymen (point Bp -0.5 cm) in 52 (93%) of 56 women. The overall POPQ ordinal stage was 0/I in 51 (65%) women, stage II in 25 (31%) women, and stage III in the remaining 3 (4%) subjects. The mean (SD) TVL was 1.3 (1.5) cm shorter at 24 months after surgery when compared with the preoperative examination. There were no significant changes in the POPQ measures between 12 and 24 months postoperatively with the exception of vaginal length, which was statistically, but not clinically, different (Table 2).

Among 25 women with postoperative stage II prolapse 24 months after surgery, the leading edge of prolapse was proximal to the hymen in 12, at the hymen in 9, and within 1 cm beyond the hymen in 4 women. The anterior vaginal wall was the leading edge in 8 women, of whom 2 prolapsed beyond the hymen. The posterior vaginal wall constituted the leading edge of prolapse in 7 women with 2 subjects prolapsing beyond the hymen. Postoperative stage III prolapse was found in 3 (4%) women. One woman had the leading edge of prolapse extend to +2.5 in the anterior compartment and another woman to +1.5 cm in the posterior compartment. In both cases, the prolapsing compartment had not been addressed at the index surgery. The third woman with POPQ stage III had an anterior vaginal wall (Ba) at +1.5 cm after undergoing a total Prolift. Among the 34 women who underwent prolapse repair with total Prolift and uterine preservation, there were 2 (5.8%) cases of recurrent apical prolapse (cervix at +1.0 cm). The points D were -6 and -5 cm, respectively. Both patients reported fewer symptoms than before operation, and both declined further treatment at last follow-up.

Symptomatic pelvic organ prolapse, as defined by the answer "yes" to PFDI questions 4, "Do you usually have a sensation of bulging or protrusion from the vaginal area?" or 5, "Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?" was present in 7 (8.5%) of 82 women 24 months after surgery. At publication, the disposition of these 7 women includes additional surgery for prolapse (1), pessary (1), and deferral from additional intervention (5). The overall rate of reoperation for prolapse was

1.6% by 24 months, and subsequent procedures were predominantly directed toward addressing the previously unreinforced compartment.

Subjective outcomes of the entire cohort at 24 months, as measured with PFDI and PFIQ, showed significant improvement from baseline in all 3 scales ($P < 0.001$), and consistent with subjective outcomes at 12 months ($P > 0.3$; Table 2). To determine if an anatomical outcome of POPQ at/distal to the hymen at 24 months postoperatively was associated with less symptom relief or deleterious impact on quality of life (QOL), we compared the QOL measures of the 63 women with the leading edge of prolapse proximal to the hymen with the 16 whose postoperative prolapse was at/distal to the hymen. Notably, the severity of prolapse symptoms did not differ between groups ($P = 0.09$; Table 3). We did observe that compared with those with the leading edge of prolapse at/distal to the hymen, women with the leading edge of prolapse proximal to the hymen reported significantly fewer urinary symptoms (UDI scores 52.7 vs 27.1, respectively, $P = 0.01$) 24 months postoperatively. There were no corresponding significant differences noted in the impact of urinary symptoms on quality of life or any other subjective measures between the 2 groups (Table 3). Interestingly, despite this lack of significant difference in most of the subjective outcomes, women with postoperative prolapse proximal to the hymen demonstrated greater improvement in most postoperative QOL measures, compared with the preoperative symptoms relative to women with postoperative prolapse at/distal to the hymen (Table 3).

Sexual function was assessed by the PISQ at baseline and 24 months in 45 (53%) of 85 women who consented to the extended follow-up study. Equal numbers ($n = 5$) of women became active or ceased to be sexually active postoperatively, with those no longer active at 24 months attributing the abstinence to their partner's erectile dysfunction. The rate of dyspareunia was similar at baseline and at 24 months of follow-up [15/45 (33%) and 13/45 (28.9%) women, respectively]. An equal number of women, 7 (15.5%), reported resolution and new symptoms of dyspareunia. Four women with de novo dyspareunia responded "somewhat tight" and 1 responded "pretty tight" to question 13 on PISQ: "Is your vaginal opening too "tight" that sexual intercourse cannot occur?" None reported their partners complaining of vagina being "too tight" (PISQ question 14). One of these 4 subjects had a concomitant perineorrhaphy. None of the subjects attributed dyspareunia to "too short" vagina, as addressed by question 15 on the PISQ. Mean (SD) estimated midvaginal width was 3.9 (0.9) cm, whereas the mean (SD) width at the apex was 4.3 (0.9) cm. Mean (SD) genital hiatus was 3.1 (0.8) cm. In 5 women with de novo dyspareunia and subjective assessment of vagina being "too tight," mean genital hiatus did not differ when compared with subjects who did not feel introital tightness ($P = 0.97$). No strictures were identified by clinicians on physical examination. The type of Prolift kit used among those reporting new-onset dyspareunia was total (5), anterior with apical modification (1), and posterior (1). Of these 7 women, 3 had concomitant procedures: TVH/retropubic sling (1), TVH (1), and transobturator sling (1). Overall PISQ scores did not change from baseline (Table 2). The PISQ scores of subjects with postoperative prolapse at/distal to the hymen were not different when compared with women with postoperative prolapse proximal to the hymen after Prolift ($P = 0.719$).

Perioperative complications within 8 weeks of surgery predominantly involved the genitourinary tract with 35.3 % experiencing incomplete bladder emptying at time of discharge, and 21.2%, urinary tract infections. Median duration of catheter use was 7 days (range, 1–90 days). Intraoperative complications included 3 visceral injuries: 2 trocar perforations of the bladder and 1 distal rectal injury, caused by the Breisky-Navratil vaginal retractor during dissection of the rectovaginal space. Two subjects required blood transfusion for symptomatic anemia after an estimated blood loss of 600 and 800 mL during total Prolift placement for stage III prolapse without concomitant procedures.

The rate of mesh exposure was at least 13%. Exposure was identified in 11 women at a median interval of 68 days (range, 43–715 days) after surgery. Ten exposures were identified in the first year after surgery with 1 exposure recognized between 12 and 24 months in the extended follow-up cohort. Seven of the subjects underwent a total Prolift; 3, anterior Prolift with modification; and 1, posterior Prolift. To determine if mesh exposure had an impact on QOL, we compared subjective outcomes of the 74 women without this complication with the 11 who had mesh exposure. Notably, subjective outcomes did not differ between groups (Table 4). Regarding the potential association of mesh exposure and hysterectomy, 1 of 11 had a concomitant hysterectomy, 5 of 11 had a prior hysterectomy, and 6 had mesh implants with uterine preservation. One subject with exposed vaginal mesh responded to topical estrogen cream, whereas 6 underwent excision: 1 in the office and 5 in the operating room under sedation, after failing conservative treatment. Five women with mesh exposure are managed expectantly as they remain asymptomatic. The overall rate of reoperation for mesh complications and prolapse retreatment was 7.4%.

De novo pain in the groin and/or gluteal region was reported at 8 weeks postoperatively in 18 (14.6%) of 123 subjects. The pain at these sites resolved in 15 (83%) of 18 women by 3 months postoperatively. One woman required release of a tense mesh arm fixed to the right sacrospinous ligament for persistent pelvic pain that radiated to the right buttock, unresponsive to pelvic floor physical therapy and nonsteroidal anti-inflammatory medication. The pain significantly improved, although it did not completely resolve and persisted at 24 months of follow-up. She declined full mesh removal and remains in follow-up. At 2 years of follow-up, 2 women (2.3%) reported pain other than dyspareunia in the vagina. All described it as discomfort “deep inside” after prolonged sitting. No subjects had vaginal tenderness upon palpation by the examiner on the 2-year postoperative examination.

The median patient global satisfaction with the procedure was 9.2 at 12 months postoperatively and was sustained at 24 months, with the median of 9.3 (range, 2.0–10.0). There was no significant difference in the median satisfaction score between subjects with mesh exposure (8.8) versus women without this complication (9.4; $P = 0.052$). Ninety-one percent of all subjects in the cohort stated that they would recommend this procedure to a friend, with an equal proportion of women with the mesh exposure complication (10/11) affirming the above.

DISCUSSION

Women undergoing transvaginal mesh-augmented prolapse repair with Prolift demonstrate significant improvement in urinary, bowel, and prolapse-related symptoms 24 months after surgery. The anatomical support achieved mirrors symptom relief and improvement in quality of life. The clinical outcomes are sustained from 12 to 24 months after surgery. These results appear to be comparable with those achieved with traditional sacral colpopexy, after which the anatomical success rates ranges from 58% to 100% when success is defined as no postoperative prolapse and possibly reflect our modification of the anterior Prolift system that allowed for apical support¹²

Our objective POPQ data revealed that 87% of treated compartments are supported above the hymen with 85% of the women at POPQ stage 0/I at the apex. This is somewhat lower than a 95% rate of optimally supported apex, defined as point C within 2 cm of total vaginal length, reported 2 years after sacrocolpopexy¹³; however, consistent with previous reports of reconstruction with vaginal mesh,¹⁴ the leading edge of prolapse among our study subjects was found to be above the hymen in 80% of study participants at 2 years postoperatively. Our observations that 31% (25/79) of women were at stage II prolapse is comparable with outcomes reported by other groups using Prolift systems.⁴ It is also analogous to the outcomes 2 years after abdominal sacral colpopexy in a population with similar prolapse.¹³ Forty-one percent of women who underwent sacral colpopexy in the Colpopexy And Urinary Reduction Efforts (CARE) study were found to be at POPQ stage II 2 years postoperatively.¹³ It is plausible that some of the persistent and progressive prolapse identified as stage II may reflect the surgeon's intraoperative decision not to address asymptomatic distal anatomical laxity of the genital hiatus or urethral mobility. Deterioration of support in the unreinforced compartment accounted for half of the prolapse to or beyond the hymen in our study, which reflects the intrinsic weakness of the native supportive tissue leading to surgery and is again similar to the sacral colpopexy recipients in CARE in which 44% of vaginal wall prolapse was noted to be in the untreated compartment. The lack of correlation between the subjective and anatomical outcomes reported may be due to the constraints of the ordinal POPQ staging system. Specifically, most women do not experience symptoms of prolapse until the leading edge is at or beyond the level of the hymen.^{15,16} Our comparison of postoperative subjective outcomes in women with prolapse proximal versus at/distal to the hymen were not significantly different; however, this is possibly due to the small number of subjects in the later group. We also know that 75% of asymptomatic women have prolapse beyond stage I detected at routine gynecologic examinations.¹⁷ This observation supports compelling arguments to anchor anatomical "success" or "prolapse cure" to vaginal support above the hymen and not to stage 0/I.^{15–18}

Absence of vaginal bulging has been identified as the most important predictor of patients' satisfaction with surgery.¹⁵ In our series, symptoms of vaginal bulging were present in 8.5% of women 2 years after reconstruction with Prolift systems. We are limited in our ability to discern if these symptoms of a bulge are due to recurrent prolapse in the previously treated compartment or from de novo prolapse in the untreated compartment. Few women overall returned for an additional prolapse surgery. The rate of reoperation was 1.6% by 24 months, and subsequent procedures were predominantly directed toward addressing the previously

unreinforced compartment. This is consistent with the 3% rate recently reported in a retrospective study of more than 500 subjects who underwent prolapse reconstruction with the Prolift system, as well as 2.6% reoperation at 24 months after sacral colpopexy.^{13,19}

Apprehension about the development of intractable dyspareunia and pelvic pain has contributed to concern about implanting mesh transvaginally. More than half of women in our cohort reported being sexually active at baseline (45/85). This is consistent with other prolapse repair cohorts of a similar mean age (65 years)²⁰ and enables us to draw some conclusions about how sexual function is impacted 2 years after prolapse repair with Prolift. It is reassuring that among women who were sexually active at baseline and 2 years, sexual function did not deteriorate. Most of the women who were sexually active before surgery remained sexually active after surgery. There was no change in the reported rate of dyspareunia, although notable, there were a substantial number of women who reported that intercourse was limited by pain before and after surgery. The etiology of dyspareunia is complex and is known to increase with age and menopause.²¹ We are limited in our ability to discern causes of dyspareunia from our data set. Our rudimentary clinical assessment of vaginal caliber did not identify stricture as a contributing cause for dyspareunia. The 3 clinical estimates of caliber in the upper, mid, and lower vagina suggest that the end result is a trapezoidal-shaped vagina consistent with the shape of the mesh implant. Our 14.3% frequency of de novo dyspareunia, although significant, is similar to the 14.5% reported after sacral colpopexy and is lower than the 18% rate after native tissue colporrhaphy in a comparably aged cohort.²² We endorse the inclusion of development of dyspareunia in surgical counselling and the informed consent process.

Patient satisfaction with the decision to undergo Prolift was high at 12 months and sustained through 24 months. Study participants would nearly universally recommend the procedure to a friend. The overall satisfaction rate at 2 years was comparable with those reported after abdominal sacrocolpopexy.¹³ The observed consistency in satisfaction among the subset of women who experienced mesh exposure or reported dyspareunia must be interpreted within the context of the study group's age (mean age, 65 years) and their level of sexual activity. It may also reflect the patient's perception of the burden of these 2 surgical morbidities bringing to light a pressing need for development of a condition-specific measure of patient burden associated with mesh morbidities. Results of this measure would better inform patients preoperatively and would contribute to the discussion on associated risks and benefits of abdominal and vaginal mesh-augmented prolapse repairs.

Mesh exposure was the most common device-attributable complication. It was identified in at least 13% of the original cohort, which is similar to 15.6% to 16.9 % reported in previous prospective trials^{4,14} and is double the 6.4 % rate reported 24 months after sacrocolpopexy.¹³ It is also substantially higher than the 2% rate reported in the retrospective studies,²³ highlighting the need for prospective follow-up. Mesh exposure is known to lead to additional surgery, expense, and other life-compromising sequelae.^{24,25} Surprisingly, the QOL measures and satisfaction with the outcomes 24 months after Prolift did not differ between women who experienced mesh exposure when compared with those who did not. This is possibly because almost half of subjects with mesh exposure in our cohort were asymptomatic and did not pursue intervention for this complication. The

etiology of this undesired outcome is not fully known. Patient characteristics that influence the selected route of surgery, devitalizing vaginal incisions, and the material properties of the mesh have each been implicated in mesh exposures; however, in the absence of a randomized trial, the attributable risk based on surgical approach for mesh insertion cannot be quantified.²⁶

The strengths of our study include its prospective design, the 2-year duration of follow-up, and the use of standardized, validated, condition-specific questionnaires for assessment and comparison of clinical outcomes. Women were well characterized, and although this cohort was recruited from a single institution, single-surgeon bias was avoided because the outcome data were pooled from the caseload of 5 urogynecologists. Limitations include the loss to follow-up that occurred with the reconsenting of our original cohort at their 12-month exit visit. The attrition rate of 28% can be a potential source for underestimation or overestimation of postoperative complications and procedure failures in our cohort. In addition, we cannot account for the selection bias intrinsic to observational studies. Our outcomes in a high-volume subspecialty program may not be generalizable to surgeons with limited experience in vaginal prolapse repair. In addition, our institutional modification of the anchoring points on the mesh in the anterior Prolift kit to include sacrospinous attachments compromises our ability to compare the anatomical and functional outcomes for this specific system to other published studies of Prolift. However, assuring apical support in the anterior Prolift with the apical modification allows us to better compare outcomes of all 3 Prolift procedures with outcomes of abdominal sacrocolpopexy, which is considered the gold standard procedure for the repair of apical prolapse.

Although the Prolift systems are no longer commercially available, our study provides clinicians and future innovators a detailed report of 2-year clinical outcomes from one of the first standardized approaches to transvaginal mesh-augmented prolapse repair. It is unclear how the various textile properties and anchoring mechanisms of other commercially available transvaginal mesh delivery systems impact on clinical outcomes, and we therefore caution against assuming that our findings are transferable to other systems. The broad adoption of vaginal mesh kits was in part spurred by the pressing and persistent need for a nonintraperitoneal procedure option to sacral colpopexy. We anticipate that this clinical need will be the impetus for a second generation of transvaginal approaches to mesh-augmented prolapse repairs. Further studies are needed to contribute to our understanding of the etiology of mesh-associated morbidity including material properties of mesh for enhanced tolerance by the vagina, atraumatic anchoring mechanisms, and identification of patient characteristics associated with an increased risk for adverse outcomes.

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TABLE 1

Demographic and Surgical Characteristics of Women Enrolled in the Extended Follow-Up Study (n = 85)

Race, n (%)	
White	80 (94)
African American	4 (5)
Other	1 (1)
Age, mean (SD), y	65.8 (8.8)
Body mass index, mean (SD), kg/m ²	28.2 (4.6)
Parity, median (range)	3 (1–8)
Current smoker, n (%)	1 (1)
Menopausal status, n (%)	
Premenopausal	5 (6)
Postmenopausal on hormone therapy	16 (19)
Postmenopausal without hormone therapy	64 (75)
Previous hysterectomy, n (%)	51 (60)
Previous surgery for POP, n (%)	23 (27)
Sexually active, n (%)	45 (53)
Self-reported dyspareunia, n (%)	15 (18)
Concomitant hysterectomy, n (%)	7 (8)
Concomitant midurethral sling, n (%)	16 (19)
Mesh exposure, n (%)	11 (13)

TABLE 2

Anatomical and Functional Outcomes After Reconstructive Surgery With Prolift Pelvic Floor Repair System

Anatomical Outcomes	Baseline	12 mo	24 mo	P*
POPQ stage, n (%) [†]				<0.001
Stage 0	0	14 (18)	12 (15)	
Stage I	0	29 (37)	39 (49)	
Stage II	17 (22)	36 (46)	25 (32)	
Stage III	59 (75)	0	3 (4)	
Stage IV	3 (4)	0	0	
Ba (overall), mean (SD), cm	2.0 (2.5)	-1.9 (1.1)	-1.9 (1.2)	<0.001
Total Prolift	3.0 (2.1)	-1.9 (1.0)	-2.0 (1.1)	<0.001
Anterior Prolift	2.3 (1.5)	-2.2 (1.0)	-2.2 (1.0)	<0.001
Posterior Prolift	-2.2 (0.8)	-1.2 (1.3)	-1.0 (1.6)	0.046
Bp (overall), mean (SD), cm	0.3 (3.0)	-2.1 (1.2)	-2.2 (1.2)	<0.001
Total Prolift	1.0 (3.4)	-2.5 (0.8)	-2.6 (0.7)	<0.001
Anterior Prolift	-2.0 (0.8)	-1.6 (1.3)	-1.5 (1.3)	0.126
Posterior Prolift	2.4 (1.6)	-2.1 (1.5)	-2.0 (1.5)	<0.001
C (overall), mean (SD), cm	-1.9 (4.2)	-6.3 (1.8)	-6.2 (1.8)	<0.001
Total Prolift	0.2 (4.4)	-5.8 (2.2)	-5.7 (2.1)	<0.001
Anterior Prolift	-3.8 (2.0)	-6.9 (0.9)	-6.7 (1.1)	<0.001
Posterior Prolift	-5.5 (1.6)	-6.7 (1.1)	-7.0 (0.9)	0.025
Genital hiatus, mean (SD), cm	4.9 (1.2)	3.1 (0.9)	3.2 (0.9)	<0.001
TVL (overall), mean (SD)	8.8 (1.3)	7.7 (1.4)	7.5 (1.4)	<0.001
Total Prolift	8.8 (1.6)	7.4 (1.3)	7.0 (1.4)	<0.001
Anterior Prolift	8.8 (1.1)	8.2 (1.4)	8.0 (1.3)	0.006
Posterior Prolift	8.7 (0.9)	8.4 (1.1)	8.3 (1.2)	0.145
Functional outcomes, mean (SD)				
PFDI [‡]				
UDI	74.7 (43.0)	30.3 (36.3)	30.5 (34.1)	<0.001
CRADI	86.7 (65.4)	48.1 (56.2)	44.4 (55.4)	<0.001
POPDI	107.3 (58.3)	34.1 (42.2)	35.2 (51.7)	<0.001
PFIQ [‡]				
UIQ	76.4 (77.5)	28.4 (41.4)	27.1 (47.5)	<0.001
CRAIQ	53.7 (81.7)	23.2 (47.2)	22.3 (41.0)	<0.001
POPIQ	75.6 (88.2)	14.9 (38.0)	16.4 (35.2)	<0.001
PISQ [§]	81.8 (21.3)	82.9 (25.1)	83.9 (20.8)	0.501

Score range for UDI (0–300), CRADI (0–400), POPDI (0–300), UIQ (0–400), CRAIQ (0–400), POPIQ (0–400), and PISQ (0–125).

* P-value from Student *t* test, comparing postoperative differences between baseline and 24 months data.[†] n = 79; total Prolift (n = 43), anterior Prolift with modification (n = 24), posterior Prolift (n = 12).[‡] n = 82.

$\S_n = 45$.

TABLE 3

Functional Outcomes in Women With the Leading Edge of Prolapse Proximal Compared With At/Distal to the Hymen 24 Months After Reconstructive Surgery With the Prolift System

	Proximal to the Hymen (n = 63)			At or Distal to the Hymen (n = 16)		
	Preoperative, Mean (SD)	Postoperative, Mean (SD)	P*	Preoperative, Mean (SD)	Postoperative, Mean (SD)	P*
PFDI						
UDI	78.6 (46.3)	27.1 (33.5)	0.000	61.2 (31.6)	52.7 (39.1)	0.207
CRADI	89.9 (69.3)	43.6 (59.8)	<0.001	82.6 (57.1)	54.6 (39.7)	0.183
POPDI	110.4 (60.0)	31.8 (45.4)	<0.001	89.5 (57.7)	56.5 (72.5)	0.045
PFIQ						
UIQ	87.4 (85.4)	30.7 (52.6)	<0.001	39.1 (28.4)	20.2 (25.7)	0.046
CRAIQ	51.1 (84.4)	22.8 (41.2)	0.001	47.0 (68.4)	25.9 (45.1)	0.379
POPIQ	82.6 (94.8)	14.5 (35.6)	<0.001	51.7 (57.9)	25.0 (37.3)	0.150
PISQ [‡]	80.9 (21.6)	81.6 (22.8)	0.496	83.7 (24.4)	83.9 (18.6)	0.959

Score range for UDI (0–300), CRADI (0–400), POPDI (0–400), UIQ (0–300), CRAIQ (0–400), POPIQ (0–400), PISQ (0–125).

* P value from paired Student *t* test for changes between preoperative and postoperative values within women with leading edge of prolapse proximal to the hymen and at/distal to the hymen.

[‡] P value from Student *t* test, comparing postoperative differences between women with leading edge of prolapse proximal to the hymen and at/distal to the hymen.

[‡] n = 32 for women with leading edge of prolapse proximal to the hymen and n = 13 for women with leading edge of prolapse proximal to the hymen and at/distal to the hymen.

TABLE 4

Comparison of Postoperative Functional Outcomes Between Women With and Without Mesh Exposure 24 months After Reconstructive Surgery with the Prolift System

	No Mesh Exposure (n = 74), Mean (SD)	Mesh Exposure (n = 11), Mean (SD)	<i>P</i> [*]
PFDI			
UDI	30.6 (35.5)	37.7 (35.1)	0.535
CRADI	47.2 (57.4)	22.5 (32.5)	0.168
POPDI	36.8 (53.4)	24.1 (34.7)	0.449
PFIQ			
UIQ	26.8 (48.5)	29.6 (39.2)	0.859
CRAIQ	23.3 (42.4)	13.8 (28.3)	0.476
POPIQ	16.9 (37.0)	10.9 (18.3)	0.600
PISQ [†]	84.8 (16.9)	69.8 (35.7)	0.280

Score range for UDI (0–300), CRADI (0–400), POPDI (0–300), UIQ (0–400), CRAIQ (0–400), POPIQ (0–400), PISQ (0–125).

^{*} *P* value from Student *t* test, comparing postoperative differences between women with and without mesh exposure.

[†] n = 37 for women without mesh exposure and n = 8 for women with mesh exposure.