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# Hysteropexy compared to hysterectomy for uterine prolapse surgery: does durability differ?

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## Abstract

**Introduction and hypothesis** The aim of this study is to assess the impact of hysterectomy on durability of uterine prolapse repair by comparing hysterectomy/uterosacral cuff suspension (VH) to a new vaginal uterosacral hysteropexy (USH).

**Methods** A retrospective chart review of uterine prolapse patients after USH or VH with concomitant procedures as indicated was conducted, analyzing Baden–Walker grading of apex, anterior, and posterior compartments (Kaplan–Meier analysis) Baden et al. (Tex Med 64(5):56–58, 1968). **Results** A total of 200 charts met criteria. USH women weighed less, were younger, and more constipated with larger rectoceles. Levator parameters did not differ Romanzi et al. (Neurourol Urodyn 18(6):603–612, 1999). Baden–Walker data were entered at recurrence or minimum of 6 months (2.4 months–10 years; median, 1.5 years). All-apex durability was 96.4%, with no difference between hysteropexy and cuff suspension (96.0% vs. 96.8%,  $p=0.90$ ), cystocele (86.8% vs. 93.8%,  $p=0.31$ ), or rectocele (97.8% vs. 100%,  $p=0.16$ ) at 2 years.

**Conclusion** In uterine prolapse patients, technically similar uterosacral hysteropexy durability did not differ from hysterectomy-based cuff suspension nor between cohorts for cystocele or rectocele.

**Keywords** Hysteropexy · Uterosacral ligament suspension · Uterine preservation · Uterine prolapse · Uterine resuspension · Vaginal hysterectomy · Pelvic organ prolapse

## Introduction

Prolapse is the third most common indication for hysterectomy in the USA, accounting for approximately 18% of the 500,000 benign disease hysterectomies performed annually [3–5]. This hysterectomy-based tradition for uterine prolapse surgery is changing, with one of the earliest uterus-sparing hysteropexy studies in 1989 describing five young women with uterine prolapse undergoing sacrospinous ligament uterine resuspension [6]. Subsequent hysteropexy studies reflect techniques adapted from methods of traditional hysterectomy vaginal cuff suspensions to the sacrum, sacrospinous ligament(s), and uterosacral ligament(s) [7, 8].

Durability of uterosacral ligament cuff suspension reported by Shull showed 13% recurrence at the clinically negligible grade 1 level and 5% grade 2 recurrence, mostly cystoceles, in a group of 289 women with at least one postoperative examination [9]. Few uterine prolapse studies compare durability between hysterectomy and non-hysterectomy native tissue techniques. The only data on intraperitoneal uterosacral suspensions compare laparoscopic uterosacral hysteropexy to vaginal hysterectomy–uterosacral cuff suspension, showing durability advantage in the hysteropexy group [10]. Uterosacral cuff suspension at time of vaginal hysterectomy demonstrated similar durability

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when compared to cervical amputation (modified Manchester) at 1-year follow-up; however, again, the techniques were not exact mimics [11]. A postal questionnaire comparison of sacrospinous hysteropexy compared to cuff suspensions showed no difference in durability [12]. The only randomized prospective native tissue study comparing sacrospinous suspension in women randomized to uterine-preserving sacrospinous hysteropexy or vaginal hysterectomy with sacrospinous cuff suspension showed a slight durability advantage in the hysterectomy group at 1 year [13].

We hypothesize that the durability of uterine prolapse surgery and related support of anterior and posterior compartments is not significantly affected by removal or preservation of the uterus when vaginal-access intraperitoneal uterosacral ligament suspension is used for either hysteropexy resuspension of the prolapsed uterus or vaginal hysterectomy with cuff suspension. This manuscript reports technique and mechanical durability of a new vaginal intraperitoneal uterosacral ligament hysteropexy (USH) method of uterine resuspension compared to traditional vaginal hysterectomy/uterosacral cuff suspension (VH).

## Materials and methods

This retrospective study was approved by the Weill Cornell Institutional Review Board (0411007549: Retrospective Evaluation of Pelvic Reconstructive Surgical Procedures). Data include women with uterine prolapse undergoing USH or VH from 1994–2011. Inclusion criteria were grade 2–4 uterine prolapse at time of surgery, with preoperative and postoperative prolapse exam data documenting degree of uterine prolapse, cervical elongation, cystocele, and/or rectocele. Secondary data points included preoperative levator muscle bulk and contraction score, age, race, parity, menopause status, medical conditions, concomitant procedures performed, date and degree of prolapse recurrence, or most recent postop exam at or after 6 months from time of surgery.

Examination of support was performed or confirmed by the authors in the resident teaching clinic and faculty practice settings using Baden–Walker [1] halfway method. House staff participated in data base formulation and chart review. Uterine position comparable to the “D point” of pelvic organ prolapse quantification (POP-Q) was used to evaluate uterine support before and after hysteropexy and “C point” for vaginal cuff support after hysterectomy. Evaluation of bladder support approximated Ba on POP-Q, and rectum support approximated Bp on POP-Q. In supine, seated and/or standing position, at rest, and maximal straining/coughing, the most severe descent of each compartment was used for data analysis. Baden–Walker grade 0, no descent from anatomic normal position; grade 1, minimal descent above the level of the mid-vagina; grade 2, descent to or below

the mid-vagina but not visible or palpable at the hymeneal ring; grade 3, descent visible/palpable at the hymen, separating the labia but not beyond the introitus; grade 4, the majority or entirety of the compartment descends distal to the introitus.

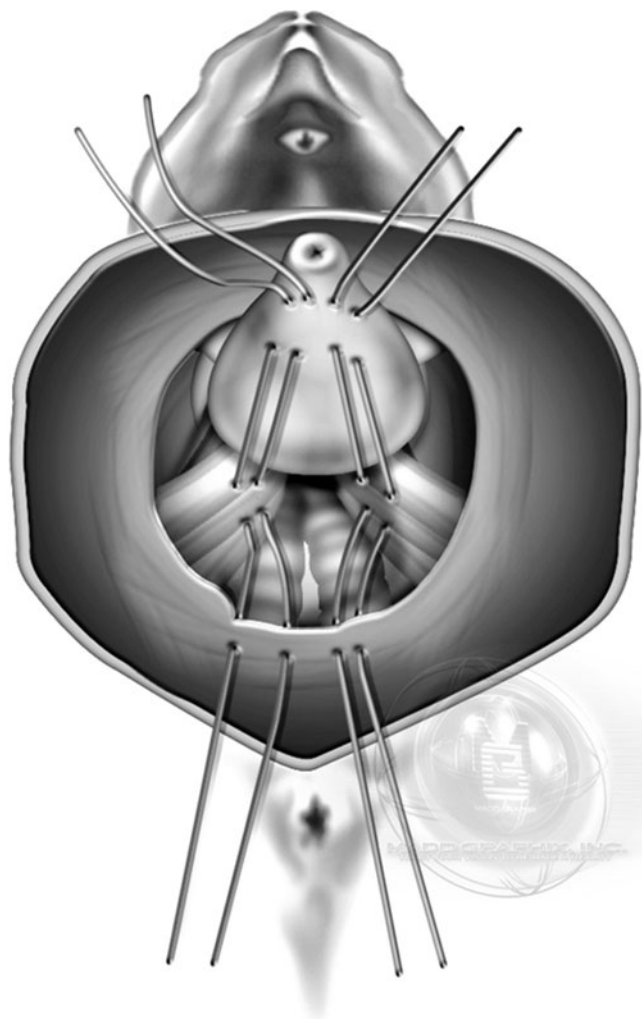
Patients participated in the choice to remove or preserve the uterus and ovaries. Counseling included disclosure of the evolving literature regarding hysterectomy-based and uterus-preserving methods of uterine prolapse surgery, gynecologic cancer risk, benign gynecologic conditions for which hysterectomy is a therapeutic option, and ovarian preservation–menopause management considerations. All patients had normal Pap smears within 1 year of the surgery date and underwent presurgical pelvic and renal imaging.

Patients choosing VH underwent vaginal hysterectomy with or without bilateral salpingoophorectomy, culdoplasty, and bilateral uterosacral fixation of the vaginal cuff using two 0 Maxon sutures anchored in each proximal uterosacral ligament. Concomitant cystocele, rectocele, and incontinence procedures were performed as indicated.

Patients selecting uterine preservation underwent USH (Fig. 1). Uterosacral ligaments are accessed via culdotomy incision. With the uterus on traction, proximal uterosacral ligaments medial to the ureters are identified by palpation. At the discretion of the surgeon, a long Allis clamp is used to further isolate the proximal ligament for suspension suture placement. Breisky-Navratil retractors are placed on either side to facilitate exposure and placement of 0 Maxon anchor sutures in each proximal uterosacral ligament, identical to anchor suture placement in the VH cohort cuff suspensions. Culdoplasty, technique at surgeon's discretion, is done, followed by partial bladder flap dissection and trachelorrhaphy for cervical hypertrophy, restoring normal 3–4 cm cervical length and contour. Trachelectomy and Sturmdorf suturing were not performed to prevent Sturmdorf-related obliteration of the cervical os.

With culdoplasty completed and cervical anatomy normal, distal placement of the uterosacral anchor sutures begins by passing the suture through the posterior vaginal cuff into the vagina, followed by deep vertical purchase through the posterior intraperitoneal surface of the lower uterine wall at the level of the isthmocervical junction—in essence treating the posterior isthmocervical surface as one does the anterior vaginal cuff when performing uterosacral cuff fixation immediately after hysterectomy. With uterosacral anchor suture placements completed, the vaginal skin is reattached to the base of the cervix circumferentially, setting the stage for uterine resuspension. Digital splinting of the prolapsed uterus into normal position at the vaginal apex, while gently placing counter-traction on the uterosacral suspension sutures, removes all slack so that each suture may be individually tied to the maximum resuspension contour possible, completing the hysteropexy portion of the prolapse operation (Fig. 2).





**Fig. 1** Uterosacral ligaments access accomplished via culdotomy incision in a modification of classic Shull technique [9]. With the uterus on traction, proximal uterosacral ligaments medial to the ureters are identified by palpation. At the discretion of the surgeon, a long Allis clamp is used to further isolate the proximal ligament for suspension suture placement. Breisky-Navratil or other retractors placed on either side of the ligament facilitate exposure and placement of two 0 Maxon sutures in each proximal uterosacral ligament. Culdoplasty, technique at surgeon's discretion, is done. In women with cervical hypertrophy, partial bladder flap dissection facilitates shortening to a normal 3–4 cm length at this juncture, without resorting to amputation or Sturmdorf suturing. The uterosacral anchor sutures are secured through the posterior vaginal cuff into the vagina. Incorporation of prolapsed uterus is accomplished with deep vertical purchase through the posterior intraperitoneal surface lower uterine wall at the isthmocervical junction—treating the posterior isthmocervical surface as one does the anterior vaginal cuff when performing uterosacral cuff fixation at time of hysterectomy. With uterosacral anchor suture placements completed, the vaginal skin is reattached to cervical base circumferentially, setting the stage for uterine resuspension. Digital splinting of the prolapsed uterus into normal position at the vaginal apex is followed by countertraction on the 0 Maxon uterosacral suspension sutures, removing all slack, then tying of each suture individually to the maximum resuspension contour possible, completing the hysteropexy portion of the prolapse operation

Concomitant cystocele, rectocele, and incontinence procedures were done thereafter as indicated; central cystoceles with midline anterior colporrhaphy (0 Vicryl); paravaginal cystoceles with vaginal paravaginal technique placing four anchor sutures (0 PDS) into the arcus tendineus. Posterior colporrhaphy included midline fascial fixation levatorplasty. Stress urinary incontinence was treated with sling procedure.

Postoperative Baden–Walker pelvic support evaluation was done at 1, 3, 6, and 12 months and annually as able thereafter. Recurrence of prolapse in any compartment to grade 2 or higher was categorized as biomechanical recurrence, regardless of symptoms.

Descriptive statistics and percentages are presented for demographic and clinical characteristics, stratified by type of repair (e.g., vaginal hysterectomy with reconstruction of apex versus uterine-preserving hysteropexy). The Chi-square test (or Fisher's exact test) and the *t* test (or Wilcoxon rank-sum test) were used, as appropriate, for comparing demographic and clinical characteristics between the two repair groups. Recurrence-free survival was analyzed using the Kaplan–Meier method, and the log-rank test was used to compare recurrence-free survival between the two repair groups. Ninety-five percent confidence intervals for survival estimates were calculated to assess the precision of the obtained estimates. All *p* values are two-sided with statistical significance evaluated at the 0.05 alpha level. All analyses were performed in SAS version 9.1 (SAS Institute, Inc., Cary, NC) and Stata version 10.0 (Stata Corporation, College Station, TX).

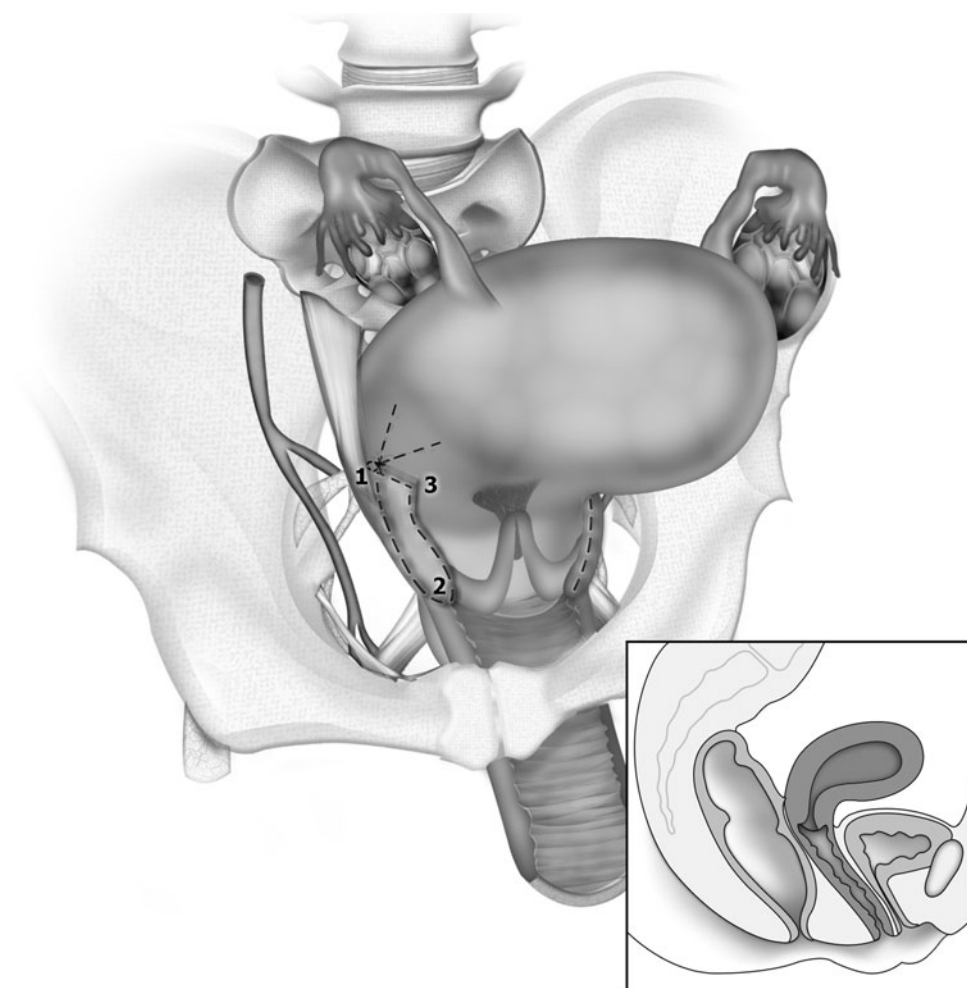
## Results

The study sample included 208 women undergoing reconstructive uterine prolapse surgery at Weill Cornell Medical Center/New York Presbyterian Hospital; 200 records, 100 USH and 100 VH, met inclusion criteria. Largest birth weight data were missing from 27 VH and 12 USH charts, body weight from 2 VH and 1 USH chart, race from 1 VH and 2 USH charts, Kegel score from 24 VH and 10 USH charts, and levator muscle bulk evaluation from 22 VH and 9 USH charts. Remaining data points were entered from each of the 200 charts. Follow-up ranged from 0.5–10 years (median, 1.5 years).

Women in the hysterectomy group were older (mean, 57 vs. 52 years;  $p=0.001$ ), heavier (mean, 157 vs. 146 lbs;  $p=0.02$ ), more likely to be menopausal (73% vs. 45%;  $p=0.0001$ ), and had higher rates of hypertension ( $p=0.03$ ) than the hysteropexy cohort, who had higher rates of chronic constipation ( $p=0.005$ ). Largest birth weight, race, Kegel muscle score, and muscle bulk did not differ between groups (Table 1).

Fifty-one women had grades 3–4 and 149 grade 2 uterine prolapse. Fourteen women choosing hysteropexy had cervical

**Fig. 2** 1 Uterosacral ligament anchors. 2 The uterosacral anchor sutures traverse posterior vaginal cuff. 3 Point of incorporation prolapsed uterus at the level of the isthmocervical junction



hypertrophy, and 108 had stress urinary incontinence. Overall prolapse severity for uterine prolapse and cystocele was equivalent between cohort groups with a higher grade of rectoceles in the hysteropexy cohort (mean, 2.29 vs. 1.84;  $p=0.0001$ ; Table 2).

Perioperative complications did not differ between groups (Table 3). Prolapse recurrence did not differ between groups for apex, anterior or posterior compartments (Table 2).

Eighty-seven women in the VH and 96 in the USH group underwent concomitant cystocele repair, including central colporrhaphy in 48 women with central cystocele and vaginal paravaginal technique in 135 women with paravaginal cystocele. Eighty-seven women in the VH and 97 in the USH group underwent rectocele repair, each with midline fascial levatorplasty plication. Sling operation was included for stress urinary incontinence in 108 women. All 14 women with cervical hypertrophy in the USH group underwent cervical shortening trachelorrhaphy.

Kaplan–Meier survival analysis showed 6 apical recurrences in the 200 patients with 1- and 2-year apical recurrence-free survivals of 98.2% (95% confidence interval (CI)=94.6%, 99.4%) and 96.4% (95% CI=91.5%, 98.5%),

respectively. Comparison of uterosacral hysteropexy vs. hysterectomy cuff suspension showed 3 recurrences in each cohort of 100 USH and 100 VH records. One-year recurrence-free durability was 97.8% (95% CI=91.6%, 99.5%) and 98.6% (95% CI=90.6%, 99.8%), respectively. Two-year comparative hysteropexy vs. cuff suspension durability was 96.0% (95% CI=87.7%, 98.8%) and 96.8% (95% CI=87.7%, 99.2%), respectively (log-rank  $p=0.90$ ). Nine cystoceles recurred in the USH and six in the VH cohorts, none de novo. One-year recurrence-free durability was 93.1% (95% CI=85.3%, 96.9%) and 97.3% (95% CI=89.6%, 99.3%), respectively. Two-year recurrence-free durability was 86.8% (95% CI=75.1%, 93.2%) and 93.8% (95% CI=84.2%, 97.7%), respectively (log-rank  $p=0.31$ ). Two rectoceles recurred in the USH and none in the VH cohorts, none de novo. One-year recurrence-free durability was 97.8% (95% CI=91.6%, 99.5%) and 100%, respectively. Two-year recurrence-free durability was 97.8% (95% CI=91.6%, 99.5%) and 100%, respectively (log-rank  $p=0.16$ ).

Of the 51 women with grade 3–4 uterine prolapse, 41 chose uterine preservation and 10 chose vaginal hysterectomy. Each of the three USH uterine prolapse recurrences was

**Table 1** Demographic data

Demographic data	Hysterectomy (N=100)		Hysteropexy (N=100)		p value
	Mean±SD	Median	Mean±SD	Median	
Age at surgery	57.1±10.31		52.3±10.66		0.001 <sup>a</sup>
Parity		2.00		2.00	0.82 <sup>b</sup>
Weight (lbs)	156.89±34.81		146.36±24.36		0.02 <sup>a</sup>
	N (% within race)		N (% within race)		
Race (White)	71 (45.5)		85 (54.5)		
Race (Asian)	6 (66.7)		3 (33.3)		
Race (Black)	11 (73.3)		4 (26.7)		
Race (Hispanic)	11 (66.7)		6 (26.6)		
Race (total)	99 (50.3%)		98 (49.7%)		0.07 <sup>c</sup>
Largest Birth weight (lbs)	7.71±1.39 (N=73)		7.73±2.0 (N=88)		0.93 <sup>a</sup>
Levator bulk	2.29±1.06	2.00	2.59±0.84	3.00	0.05 <sup>b</sup>
Kegel score	4.30±2.34	4.00	4.31±1.81	4.00	0.81 <sup>b</sup>
Menopausal	73 (61.9)		45 (38.1)		0.0001 <sup>c</sup>
Diabetes	0		1		0.99 <sup>d</sup>
Hypertension	25		13		0.03 <sup>c</sup>
Connective tissue disorder	2		3		0.99 <sup>d</sup>
Asthma	9		9		0.98 <sup>c</sup>
Constipation	2		12		0.006 <sup>c</sup>
Obesity	8		6		0.57 <sup>c</sup>

SD standard deviation

<sup>a</sup>t test

<sup>b</sup>Wilcoxin rank-sum test

<sup>c</sup>Chi-square test

<sup>d</sup>Fisher's exact test

grade 3 before surgery, all recurring acutely, within 3 months of initial hysteropexy, with recurrence involving all compartments (recurrent uterine prolapse, cystocele, and rectocele) in two of the three. The vaginal cuff prolapse of three women recurred at 8 months–2 years, one with recurrent cystocele.

Six of the seven nulliparous women, age range 35–68 years old, chose hysteropexy, none of whom sustained recurrence. Two suffered severe dysmotility constipation, one connective tissue disorder, and one reported professional repetitive strain history (heavy lifting). One 35-year-old nulliparous, hysteropexy patient with grade 3 uterine prolapse conceived her first pregnancy 15 months after uterine resuspension. Three hysteropexy women underwent subsequent vaginal hysterectomy

for non-prolapse indications (breast cancer, rapidly enlarging fibroids, BRCA gene positivity).

**Discussion**

These biomechanical pelvic support outcome data are the first to compare traditional vaginal hysterectomy–uterosacral cuff suspension to an identical vaginal hysteropexy adaptation, showing no durability advantage between the groups. This new vaginal uterosacral hysteropexy method of uterine resuspension expands the surgical options and outcomes counseling for women considering uterine prolapse surgery, women whose salient concerns typically include “how long it will

**Table 2** Grade of prolapse before surgery and postop recurrence rates

Compartment	Hysterectomy			Hysteropexy			p value <sup>a</sup>	Recurred		p value <sup>b</sup>
	Mean±SD	Median	N	Mean±SD	Median	N		Hysterectomy	Hysteropexy	
Uterus	2.68±0.71	3.00	100	2.62±0.58	3.00	100	0.51	3	3	0.90
Cystocele	2.84±1.02	3.00	87	2.91±0.91	3.00	96	0.82	6	9	0.31
Rectocele	1.84±0.92	2.00	87	2.29±0.77	2.00	97	0.0001	0	2	0.16

SD standard deviation

<sup>a</sup>Wilcoxin rank-sum test

<sup>b</sup>Log-rank test

**Table 3** Perioperative complications

Complication	Hysterectomy ( <i>n</i> =100) <i>N</i> (%)	Hysteropexy ( <i>n</i> =100) <i>N</i> (%)
Hemorrhage	3	4
Cystotomy	3	0
Ureteric obstruction	2	0
Pericervical dehiscence	0	1
Rectal enterotomy	1	1

last” and whether or not the uterus “should be removed” or “really needs to be removed” [6–13].

The primary goal of this paper is to compare biomechanical outcomes of all compartments in hysteropexy and hysterectomy cohorts to see how the mechanical retention or removal of the uterus accomplished by fairly identical suspension technique affected the entirety of pelvic organ support durability. This new native tissue hysteropexy is a low-tech, vaginal method of uterine resuspension that avoids the sacrospinous ligament and cervical amputation, adding to the armamentarium of minimally invasive uterine prolapse surgery options.

These prolapse surgery durability data are similar to prior studies of uterosacral ligament suspensions, including Shull's uterosacral cuff fixation, reporting 5% grade 2 or greater persistent or recurrent support defects in any compartment in 289 patients [9]. Kohli reported 0% failure in 25 laparoscopic uterosacral hysteropexy patients and 3 (12%) recurrences in 25 vaginal hysterectomy patients, with essentially no recurrence of cystocele and rectocele [10]. Similarly, de Boer's group reported no recurrence in the cervical amputation–modified Manchester hysteropexy group, and 4% “middle compartment” recurrence in the hysterectomy group at 1 year, with no recurrence of severe cystocele or rectocele and approximately 50% recurrence of POP-Q stage 2 cystocele and rectocele, mostly asymptomatic [11]. By comparison, our hysteropexy and hysterectomy apex durabilities (approximating POP-Q points D and C, respectively) were similar to these uterosacral ligament suspension studies with 4% and 3.2% recurrence, respectively, also showing highest recurrence among cystoceles, at 6% in the hysterectomy and 13% in the hysteropexy group at 2 years ( $p=0.31$ ). Our minimal rectocele recurrence may be due to the classic fascial levatorplasty technique employed. Both rectocele recurrences occurred in women suffering from chronic constipation. We find detailed discussion of recuperation expectations and the use of Valium suppositories, similar to protocols for vaginismus and dyspareunia, to be of value in the postoperative management of midline fascial levatorplasty colporrhaphy [14, 15].

Thus far, three hysteropexy patients returned for hysterectomy, one for personal history breast cancer, another for

BRCA+testing, both at the request of the managing oncology team, and a third for rapidly enlarging fibroids. Each underwent vaginal hysterectomy with no technical challenges or complications presented by the preceding vaginal uterosacral hysteropexies.

All uterosacral hysteropexy recurrences of uterine prolapse occurred within 3 months of the operation, with recurrence in all three compartments in two of the three. The possibility of “rapid recurrence” using this uterosacral uterine resuspension technique is included in preoperative counseling.

Two patients in the vaginal hysterectomy group sustained unilateral ureteric impingement, one diagnosed cystoscopically on completion of uterosacral suspension, with no efflux noted from the affected orifice. Brisk efflux resumed with immediate removal and replacement of the suspension sutures on the ipsilateral side, with brisk efflux noted again after completion of the revised cuff suspension, after which the remainder of planned pelvic floor procedures were completed with no postoperative sequelae. The second patient was diagnosed on postop day 2; despite apparent efflux from the affected ureter intraoperatively, the obstruction required antegrade stent placement through a nephrostomy port. Since stent removal, renal function and sonographic anatomy remain normal 4 years later.

Nulliparas comprised 3.5% of the study population. The single premenopausal nullipara has since given birth at term by elective cesarean section, conceiving 1.5 years after hysteropexy. She originally presented with grade 3 uterine prolapse without cervical hypertrophy, cystocele, or rectocele. Throughout the pregnancy and at 6 weeks postpartum, she remains prolapse-free, with plans to continue annual pelvic support monitoring examinations.

Given the growing body of data evaluating the form and function of levator muscles as regards pelvic organ prolapse, levator muscle bulk and voluntary contraction score data are reported here, similar in both VH and USH cohorts [16, 17]. A validated technique of voluntary levator muscle contraction was used [2].

Weaknesses of this manuscript include use of traditional Baden–Walker [1] system for prolapse grading instead of the contemporary POP-Q method. With follow-up reaching back 10 years, we used Baden–Walker [1] for the sake of consistency. Yet to be summarily dismissed from pelvic organ prolapse outcome measure tools, Baden–Walker is still commonly cited, albeit with ever decreasing frequency, in works from the USA and, more commonly, from manuscripts generated outside the USA. While the POP-Q is of arguable superiority, it is cumbersome and was highlighted among a short list of disliked outcome measures in one recent survey of the Society for Urodynamics and Female Urology (SUFU) [18]. This survey included the Baden–Walker [1] system, currently in use by 38% of SUFU respondents and conspicuously absent from the “disliked outcome measures” group.



Other weaknesses include the retrospective design and demographic differences, with the hysterectomy group including women who were older, heavier, and more frequently menopausal. Despite these factors, which may, but have not been clearly shown to, affect reconstructive pelvic surgery integrity, the outcomes between the groups were similar, with the hysterectomy patients skewing toward superior durability of cystocele repair, although this difference was not statistically significant ( $p=-0.31$ ). The skew in our population echoes de Boer's recent work, in which the vaginal hysterectomy group had higher grade of preoperative global pelvic organ prolapse [11]. Avoiding some element of demographic and/or clinical skew when comparing hysterectomy to hysteropexy groups is indeed challenging, but perhaps less so than prospective randomization of the prolapsed uterus, as detailed in one prospective randomized trial of sacrospinous fixation hysteropexy vs. hysterectomy in which only 17% of eligible candidates agreed to randomized removal or retention of the uterus [13]. Nevertheless, as with any retrospective analysis, a prospective randomized study would improve accuracy of outcomes analysis, as would longer term of follow-up.

Used increasingly in cardiovascular, orthopedic, and soft tissue plastic surgical outcomes data, Kaplan–Meier survival analysis follows participants beginning at a certain starting point until such time that an event of interest occurs, such as prolapse recurrence. We propose increased adoption of Kaplan–Meier probability estimates in evaluating durability of pelvic floor disorder therapies.

In conclusion, no significant durability difference was demonstrated between hysteropexy and hysterectomy groups in any compartment in 200 women with uterine prolapse who underwent either removal or resuspension of the prolapsed uterus. Uterosacral hysteropexy is a new vaginal prolapse operation that uses the uterosacral ligaments for uterine resuspension in a fashion similar to uterosacral vaginal cuff suspension. This study expands the challenge to the tradition of mandatory hysterectomy for uterine prolapse, a hysterectomy indication that, by itself, may be obsolete [6, 7, 8, 10, 11, 12, 13].

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**Conflicts of interest** None.

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