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#### Abstract

outcomes

**Background:** Our aim was to investigate longer-term surgical and quality of life (QOL) outcomes in a cohort of women undergoing robotic-assisted laparoscopic sacrocolpopexy (RALS) for pelvic organ prolapse (POP).

Robotic sacrocolpopexy for the management

of pelvic organ prolapse: quality of life

**Methods:** We performed a retrospective cohort study at a single institution of female patients undergoing RALS with and without concomitant robotic-assisted laparoscopic hysterectomy, urethral sling, and rectocele repair. Scores from the Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ) surveys were used to evaluate QOL outcomes. Clinical improvement was defined by a decrease in a patient's PFDI and PFIQ postoperative score by  $\geq$ 70%.

**Results:** Clinical improvement was seen in 62.6% by the PFIQ and in 64% by the PFDI survey. Younger patient age (OR 0.92, p = 0.011) and worse preoperative American Urological Association (AUA) Quality of Life score (OR 1.42, p = 0.046) were associated with clinical improvement. Within the PFIQ, 35.6% of patients saw clinical improvement with their bowel symptoms, compared with bladder (54.1%, p < 0.001) and prolapse (45.6%, p = 0.053) symptoms. Within the PFDI, 45.5% of patients reached clinical improvement with their bowel symptoms, compared with bladder (56.7%, p = 0.035) and prolapse (62.6%, p < 0.001) symptoms. Of the patients who had a rectocele repair, 46.3% reached clinical improvement in their CRADI-8 score, and 51% saw clinical improvement in the bowel portion of the PDFI. **Conclusions:** Significantly fewer patients reached clinical improvement within the portions of the surveys that focus on bowel symptoms, compared with symptoms related to urination and POP. Of those that had a concomitant rectocele repair, approximately half reached clinical improvement with their bowel symptoms.

Keywords: pelvic organ prolapse, quality of life, sacrocolpopexy

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#### Introduction

Approximately 3% of women will have symptomatic pelvic organ prolapse (POP) in their lifetime,<sup>1</sup> and, in the United States alone, 200,000 surgical repairs for POP are performed annually.<sup>2,3</sup> Defined as the descent of the vaginal cuff or cervix, apical vaginal prolapse can be associated with prolapse of the anterior and posterior vaginal compartment. In clinical practice, these anatomic changes are often associated with not only symptoms of vaginal bulging, but also with pelvic floor dysfunction symptoms, such as urinary urgency, incontinence, and obstruction.<sup>4,5</sup> Symptoms related to bowel function are also commonly experienced, such as fecal incontinence and obstruction.<sup>4,5</sup>

Robotic-assisted laparoscopic sacrocolpopexy (RALS) is a commonly performed surgical procedure for apical POP. To address other associated pelvic floor symptoms, oftentimes, concomitant surgeries such as rectocele repair to address

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1

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prolapse of the posterior compartment, and urethral sling placement to surgically treat or prophylactically occult prevent occult stress urinary incontinence (SUI).

The aim of our study was to investigate the longer-term quality of life (QOL) outcomes in terms of prolapse, bladder, and bowel symptoms in a cohort of women undergoing RALS for apical POP, with and without concomitant rectocele repair and distal urethral sling placement.

#### **Materials and methods**

We performed a retrospective analysis of all women undergoing RALS for symptomatic apical POP November 2010–June 2015 at a single institution by one female pelvic medicine and reconstructive surgery (FPMRS) fellowship-trained urologist. Demographic variables, initial history, preoperative and postoperative physical examination, and preoperative and postoperative QOL questionnaire data collection was collected.

Outcomes included objective data analysis obtained by Baden-Walker (B-W) preoperative POP grading and subjective data retrieved from self-reported QOL validated questionnaires administered preoperatively and postoperatively. Questionnaires were completed in the waiting room before the history and physical examination and without the influence of health care providers. The B-W grading system was used over the Pelvic Organ Prolapse Quantification (POP-Q) system due to the surgeon's preference. The B-W grading system consists of 4 grades: grade 0, no prolapse; grade 1, halfway to hymen; grade 2, to hymen; grade 3, halfway past hymen; and grade 4, maximum descent.<sup>6</sup> When assessing objective data by B-W grading, clinical improvement (clinical significance) was determined if there was no apical prolapse recurrence (grade 0/1).

Scores from the Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ) surveys were used to evaluate QOL outcomes. The Pelvic Floor Impact Questionnaire (PFIQ) and the Pelvic Floor Distress Inventory (PFDI) were selected because they represent a reliable and valid tool to assess QOL in women with pelvic floor disorder.<sup>6–8</sup> The PFDI is comprised of three subscales assessing the severity of symptoms related to prolapse (POPDI-6), colorectal (CRADI-8), and urinary (UDI-6) bother.

The PFIQ is also structured with three comparable subscales: prolapse, colorectal, and urinary symptoms. Each survey was evaluated by the total score (TS) range and their three respective subscales.<sup>9</sup>

To assess the subjective outcomes, we calculated the improvement rate for each questionnaire. Clinical improvement was defined by a decrease in a patient's PFDI and PFIO postoperative score by  $\geq$ 70%. We selected the improvement threshold of 70% or more to assess OOL data based on other studies that have used this cutoff when assessing validated questionnaires, such as the 2012 Value of Urodynamics Evaluation trial.9-11 The American Urological Association (AUA) Symptom Score on QOL was also used, asking specifically, 'How would you feel if you had to live with your current condition for the rest of your life?' Higher scores represent worse QOL (range, 0-6). Questionnaires were completed in the waiting room before the history and physical examination, and without the influence of any health care provider.

Robotic sacrocolpopexy was performed using the Da Vinci Si robot (Intuitive, Sunnyvale, CA, USA) by a single fellowship-FPMRS-trained surgeon. We perform the RALS as previously described in Barboglio and colleagues.<sup>10</sup> Once the robotic arms are undocked, the fascia was closed at camera port site, and then skin was closed.

In patients with symptomatic SUI, or who desired a prophylactic procedure for occult SUI, a distal urethral polypropylene sling was placed.<sup>12</sup> Per surgeon preference, distal urethral sling, instead of a midurethral sling, was performed using the Raz technique to help prevent proximal migration and recurrent stress urinary incontinence.<sup>12</sup>

Concomitant posterior compartment defect repairs were performed if present and symptomatic preoperatively Rectoceles were repaired *via* the midline, transvaginal approach. Hydrodissection was performed, and a vaginal midline epithelial incision made just past the proximal aspect to the rectocele. The epithelium was dissected off the rectovaginal tissue. The deficient rectovaginal fascia was repaired cranial to caudal, using interrupted polyglactin suture, with careful attention to avoid placating the levator muscles. Perineorrhaphy was then performed if indicated.

Patients were subsequently evaluated postoperatively at 2weeks, and then at 3, 6, and 12months,

# Table 1. Demographics.

	All patients <i>N</i> = 205	Patients with complete pre- and postoperative survey data <i>N</i> = 179	p value			
History and physical variables	n (%)	n (%)				
Age, mean	58.72	58.95	0.913			
BMI, mean (SD), kg/m²	29.30	28.40	0.957			
Diabetes	12 (5.9)	11 (6.1)	0.934			
Menopause	162 (79.0)	141 (78.8)	0.961			
Oral estrogens	15 (7.3)	14 (7.8)	0.853			
Prior prolapse repair	31 (15.1)	28 (15.6)	0.892			
Current smoker	21 (10.3)	18 (10.1)	0.950			
OAB	22 (10.8)	17 (9.5)	0.675			
SUI	36 (17.2)	34 (19.0)	0.647			
MUI	109 (53.2)	98 (54.7)	0.769			
Use of pessary	85 (41.5)	73 (40.8)	0.890			
Parity ≥2	186 (90.7)	164 (91.6)	0.757			
Urethral hypermobility	171 (83.4)	155 (86.6)	0.383			
RML Rody mass index: MIII, mixed incontinence: OAR, overactive bladder: SIII, stress urinary incontinence						

and then annually unless issues arose. Both postoperative questionnaire data and postoperative physical exam data were collected from the most recent clinic appointment.

Data collection was performed in Microsoft Excel (Microsoft Corporation, Redmond, WA, USA). Data analysis and graphing was performed using SPSS Version 23. Chi square analysis was used to assess differences between categorical variables. For numerical variables, a *t*-test for difference in means was used. A logistic regression analysis was performed to investigate what demographic and medical factors are associated with those women who did, and did not, reach clinical improvement.

# Results

A total of 205 patients from November 2010 to June 2015 were included in our review, with a mean follow-up time of 23 months (1–84 months, SD 19.2) and a median follow-up time of 15 months. Patient mean (SD) age was 58.7 (10.6) years, mean (SD) body mass index (BMI) was 29.3 (14.2) kg/m<sup>2</sup>. Complete pre- and post-operative survey data was available in 179 patients. Demographic data from the total 205 patients, as well as the 179 with complete pre- and postoperative survey data, is displayed in Table 1. No significant differences were seen between these two groups, making the 179, with complete pre- and postoperative survey data, a representative sample.

Subjective data (Table 2) revealed clinical improvement ( $\geq$ 70% decrease) on PFIQ TS in 62% of patients. When assessing the subscales of bladder, bowel, and prolapse categories, there was clinical improvement ( $\geq$ 70% decrease) in 61.7%, 35%, and 45.6% of patients, respectively. Within the PFIQ, an additional 21.8% of patients had an improvement in their postoperative TS, but not at our defined clinical significance of  $\geq$ 70%, while 8.9% had no change in their postoperative TS, and 6.8% had an increase in their postoperative TS, thus suggesting worse symptoms.

Questionnaire	Status	Score	Scale	Median	Interquartile	Improvement ≥70%, <i>n</i> , (%)
PFIQ-7	Preoperative	0–100	Bladder	33.33	14–57	
	Preoperative	0–100	Bowel	4.76	0–29	
	Preoperative	0–100	Pelvis	14.28	0-43	
	Preoperative	0-300	TS	57.14	24-114	
	Postoperative	0–100	Bladder	0	0–13	111 (61.7)
	Postoperative	0–100	Bowel	0	0-8	64 (35.6)
	Postoperative	0–100	Pelvis	0	0-0	82 (45.6)
	Postoperative	0-300	TS	4.17	0–25	111 (62.6)
PFDI-20	Preoperative	0–100	POPDI-6	33.33	17–58	
	Preoperative	0–100	CRADI-8	18.75	0–38	
	Preoperative	0–100	UDI-6	37.50	21–58	
	Preoperative	0-300	TS	102.81	46-143	
	Postoperative	0–100	POPDI-6	4.20	0–13	115 (64.6)
	Postoperative	0–100	CRADI-8	3.13	0–13	81 (45.5)
	Postoperative	0-100	UDI-6	4.17	0–17	101 (56.7)
	Postoperative	0-300	TS	19.80	6-44	114 (64.0)
RAL, robotic-assisted laparoscopic; TS, total score.						

Table 2. Questionnaire data results at last follow-up s/p RAL-sacrocolpopexy in women with symptomatic apical prolapse.

Clinical improvement on PFDI TS was reached in 64% women. Individual categorical analysis of prolapse (POPDI-6), colorectal (CRADI-8), and the short version of the urinary distress inventory (UDI-6) revealed clinical improvement in 64%, 45.5%, and 56.7%, respectively. Within the PFDI, an additional 25.4% of patients had an improvement in their postoperative TS, but not at our defined clinical significance, while 1.7% had no change in their postoperative TS and 9% had an increase in their postoperative TS, thus suggesting worse symptoms.

Subanalysis was performed to evaluate factors associated with those women who did, and did not, reach clinical improvement ( $\geq$ 70% decrease) on both the PFDI and PFIQ TS. There were 33 patients who failed to improve in both questionnaires, and 146 who clinically improved in either the PFDI or PFIQ questionnaire. Table 3 illustrates the demographics of these two groups. Average age and a higher preoperative AUA symptom score were significantly different between the two groups (p=0.010, 0.017, respectively). Logistic regression was performed with the odds ratio results also displayed in Table 3. Only younger patient age (OR 0.92, p=0.011) and a higher preoperative AUA QOL score (OR 1.42, p=0.046) were still associated with clinical improvement.

When assessing the objective anatomical outcomes, we compared postoperative physical exam data between those who reached clinical significance for total score in both surveys versus and those who did not. There was no significant difference in the pre- and postoperative anatomic POP B-W grading between those who reached clinical significance and those who did not. Thus, there was no association between objective and subjective outcomes.

Table 4 compares the rates of clinical improvement between the bowel, pelvis, and bladder categories

Demographic variables	Clinical improvement	No clinical improvement	p value	Odds ratio, <i>p</i> value (CI)	
	n=146	n = 33	-		
Age, mean, years (SD)	58.03 (10.22)	63.15 (9.79)	0.010	0.92, 0.011 (0.86–0.98)	
BMI, kg/m², mean (SD)	28.11 (5.77)	29.67 (5.07)	0.182	0.96, 0.279 (0.88–1.04)	
Diabetes	9	2	0.982	1.42, 0.780 (0.12–16.46)	
Menopause	113	28	0.344	2.57, 0.242 (0.53–12.57)	
Oral estrogens	12	2	0.677	2.0, 0.435 (0.35–11.5)	
History of prior prolapse repair	23	5	0.931	0.76, 0.667 (0.22–2.64)	
Smoker	59	14	0.946	0.81, 0.639 (0.34–1.95)	
OAB	14	3	0.921	1.15, 0.873 (0.22–6.06)	
SUI	29	5	0.523	1.33, 0.712 (0.3–5.93)	
Μ	76	18	0.825	0.91, 0.868 (0.3–2.73)	
Parity ≥2	134	30	0.87	1.47, 0.622 (0.32–6.73)	
History of pessary usage	61	12	0.567	1.48, 0.412 (0.58–3.78)	
Preoperative AUA-QOL, median	5 (3–5)	4 (3–5)	0.017	1.42, 0.46 (1.01–2.01)	
Urethral hypermobility	128	27	0.908	0.74, 0.697 (0.17–3.33)	
Preoperative POP grade (B-W)					
Anterior POP G >2	123	26	0.616	1.65, 0.452 (0.45–6.13)	
Apical POP G $>2$	80	18	0.943	0.83, 0.707 (0.32–2.17)	
Posterior POP G >2	53	10	0.571	1.54, 0.380 (0.59–4.07)	

**Table 3.** Preoperative demographic variables of women based on clinical improvement ( $\geq$ 70%) on subjective data at last follow-up.

IQ, interquartile range (25%Y75%); MUI, mixed incontinence; OAB, overactive bladder; P, Parity; RASCH, robotic supracervical hysterectomy (concomitant surgery); SUI, stress urinary incontinence.

of the PFIQ and the PFDI In both surveys; there were significantly fewer patients who reported an improvement in their bowel symptoms, compared with the pelvis and bladder symptoms.

Lastly, we compared rates of bowel symptom improvement in those who underwent rectocele repair compared with those who did not. As displayed in Table 5, of the 19 patients who had a concomitant rectocele repair and complete preoperative and postoperative PFDI data, 46.3% reached clinical improvement in their CRADI-8. Of the 21 patients who had a concomitant rectocele repair and complete preoperative and postoperative PFIQ data, 51.2% saw clinical improvement in the bowel portion.

### Discussion

There have been several studies assessing results after robotic sacrocolpopexy.10,13,14 Gupta and colleagues showed only two apical recurrences in 196 women undergoing robotic prolapse repair, with a mean follow-up time of 9 months.<sup>13</sup> Other studies, too, have shown improvement in QOL scores using the PFDI and the PFIQ.14-18 In a recently published study by Jong and colleagues, following robotic mesh sacrocolpopexy of 56 women with a mean follow-up time of 3 years, mean AUA QOL score improved significantly from a mean of 4-1.78 postoperatively. However, the mean UDI-6 score did not improve to a level of statistical significance (5-4.59, p=0.40).<sup>14</sup> In a mean 12-month follow-up time, Geller and colleagues report a decrease in PFDI TS from 117 to

### Therapeutic Advances in Urology 11

Table 4. PFIQ-7 and PDFI-20 subscore improvement results.

PFIQ-7 subscores							
	Bladder	Bowel	p				
Improvement ≥70%, <i>n</i> , (%)	111 (54.1)	64 (35.6)	<0.001				
	Pelvis	Bowel					
Improvement ≥70%, <i>n</i> , (%)	82 (45.6)	64 (35.6)	0.053				
	Pelvis	Bladder					
Improvement ≥70%, <i>n</i> , (%)	82 (45.6)	111 (61.7)	<0.001				
PDFI-20 subscores							
	POPDI-6	CRADI-8	p				
Improvement ≥70%, <i>n</i> , (%)	115 (64.6)	81 (45.5)	<0.001				
	UDI-6	CRADI-8					
Improvement ≥70%, <i>n</i> , (%)	101 (56.7)	81 (45.5)	0.035				
	UDI-6	POPDI-6					
Improvement ≥70%, <i>n</i> , (%)	101 (56.7)	115 (64.6)	0.127				

Table 5. Clinic improvement in bowel symptoms in those with concomitant rectocele repair.

	CRADI-8 subscale from PDFI-20				Bowel subscale of PFIQ-7			
	Clinical improvement (≥70% decrease)		No clinical improvement		Clinical improvement (≥70% decrease)		No clinical improvement	
	Count	Row N%	Count	Row N%	Count	Row <i>N</i> %	Count	Row N%
No rectocele repair	62	45.3%	75	54.7%	43	30.9%	96	69.1%
Rectocele repair	19	46.3%	22	53.7%	21	51.2%	20	48.8%
Total	81	45.5%	97	54.5%	64	35.6%	116	64.4%

38, and a decrease in PFIQ TS from 60 to 10. However, this study did not report differences in individual subscores.<sup>16</sup> In their follow-up study from 2012, with a mean follow-up time of 44 months, PFDI TS increased back 61 and the PFIQ score increased to 19.1, reflecting worsening symptoms the further out from surgery.<sup>19</sup> Concomitant procedures were not reported in these studies. Paraiso and colleagues showed a decrease in 1-year postoperative PFDI TS to 44 from 128, with a dramatic decrease in prolapse score to 6 from 50, and a decrease in bowel subscore to 18 from 31, and urinary symptoms from

44 to 18. Interestingly, PFIQ score showed a drastic decrease to 0 from  $63.^{17}$ 

Our decision to perform a rectocele repair was based on clinical symptoms preoperatively (such as difficulty with defecation, rectal pressure, sense of incomplete rectal emptying after a bowel movement) and anatomic physical exam at the time of apical repair. Our concomitant rectocele repair rate of 24.4% is slightly higher than those reported in a 2014 meta-analysis of 13 studies, showing that 18.5% of patients have a rectocele repair at the time of robotic sacrocolpopexy.<sup>15</sup> However, in a Paraiso's cohort of 40 robotic sacrocolpopexy cases, rectocele was performed in 29% of patients.<sup>17</sup>

The decision to place a prophylactic urethral sling at the time of sacrocolpopexy for occult SUI is well-supported by the results of the Pelvic Floor Disorders Network randomized control trial.<sup>20</sup> However, the decision to perform a prophylactic rectocele repair for asymptomatic posterior vaginal wall prolapse at the time of sacrocolpopexy has not yet been studied. The Pelvic Floor Society (TPFS) recently conducted a systematic review of evidence for the perioperative and long-terms benefits and harms of recto-vaginal reinforcement procedures, which concluded that the current available evidence was characterized almost exclusively by observational studies with poor methodological quality and heterogeneous findings.<sup>21</sup> This suggests that higher quality studies are needed to further investigate the symptomatic and OOL outcomes after rectocele repair.

The difference in postoperative bowel symptoms as compared with the prolapse and bladder symptoms was not as pronounced in our study. This held true for both the PFIQ and the PFDI. This is useful information for preoperative counseling in patient considering RALS. If bowel symptoms, such as splinting to have bowel movements, are the predominant symptomatic complaint in women with apical POP, they should be counseled that their bowel symptoms may not improve as much as prolapse or urinary symptoms. In those who did not have a rectocele repair, fewer patients reached clinical improvement (≥70% decrease) in their bowel symptoms subscores on both the PFDI and PFIQ, at 45.3% and 30.9%, respectively. This trend held true for those who had a rectocele repair, though with less discrepancy, as clinical improvement was reached in 46.3% based on their CRADI-8 score and 51.2% based on their bowel subscore of the PFIQ. The improvement in bowel symptoms, even in those patients who did not have a rectocele, may have contributed to the repair of the apex alone.

There have been other studies that show that the extent of the posterior vaginal prolapse does not correlate with the severity of symptoms. Gutman and colleagues showed in their cohort of 296 patients that the maximum vaginal decensus of 0 cm or more distal to the hymenal remnant was the threshold at which bulging and protrusion symptoms occur, but prolapse severity was not predictor of bowel symptoms based on the CRADI-8.<sup>22</sup>

Interestingly, the severity of POP based on preoperative POP B-W grade was not associated with clinical improvement ( $\geq$ 70% decrease) of survey scores. We did not find an association between POP grading system on either subjective or objective outcomes. However, we recognize that the POP-Q system of examination, not the B-W grading system, is the currently recommended physical examination grading system.

Limitations of our study include the retrospective nature of the study. We feel the fact that all procedures were performed by a single FPMRStrained surgeon using the same surgical technique is a strength, as well our longer-term follow-up. In addition, we did include a strict  $\geq$ 70% decrease in survey scores to define clinical significance. Minimally important differences in the urinary symptom subscores of the PFIQ and the PFDI have been reported,<sup>23</sup> but this data is not yet available for the subscores of the prolapse and bowel symptoms.

Currently there are no specific clinic guidelines from the AUA, Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) or the American Urogynecologic Society (AUGS) as to the surgical repair apical prolapse and the use of concomitant surgeries for the rectocele repair and SUI. While several studies have addressed the association of urinary and bowel symptoms with pelvic organ prolapse,4,5,24 to our knowledge, this is the largest study of its kind to specifically assess postoperative bowel function symptoms, compared with prolapse and urinary symptoms, in patients who have undergone RALS with or without rectocele repair. In summary, most patients undergoing RALS saw clinical improvement overall. However, there were significantly fewer patients who reached clinical improvement with their bowel symptoms, compared with urinary and prolapse symptoms, regardless of concomitant rectocele repair. This suggests bowel dysfunction cannot be treated with anatomic repair alone, which can be helpful when counseling patients preoperatively regarding expectations of improving pre-existing bowel symptoms after sacrocolpopexy.

#### Authors' note

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### Author contributions

AJ Vollstedt: project development, data collection and management, data analysis, manuscript writing editing

W Meeks: project development, data analysis, manuscript writing

V Triaca: project development, data collection and management, data analysis, manuscript writing editing

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#### **Conflict of interest statement**

The authors declare that there is no conflict of interest.

## **Ethical statement**

Our study was exempt from ethical board approval at Concord Hospital, New Hampshire because it did not contain identifying information and involved the collection of existing data.

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