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Prospective assessment of patient-reported outcomes in gynecologic cancer patients before and after pelvic exenteration

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Abstract

Objective—Pelvic exenteration (PE) is a surgical procedure associated with significant morbidity offered to select women with locally advanced or recurrent gynecologic cancers. This ongoing study examines an array of patient-reported outcomes and satisfaction with PE.

Methods—Since February 2009, prospectively enrolled participants completed questionnaires evaluating body image (BIS), depression (CESD), social support (DUFSS), symptoms (MDASI), sexual function (SAQ), functional status (SF-12), quality of life (The Stoma-QOL), satisfaction with decision (SWD) and an investigator-designed survey at baseline, 6, and 12 months after PE. Mann-Whitney and Wilcoxon signed-rank tests were used to evaluate the data.

Results—Fifty-four women enrolled. Median age was 56 years (31, 85). Median BMI was 30.7 kg/m² (16.8, 54.4). The majority of patients (78%) were white. Cancer diagnoses included 41% cervix, 22% uterus, 19% vagina, 17% vulva and 2% ovary. Most surgeries were total PEs (76%).

Patients were satisfied with their decision to undergo PE at 6 and 12 months. One year after exenteration, 79% of women stated they would have a PE again. Sexual pleasure decreased from baseline to 12 months after PE ($p=.02$), while sexual discomfort remained unchanged ($p=.42$). Body image worsened over time ($p=.003$). Physical functioning (SF-12) declined ($p=0.001$), while mental functioning remained stable ($p=.46$). There were no significant changes in stoma-related QOL, social support, or depression scores.

Conclusions—Despite a decrease in physical functioning, persistent low body image and sexual pleasure, most women were satisfied with their decision and would undergo pelvic exenteration again. This study identifies survivorship issues that should be addressed after PE.

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CONFLICTS OF INTEREST

None of the authors have any relevant financial interests or conflicts to disclose.

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Keywords

Patient-reported outcomes; pelvic exenteration; quality of life; survivorship

Introduction

Pelvic exenteration (PE) was first described in 1948 as the removal of the pelvic viscera en bloc for persistent or recurrent gynecologic cancer [1]. The procedure is currently used for advanced primary or locally recurrent cancers to provide curative care for women with isolated central disease [2–4]. PEs are classified as total or partial (anterior or posterior) based on the level of surgical involvement. All PEs are extensive operations resulting in the removal of the vagina and formation of at least one permanent stoma [5].

Due to the extensive nature of the surgery, physical and mental complications are common [6]. Major surgical complications, such as anastomotic leaks, fistulas, infections, and small bowel or ureteral obstructions occur in 40–50% of procedures while minor complications occur in 80–94% of cases [4, 7]. The 5-year overall survival following a PE is 40–63% [7–9]. Given the well-documented morbidity associated with the procedure, researchers have sought to understand these patients' post-operative quality of life (QOL) [10–12].

PE impacts a wide array of QOL concerns including sexual health, body image, symptoms, communication, social issues, psychological distress, and relationship issues [13]. Patient-reported outcomes (PROs) are one way to assess these issues. PROs in oncology represent how patients feel and function by inquiring about symptoms related to disease or treatment, physical functioning, and QOL factors [14]. A QOL assessment using PROs should include a prospective approach, accounting for baseline differences, and a wide-reaching compilation of questionnaires. Research using this comprehensive evaluation of pelvic exenteration outcomes is limited. The majority of the data have been collected from retrospective studies [13]. Although prospective data exist, limitations exist based on sample size [15, 16], lack of comparison pre-operative data [17], or utilization of limited or non-validated questionnaires [18–20]. Furthermore, studies have yet to examine patient perspectives on their decision for surgery and if they would make the same decision again. Therefore, the aim of this prospective longitudinal study was to assess a diverse array of PROs for gynecologic patients during the first year after their PE.

Methods

Study Design

This prospective, longitudinal study was approved by the Institutional Review Board at The University of Texas MD Anderson Cancer Center and is ongoing. Patients scheduled for a pelvic exenteration in the Department of Gynecologic Oncology and Reproductive Medicine were identified pre-operatively and approached to participate in this longitudinal study. Patients consented to complete a series of questionnaires from preoperative assessment to ten years post-operation or death. This report represents an interim analysis of PROs

collected preoperatively (baseline) as well as at 6 months and 12 months after pelvic exenteration.

Since February 1, 2009, patients scheduled for pelvic exenteration have been identified through the Gynecologic Center database and by physician referral. Inclusion criteria required a history of gynecologic malignancy and associated plan for PE, age greater than 18 years, English or Spanish proficiency, and a willingness to complete self-administered PRO questionnaires. Eligible patients were offered enrollment at their pre-operative clinic appointment by the research team. Patients enrolled on the study provided written informed consent. Preoperative demographic and clinical data were abstracted from the medical record. Patients were asked to complete PRO instruments prior to undergoing PE. Patients whose PE was aborted due to the discovery of distant metastasis or unresectable disease at the time of surgery were removed from the study. Patients were considered eligible for questionnaire participation until their consent was withdrawn or death.

At baseline, six months and 12 months after PE, patients were approached at their regular clinic visits to complete all PRO surveys except for sexual function which was measured at baseline and 12 months. PRO surveys were completed in person during regular clinic visits or were mailed to patients in a prepaid envelope with return mailing materials. If surveys were not returned within one month of mailing, a study staff member called patients and offered the opportunity to provide responses via the telephone.

PRO Measures

The issues affecting gynecologic oncology patients who undergo exenteration patients are multi-faceted and complicated. Since a comprehensive, validated PRO instrument has not yet been developed for this patient population, we included several validated measures to address a wide array of patient issues:

- Patient satisfaction surrounding decision for exenteration was determined using the Satisfaction with Decision Scale (SWD), with a score of 6 indicating poor satisfaction and 30 representing complete satisfaction [21].
- An investigator-developed questionnaire was designed to assess patients' perspectives on their decisions for undergoing PE. For example, "If given the opportunity, would you choose an exenteration again?", (possible answers include "I would choose an exenteration again", "I would not choose an exenteration again", or "I am unsure about undergoing an exenteration again").
- Stoma-related QOL was assessed using The Stoma-QOL, a 20-item validated scale developed to assess quality of life with regards to bowel reconstruction stoma and bladder reconstruction stoma. Higher scores indicate better QOL; the max score is 80 [22].
- The Sexual Activity Questionnaire (SAQ) is composed of three components, pleasure, discomfort and habit. Pleasure scores range from 0 (no desire, enjoyment) to 18 (very enjoyable, more desire), while discomfort scores range from 0 (no discomfort) to 6 (severe discomfort). Finally, a habit scores of 0

indicates “less than normal” amount of sexual activity and 3 indicates “much more” than usual sexual activity [23].

- The Body Image Scale (BIS) assesses body image changes with scores ranging from 0 to 30, where 0 indicates no distress and 30 specifies a high-degree of symptoms or stress. Scores of 8 or below suggest poor body image [24].
- Social support was determined using Duke-UNC Functional Social Support Scale (DUFSS), with a score of 0 signifying poor social support and 5 designating high social support [25].
- Depression was assessed using the Center for Epidemiologic Studies-Depression Scale (CES-D), with scores ranging from 0 to 60. Higher scores suggest more severe depression and a score of 16 or greater identifies possible depression [26]. The principle investigator and primary attending physician were notified within 24 hours of receiving a questionnaire with a score of higher than a 16. The primary attending made an assessment of suicide risk and made recommendations according to the severity of the situation.
- Functional status was evaluated using the 12-Item Short Form Survey (SF-12), which includes a physical component score (PCS) and a mental component score (MCS). Scores span 0 to 100, with 0 indicating the lowest level of health and 100 representing the highest health level [27].
- The MD Anderson Symptom Inventory (MDASI) was used to determine how the patient’s symptoms interfered with her well-being. The MDASI consists of 13 core symptom items (pain, fatigue, nausea, sleep disturbance, distress/upset, shortness of breath, memory, appetite, sleepiness, dry mouth, sadness, vomiting, and numbness/tingling) and 6 interference items (work, general activities, walking ability, relations with others, enjoyment of life, and mood). MDASI interference scores are comprised of physical and emotional interference subscale scores. Items are rated from 0 to 10, with 0 representing no symptom burden and 10 indicating maximal symptom burden [28].

Statistical analysis

Descriptive statistics were used to characterize clinical, demographic, and treatment information. Mann-Whitney, Wilcoxon signed-rank, and Kruskal-Wallis tests were used to compare data at individual time points. *P*-values were two-sided and considered significant if the *p*-value was less than 0.05. Statistics were performed using IBM SPSS Statistics, version 23 (Armonk, NY: IBM Corp.). Data were collected and managed using REDCap (Research Electronic Data Capture) electronic data capture tools hosted at MD Anderson [29]. REDCap is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

Results

Between February 2009 and April 2017, 54 patients were consented for participation in the study prior to undergoing exenteration. Demographic and clinical characteristics are shown in Table 1. Median age at time of exenteration was 56 years (range 31, 85). Median BMI was 30.7 kg/m² (range 16.8, 54.4). The majority of patients (78%) were White and non-Hispanic (96%). Most participants (72%) were married or in a committed relationship at the time of enrollment. Cancer diagnoses included n=22 (41%) cervix, n=12 (22%) uterus, n=11 (19%) vagina, n=9 (17%) vulva and n=1 (2%) ovary. Total PE was the most common procedure performed (76%), followed by anterior PE (11%), and posterior PE (7%). Three cases (6%) were cancelled or aborted. Vaginal reconstruction in the total pelvic exenteration group included: n=32 (78%) vertical rectus abdominis myocutaneous flap, n=2 (5%) gracilis flap, and n=7 (17%) no vaginal reconstruction.

Patient participation, including the reasons participants became ineligible at each time point, is illustrated in Figure 1. Participation was determined by completion of at least one survey per time point. Loss of study eligibility occurred if a PE was not completed, death occurred, or consent was withdrawn. Patients were asked to complete their baseline PRO surveys approximately 1 to 7 days prior to undergoing exenteration. Of the 54 patients enrolled on the study at baseline, 43 women (79.6%) returned at least one questionnaire at baseline. By the 6-month postoperative time point, 41 of the 54 women remained eligible for our study. Thirty-four of these 41 patients returned at least one questionnaire for an 82.9% participation rate. At the 12-month time point, 37 patients remained eligible; 34 patients returned at least one survey for a 91.9% participation rate. The percentage of participants who completed each measure, at each designated time point is shown in Table 2. For each measure, 20–27 of participants were compliant at all time points.

Patient reported Outcomes

A summary of the median PRO scores for each measure, at each time point, is shown in Table 3. Median SWD scores did not differ between 6 months and 12 months post-operation (29.0 and 28.5, $p=0.42$). Among women who completed the investigator-designed survey, 27/33 (81.8%) reported that they would have a PE again at 6 months; the remaining women ($n=6$, 18.2%) were unsure if they would undergo the PE again. At the 12-month time point, 26/33 patients (78.8%) responded they would have a PE again, one person said she would not have the exenteration again, and the five remaining patients were unsure (Table 4).

Thirty-one women completed the Stoma-QOL at the 6-month time point while 27 women completed this questionnaire at the 12 month time point. There was no significant difference between scores for these two time points ($p=0.65$).

In regard to sexual health, women were asked to complete the SAQ at baseline (preoperatively), and again at 12 months after undergoing PE. Only 12/42 (28.6%) reported that they were sexually active at baseline. Of the 30 women who reported they were not sexually active, the most frequent reasons for sexual inactivity were a “physical problem which makes sexual relations difficult or uncomfortable” ($n=12$), and not having a partner ($n=12$), followed by lack of interest in sexual activity ($n=8$). Two patients did not give any

reasons for sexual inactivity. Of the 12 women who reported being sexually active at baseline, 5 patients (41.6%) were “somewhat” to “very satisfied” with their frequency of sexual activity in the past month. When asked in the past month how the frequency of “sexual activity compared with what is usual for you” (SAQ habit), responses showed that 7 patients reported “less than usual” frequency and 5 patients reported “about the same.” When asked “Was having sex an important part of your life this month?” 50.0% responded “somewhat” or “very much”, 25.0% said “a little”, and 16.7% of the women responded “not at all”.

Compared to baseline, percentage of women who reported being sexually active decreased (28.6% vs. 23.5%) one year after PE, but this was not statistically significant ($p=0.62$). Of the 26 women who reported not being sexually active, the most common reason for sexual inactivity (check all that apply) was a “physical problem which makes sexual relations difficult or uncomfortable” ($n=15$), followed by no interest in sex ($n=12$), lack of a partner ($n=7$), too tired ($n=7$) or other ($n=1$). Of the 8 women who reported being sexually active at 1 year, 5 (62.5%) were “a little” to “not at all” satisfied with the frequency of sexual activity, 2 were “somewhat” to “very much” satisfied, and 1 patient chose not to respond. From baseline to 1 year after PE, women reported reduced sexual pleasure ($p=0.02$), while sexual discomfort remained stable ($p=0.42$). There were no significant differences in the frequency of sexual activity from baseline to 1 year after PE ($p=1.0$). When asked about the importance of sexual activity, 100% responded “not at all” or “a little” and 0% “somewhat” or “very much” and one patient did not respond ($p=.04$).

Sexual activity was examined based on the presence or absence of a vaginal reconstruction for the 34 women who indicated their level of “sexual activity” one year after PE. Of note, the question did not provide a definition of sexual activity. Twenty-five had a vaginal reconstruction, while 9 did not. Of those with a vaginal reconstruction, 5 were sexually active, while 20 were not. Of the 9 women without a vaginal reconstruction, 3 were sexually active and 6 were not.

Body image declined significantly after PE. At the preoperative time point, 33% of women who completed the BIS had poor body image scores, defined as a score of 8 or below; at 6 months this percentage increased to 61%, and 12 months after exenteration, the percentage rose to 68% of patients reporting poor body image ($p=.004$).

To measure social support, patients completed the DUFSS at all 3 time points. There were no changes over time in the level of social support. DUFSS scores reflected consistently high levels of social support at all time points ($p=0.11$).

Depression scores were also stable over the study period. Across time points, median scores on the CES-D were 13, 12, and 13.5 at baseline, 6 months, and 1 year, respectively ($p=.78$). CES-D scores of 16 or higher suggest possible depression. The percentage of women with scores of 16 or higher prior to PE, and at 6 and 12 months after PE were 34.9%, 24.2%, and 38.2%, respectively ($p=0.39$).

Physical well-being, measured by the physical component score (PCS) of the SF-12, worsened over time. Specifically, PCS declined from baseline to the 6 months postoperative

time point ($p=.001$). PCS remained essentially unchanged from 6 months to 12 months ($p=.67$). The mental component score (MCS), signifying mental well-being, improved from the baseline time point prior to PE to 12 months after PE, but was not statistically significant ($p=0.46$).

Symptom burden, as measured by the MDASI, appeared to be the greatest 6 months after PE, however, neither the symptom severity nor symptom interference changed in an appreciable manner between baseline, 6 months, or 12 months ($p=0.33$ and $p=0.14$, respectively). The core symptoms with the most severe median ratings prior to surgery and at the 6 month postoperative time point were fatigue, feeling distressed or upset, feeling sad, disturbed sleep, and pain (range of median ratings (2.40, 3.12) prior to surgery and (2.62 to 4.82) 6 months after surgery). At one year after surgery, fatigue, pain, disturbed sleep, and feeling distressed or upset continued to have the most severe median ratings, while feeling drowsy replaced feeling sad (range of median ratings (2.56, 4.00)). There were no statistically significant differences across time points for the degree of physical or psychological interference caused by symptoms. At all 3 time points, patients reported their symptoms interfered the most with the ability to work.

Differences in participant response location at 6 months post operation were compared between patients who answered surveys in the clinic ($n=25$) and those who were mailed the surveys ($n=9$). The median MCS of the SF-12 for clinic patients was 56.7 and 41.8 for the patients who completed mailed surveys ($p=0.015$). Additionally, those who complete questionnaires in the office reported higher social support (median DUFSS= 5.0) when compared to those who completed surveys by mail (median DUFSS= 4.25) ($p=0.034$). No differences were seen in MDASI, SF-12 PCS, CES-D, BIS, STOMA, or satisfaction with decision scores.

Correlation between measures

Symptom severity (MDASI) exhibited a strong positive correlation with depression scores ($\rho = .68$; $p<.001$) and SAQ sexual discomfort scores ($\rho = .67$; $p=.003$). Symptom interference scores from the MDASI showed a strong positive correlation with CESD depression scores ($\rho=.64$; $p<.001$) and a strong inverse correlation with the physical component score of the SF-12 ($\rho= -.66$; $p<.001$). CESD depression scores demonstrated a strong inverse correlation with the physical component scores from the SF-12 and stoma-related QOL ($\rho = -.69$; $p<.001$ for both). Stoma-related QOL exhibited a strong inverse correlation with body image scores ($\rho= -.77$; $p<.001$) and sexual discomfort scores from the SAQ ($\rho= -.65$; $p<.001$). Age and satisfaction with decision scores did not correlate with any of the PRO instruments.

Discussion

In our study, most women who underwent a pelvic exenteration for a gynecologic cancer were satisfied with their decision to undergo surgery. While there were no significant differences in the quality of life measures for many components over the study time period, we found that postoperative physical well-being remained lower than baseline levels. Sexual function, specifically sexual pleasure, was significantly decreased one year after surgery compared to baseline. In addition, there was a steady decline in body image at 6 months and

again at 12 months, ultimately impacting over two thirds of respondents. Additionally, approximately 1/3 of respondents suffered from depression. Despite these findings, a majority of women would choose to undergo pelvic exenteration again.

Previous work also utilizing the SF-12 has investigated the functional status of cancer and non-cancer survivors, reporting baseline physical and mental scores similar to those reported by our patients [30, 31]. However, the physical scores reported at one year post PE (median=36.6) were less than those reported by colon cancer survivors (mean=49.4) or found in the general population (mean=54.0). These findings demonstrate the physical impact of undergoing a complex surgical procedure and identify an area for survivorship support.

At one year post exenteration, a majority of the quality of life outcomes returned to baseline, which is consistent with the published literature. The interim analysis of a prospective study by *Rezk et al*, reported quality of life outcomes for 16 women with gynecologic cancer, finding reductions in overall QOL, body image, sexual function, and performance of activities of daily living a 3 months post-exenteration that approached baseline levels 9 months later[15]. Similarly, patients with rectal and pelvic cancer who underwent a pelvic exenteration were compared with those that did not undergo surgery, and the exenteration group had a significant decrease in QOL 3 months post-exenteration, but their QOL improved, equaling that of the non-surgery group, by 9 months post-operation [18]. Furthermore, a retrospective cohort study followed healthy and post-exenteration women for a median of 59 months, finding no difference in QOL outcomes between the groups [12]. These data parallel our findings of the normalizing of several QOL factors after pelvic exenteration.

Given the surgical complexity and high complication rate, it is possible that women who undergo exenteration actually return to baseline levels of function, but more likely, they adapt to their new body and life. One of our patients commented, “I didn’t have any option for a cure so whatever results came with the surgery of lifestyle change I just had to accept.” This persevering attitude was also noted in a survey study reporting that women undergoing pelvic exenteration have a higher “fighting spirit attitude” compared to those the general cancer population [32]. Additionally, in one study of exenteration patients, all women exceeded the cut off for depression, and a subset noted poor physical and emotional well-being. Interestingly, upon further inquiry, these negative quality of life indicators were tempered by their extended survival [33]. The warrior mindset and importance of survival may help to explain the adaption and normalization experience by women who have undergone pelvic exenteration.

While some quality of life domains normalized with time, poor body image and sexual dysfunction persisted through the study period. Longitudinal studies report that post-exenteration patients struggle with poor body image to differing degrees. One study shows an initial worsening of body image followed by a rise approaching, but not reaching baseline levels [15], while another reports a sustained decrease in body image with worse outcomes associated with higher surgical complexity[20]. Unlike body image, the data surrounding post-exenteration sexual health is contradictory. A recent systematic review reported that a majority of studies show a decrease in sexual activity as well as a significant decline in

sexual function after surgery, however, a few studies show satisfactory levels of sexual activity after surgery [13]. Some of this variation may be explained by patients' variable perception of "sexual activity" that may or may not include intercourse. In our study, the majority of women were not sexually active and were not satisfied with their sexual life even before they underwent surgery. Many women also indicated, however, that sexual activity was not a priority for them. This may account for some of the 30–45% of women who did not indicate any level of satisfaction with their sexual health, possibly because they were not sexually active, due to discomfort with the question, because sexual health is not important to them or they were dealing with other issues such as depression. Our data show a significant decrease in the proportion of women who felt that sexual activity was important to them throughout the study period. Additionally, sexual activity was not related to presence or absence of a vaginal reconstruction, which points to the complexity of sexual fulfillment that does not necessarily involve intercourse.

Our results show differences in social support and mental function based on the location of survey completion. Patients who completed surveys at home were more likely to report lower social support and worse mental functioning. It is possible these women had difficulty making it to their appointments due to poor social support and hence the need to complete surveys at home. Additionally, those patients with low MCS scores may have not been mentally or emotionally able to get to clinic for their appointments. However, regardless of social support or mental functioning, patients' rates of depression were similar and they remained satisfied with their decision for exenteration.

The main strength of our study is the prospective collection of patient reported outcomes in a population of women undergoing a unique procedure. As seen in previous reports, studies evaluating patients who undergo PE have a limited number of participants even when conducted over a long period of time. In addition, our study is one of the first studies to focus on satisfaction with decision, including whether or not patients would elect to undergo the procedure again, after fully understanding the consequences of such a complex procedure. The main limitation of our study is that not all participants completed all of the study measures at each time point. We did analyze all of the changes in PRO scores among the group who completed all time points (n=27, data not shown) and there were no changes in the statistical differences in PRO over time. In addition, we acknowledge that the women who completed surveys may have different opinions compared to those who did not respond and our findings may reflect some bias. It is possible that women who were dealing with complications or feeling poorly would not complete questionnaires. On the other hand, women who are feeling well may not want to focus on their cancer and could also decline participation. It is possible that survey response rates may have differed based on participants' disease status at the time of survey receipt; however we saw no differences in response rate from women with active disease and those without disease. Due to our sample size, we also did not analyze PROs based on specific procedures performed during their PE, such as continent versus incontinent conduit. Responses between these groups may differ.

In summary, we found that most patients were satisfied with their decision for exenteration and would undergo PE again if necessary. Additionally, our findings encourage continued enhancement of pre- and post-operative care relating to QOL issues, especially physical

QOL, body image, sexual health, and depression within the first year of surgery. Multiple correlations between PROs exist, pointing to the complex relationships that impact the survivorship of our patients. Therefore, providers should take a comprehensive approach that encompasses a wide range of potential QOL issues. Additional long-term follow-up of these patients will offer more information on how clinicians can address QOL in women undergoing pelvic exenteration.

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HIGHLIGHTS

- 1** One year post exenteration, most women would have an exenteration again.
- 2** Post-exenteration, most women were satisfied with their decision for exenteration.
- 2** Physical function worsened from baseline to 1 year post surgery.
- 3** Sexual pleasure and body image declined from baseline to 1 year post surgery.

Figure 1.

CONSORT diagram illustrating patient participation and reasons for exclusion from study at each time point

¹11 patients did not complete preoperative assessments, but completed questionnaires at subsequent time points.

²7 patients did not complete 6 month assessments but completed questionnaires at the 12 month time point.

³3 patients did not complete 12 month assessments but completed questionnaires at prior time points.

Table 1

Demographic and clinical characteristics of women enrolled on the study (N=54)

Characteristic	Median (range)
Age, years (range)	56.1 (30.8, 85.3)
Body mass index, kg/m ² (range)	30.7 (16.8, 54.4)
	n (%)
Race	
White	42 (77.8)
Black	6 (11.1)
Asian	2 (3.7)
Other	4 (7.4)
Ethnicity	
Not Hispanic or Latino	52 (96.3)
Hispanic or Latino	2 (3.7)
Relationship Status	
Married or in an intimate relationship	39 (72.2)
Not married or in an intimate relationship	12 (22.2)
Unmarried & unknown intimate relationship status	3 (5.6)
Primary Malignancy	
Cervix	22 (40.7)
Uterus	12 (22.2)
Vagina	10 (18.5)
Vulva	9 (16.7)
Ovary	1 (1.9)
Type of exenteration	
Total exenteration	41 (75.9)
Anterior only	6 (11.1)
Posterior only	4 (7.4)
Surgery cancelled or aborted	3 (5.6)
Type of vaginal reconstruction (total exenteration group)	
Vertical rectus abdominis myocutaneous flap (VRAM)	32 (78)
No vaginal reconstruction	7 (17.1)
Gracilis flap	2 (4.9)

Table 2

Number of women who completed PRO measures

PRO measure	Preoperative (54 eligible women) n (%)	Postoperative		Number of women who completed PRO measures at all time points
		6 months (41 eligible women) n (%)	1 year (37 eligible women) n (%)	
SWD	N/A	28 (68.3)	28 (75.7)	22
Investigator-designed exenteration instrument	N/A	33 (80.5)	33 (89.2)	26
Stoma-QOL	n/a	31 (75.6)	27 (73.0)	20
SAQ	42 (77.7)	N/A	34 (91.9)	27
BIS	43 (79.6)	33 (80.5)	34 (91.9)	22
DUFSS	39 (72.2)	32 (78.0)	34 (91.9)	20
CES-D	43 (79.6)	33 (80.5)	34 (91.9)	22
SF-12	43 (79.6)	32 (78.0)	34 (91.9)	22
MDASI	43 (79.6)	34 (82.9)	34 (91.9)	23

N/A = Not applicable (PRO measure was not collected at time point)

Table 3

Median PRO scores for all women who completed PRO measures at any time point

Measures	Baseline (Pre-op)	T1 (6 months post-op)	T2 (12 months post-op)	p-value
SWD ¹ (range)	N/A	29.0 (6.0, 30.0)	28.5 (6.0, 30.0)	.42
Stoma-QOL ² (range)	N/A	54.1 (30.0, 82.8)	55.5 (32.1, 82.8)	.65
SAQ ³ (range)				
Pleasure	10.0 (5.0, 18.0)	N/A	7.0 (0.0, 13.0)	.02
Discomfort	4.0 (1.0, 6.0)		3.0 (0.0, 6.0)	.42
Habit				1.0
About the same (n)	4		2	
Less than usual (n)	7		5	
BIS ⁴ (range)	3.0 (0.0, 26.0)	10.0 (0.0, 23.0)	9.0 (0.0, 29.0)	.003
DUFSS ⁵ (range)	5.0 (3.3, 5.0)	5.0 (2.8, 5.0)	4.69 (2.89, 5.0)	.11
CES-D ⁶ (range)	13.0 (0.0, 51.0)	12.0 (0.0, 43.0)	13.5 (1.0, 40.0)	.78
SF-12 ⁷ (range)				
PCS	47.0 (14.0, 64.3)	35.9 (20.4, 56.2)	36.6 (18.7, 56.2)	.001
MCS	49.4 (25.5, 64.5)	54.1 (20.8, 64.1)	54.0 (25.5, 61.8)	.46
MDASI ⁸ (range)				
Symptom severity	1.23 (0.0, 6.8)	1.85 (0.0, 7.3)	1.69 (0.0, 8.5)	.33
Symptom interference	.67 (0.0, 7.5)	2.25(0.0, 9.0)	1.50 (0.0, 9.0)	.14
Physical	0.33 (0.0, 10.0)	2.3(0.0, 9.0)	1.67 (0.0, 9.3)	.07
Psychological	.68 (0.0, 8.7)	2.0 (0.0, 9.0)	1.17 (0.0, 8.7)	.75

¹The SWD scores range from 6 to 30. Higher scores indicate more satisfaction with a decision.

²The Stoma-QOL ranges from 0 to 100. Higher scores indicate better quality of life.

³The SAQ consists of the pleasure, discomfort, and habit domains. Pleasure scores range from 0 to 18, with higher scores indicating more desire/satisfaction. Discomfort scores range from 0 to 6, with higher scores indicating more discomfort. Habit scores range from 0 to 3, with higher scores indicating more sexual activity than normal.

⁴The BIS scores range from 0 to 30. Higher scores indicate worse body image. The adjusted p-value for BIS from baseline to 6 months is .033.

⁵The DUFSS scores range from 1 to 5. Higher scores indicate better social support.

⁶The CES-D scores range from 0 to 60. Higher scores indicate worse depression.

⁷The SF-12 consists of the physical component score (PCS) and mental component score (MCS). Scores range from 0 to 100. Higher scores reflect better health. The adjusted p-value for PCS from baseline to 6 months is .003.

⁸The MDASI consists of symptom severity and symptom distress scores. Scores range from 0 to 10. Higher scores indicate more symptom burden.

N/A = Not applicable (PRO measure was not collected at time point)

Table 4

Patient experience (number of patients (percentage of responders)) *: “If you had to make the decision to have an exenteration again, what would you do?”

	6 months post-op (n=33)	12 months post-op (n=33)
I would have a pelvic exenteration again.	27 (81.8%)	26 (78.8%)
I am unsure.	6 (18.2%)	6 (18.2%)
I would not have a pelvic exenteration again.	0 (0.0%)	1 (3.0%)

* Percentages may not equal 100% due to rounding and were calculated using the number of responders at each time point.