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Early ambulation after colorectal oncologic resection with perineal reconstruction is safe and effective

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ABSTRACT

Background: Post-operative bedrest is common following perineal reconstruction despite little supporting data. We sought to determine the safety of early ambulation following colorectal oncologic resection and flap-based perineal reconstruction.

Methods: A retrospective cohort study was conducted with two cohorts: standard bedrest (BC) and early ambulation (EAC). Ambulation capacity was objectively assessed. Regression analysis was performed to determine the effects of ambulation timing on 60-day reoperations or readmissions and other surgical outcomes.

Results: There were 57 participants. Those in the EAC were significantly more ambulatory on post-operative days one through three ($p < 0.0001$). There was no significant difference in 60-day reoperations (25% BC versus 9% EAC, $p = 0.14$) or readmissions (33% BC versus 15% EAC, $p = 0.12$). Early ambulation significantly reduced minor complication rates (38% BC versus 9% EAC, $p = 0.02$).

Conclusions: Early ambulation following perineal reconstruction is safe and may potentially decrease wound complications.

Summary and keywords: Institution of early ambulation protocols is rapidly becoming the standard of care for many oncological surgery patients. In cases requiring perineal reconstruction with vascularized flaps, however, there is no data to uproot the historical practice of mandatory bedrest. Our study demonstrates that the benefits of early ambulation are attainable in these patients without compromising reconstructive outcomes.

Introduction

Cancers of the pelvis, especially rectal cancer, demand multimodal treatment strategies that incorporate chemotherapy, radiation therapy, and surgical tumor extirpation. This trifurcated approach has led to improved survival, a reduction in local recurrence, and a minimization of distant metastatic disease.[1,2] With regard to surgical treatment, the low anterior resection (LAR), abdominoperineal resection (APR), and pelvic exenteration represent a spectrum of options available to oncological surgeons.[3–7] If not reconstructed appropriately, these can lead to dehiscence, evisceration, and herniation.

These perineal defects are a widely recognized surgical challenge, with some reports stating complication rates of over 50%.[8,9] The use of locoregional flaps, such as the vertical rectus abdominis myocutaneous (VRAM) flap,[10,11] gracilis muscle flap,[12,13] and anterolateral thigh (ALT) flap,[14,15] has been shown to dramatically reduce perineal complication rates. One persistent issue with these flaps is the institution of post-operative bed rest orders; these are seen as necessary to avoid compromising the integrity of the reconstruction from any tension applied across the suture line. Such practice is contradictory to the ideal tenets of enhanced recovery after surgery (ERAS), which advocates for swift return to normal physiology, including ambulation. ERAS has been demonstrated to be effective in several fields, particularly colorectal

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surgery.[16–19] As ERAS programs continue to gain popularity and wider implementation, oncological surgeons and plastic surgeons will be required to reconcile the proven benefits of early ambulation with the perceived need to protect a healing flap by limiting ambulation.

In light of the dearth of clinical data to guide post-operative ambulation, this study seeks to study the effect of early ambulation on reconstructive outcomes. We hypothesized that early ambulation would not increase surgical complications or medical complications. The specific aims of this study were three-fold: 1) to identify two cohorts of patients undergoing flap-based perineal reconstruction, depending on timing of post-operative ambulation; 2) to estimate the frequency of medical and surgical complications in these cohorts; 3) to compare the effectiveness and safety outcomes associated with ambulation timing.

Materials and methods

Study design and subjects

This study was approved by our Institutional Review Board. Following approval, we conducted a retrospective cohort study of subjects derived from a prospective database. Participants included those who were treated at our institution within the Colorectal Surgery Service and the Plastic and Reconstructive Surgery Service. Those enrolled in the study satisfied the following inclusion criteria: 1) age 18–100 at the time of index oncological operation; 2) tumor extirpation performed by a colorectal surgeon with subsequent flap-based perineal reconstruction; 3) confirmed application of the Enhanced Recovery After Surgery (ERAS) order sets in the post-operative period; 4) minimum two months follow-up with the plastic and/or colorectal surgeon.

Assignment to the early ambulation or late ambulation cohort was determined based on date of operation. Early ambulation is part of the ERAS protocol that became the standard practice beginning February 1, 2014 (Table 1). Consequently, all patients who were operated on between January 1, 2013 and February 1, 2014 were treated within the Traditional Recovery After Surgery (TRAS) model, which stipulated a minimum of three days' bedrest after perineal reconstruction. This constituted our control cohort (the "standard bedrest" cohort). All patients receiving surgery between February 1, 2014 and January 31, 2015 were cared for within the ERAS scheme, which emphasized ambulation beginning on post-operative day one. This constituted our experimental cohort (the "early ambulation" cohort).

Study variables

The predictor variable in this study was ambulation on a standard timeline or an early ambulation timeline. For those participants in the standard bedrest cohort, bedrest orders were written for post-operative day zero to three, with out of bed orders written on post-operative day four. In the early ambulation cohort, ambulation was begun on post-operative day one.

The primary outcome variable was the development of a major post-operative complication (unplanned 60-day re-admission or re-operation). Secondary outcome variables included the development of a minor post-operative complication (donor or recipient site infection, seroma, hematoma, or dehiscence > 5 mm; pelvic abscess formation; partial flap necrosis; and development of a medical complication [pneumonia, urinary tract infection, or deep venous thrombosis/pulmonary embolism]), ambulation scores, and post-operative length of stay (LOS).

Ambulation scores were based on the ordinal Johns Hopkins – Highest Level of Mobility Scale (JH-HLM), a validated eight point ordinal scale that captures mobility milestones.[20] On the JH-HLM, 1 = only lying, 2 = bed activities, 3 = sit at edge of bed, 4 = transfer to chair/commode, 5 = standing for ≥1 min, 6 = walking 10 + steps, 7 = walking 25 + feet, and 8 = walking 250 + feet. These values are entered into the electronic medical record by physical or occupational therapists.

Other variables collected in this study included demographic data (age, gender, body mass index [BMI]), medical information (diabetes, hypertension, coronary artery disease, chronic obstructive pulmonary disease, clotting disorders [previous deep venous thrombosis/pulmonary embolism, collagen vascular disease, inherited coagulopathy], type of cancer, primary/recurrent cancer, and smoking status within four weeks of surgery), and surgical variables (chemotherapy, peri-operative radiation therapy to the wound, type of oncological operation, and reconstructive operation).

Data collection, management, and analyses

Descriptive statistics were computed for demographic variables. Two-sided bivariate analysis with the Mann-Whitney *U* Test or Fisher's Exact Test was used to determine significance of associations. Multivariable logistic regression analysis was performed; univariate $p < 0.15$ was used as the cutoff for inclusion. All multivariable logistic regression models were subject to goodness-of-fit tests. A p value of less than 0.05 was set as the threshold for significance. Statistical calculations were carried out using JMP Pro, version 12 (SAS Institute, Inc., Cary, NC, USA).

Results

Demographics

The study enrolled 54 participants, with 23 in the standard bed rest cohort and 31 in the early ambulation cohort. The demographic

Table 1
Description of the post-operative colorectal ERAS pathway.

- Mobilization to a chair post-operative day zero
- Early ambulation protocol with goal of walking post-operative day one under supervision of physical and occupational therapists
- Urinary catheter removal on postoperative day one if no epidural; removal on day two if epidural or pelvic procedure (CAUTI prevention)
- Discontinue intravenous fluids when tolerating oral intake
- Rapid resumption of regular oral intake
- Multimodal analgesia (with or without epidural analgesia) delivered by acute pain team (physicians and nurses)
- Risk-stratified VTE prophylaxis (VTE prevention)
- Education by enterostomal therapist about ostomy (if applicable)
- Phone call from hospital nurse to review discharge instructions 2 days after hospital discharge
- Referral to home health care agency for transition to home if new ostomy
- Return office visit in 10–14 days with surgeons and enterostomal therapist (if applicable)

CAUTI: Catheter-Associated Urinary Tract Infection; VTE: Venous Thromboembolism.

distribution across both cohorts was similar. 70% of participants in the standard bedrest cohort suffered from a pre-operative medical morbidity compared to 81% of those in the early ambulation cohort ($p = 0.48$). Rectal cancer was the primary oncological diagnosis in about 70% of patients in both cohorts ($p = 0.83$). Recurrent cancer affected over half of the participants in both cohorts; 57% of those in the standard bed rest arm compared to 55% in the early ambulation group ($p = 0.82$) (Table 2).

Medical and surgical variables

The majority of participants in both cohorts received peri-operative chemotherapy and radiation. The distribution of oncological operations was slightly different between the two cohorts; there was a higher rate of abominoperineal resection (APR) in the standard bed rest group compared to the early ambulation group (73.9% versus 45.2%, $p = 0.04$). This was largely driven by a trend, though non-significant, toward more frequent pelvic exenteration in the early ambulation arm (41.9%) compared to the standard bed rest arm (20.8%) ($p = 0.16$). In terms of reconstructive surgery, the VRAM flap was the most common procedure in both cohorts (57% and 65%, $p = 0.57$). There were no significant differences in reconstructive techniques, though the rate of ALT flap coverage in the standard bedrest group (30.4%) approached a significant difference compared to the rate in the early ambulation group (9.7%) ($p = 0.06$). (Table 2).

Ambulatory and ERAS data

Table 3 demonstrates the post-operative ambulation and ERAS data. In general, the early ambulation cohort was significantly more ambulatory on post-operative days one through three (Fig. 1). Moreover, the principles of ERAS were largely in place before the formal adoption of the program.

Early ambulation and specific outcome variables

The primary outcome variable, 60-day major complication rate, was 42% for the standard bedrest cohort and 27% for the early ambulation cohort ($p = 0.27$). Neither the 60-day reoperation rate (25% versus 9%, $p = 0.14$) nor 60-day readmission rate (33% versus 15%, $p = 0.12$) were significantly different. The rate of minor complications was 38% in the control arm compared to 9% in the experimental group, which was a significant difference ($p = 0.02$). Most interestingly, the differential rates of wound dehiscence nearly reached statistical significance; 38% of standard bedrest participants suffered wound dehiscence while only 12% of early ambulators were affected ($p = 0.06$). Other specific outcome variables are presented in Table 4.

Multivariable logistic regression analysis

The multiple variable models considered the following variables: obesity (BMI> 30 kg/m^2), smoking status, peri-operative chemotherapy or radiation, recurrent cancer, medical comorbidity, oncological operation (APR), reconstructive operation (VRAM), and age > 65 years. The primary covariate controlled for in the multiple variable model for the primary outcome variable, major complication rate, was use of VRAM for the reconstructive surgery (univariate $p = 0.05$). Controlling for this, early ambulation remained a non-predictor of major complication (OR 0.42, 95% CI 0.12–1.39).

Table 2
Demographic, medical, and surgical data.

	Standard Bedrest (N = 23)	Early Ambulation (N = 31)	P Value
Mean Follow-up (months)	19	15	–
Males, N (%)	12 (52.2%)	17 (54.8%)	0.86
Mean Age (years) (Range)	54 (29–76)	57 (38–76)	0.35
BMI (kg/m^2)	27.0	26.5	0.74
Smokers, N (%)	8 (34.8%)	7 (22.6%)	0.39
Medical Morbidity, N (%)	16 (69.6%)	25 (80.6%)	0.48
Diabetes Mellitus, N (%)	6 (26.1%)	9 (29.0%)	0.86
Hypertension, N (%)	7 (30.4%)	12 (38.7%)	0.44
CAD, N (%)	4 (17.4%)	4 (12.9%)	0.75
COPD, N (%)	1 (4.3%)	4 (12.9%)	0.29
Clotting Disorder[a], N (%)	3 (13.0%)	6 (19.4%)	0.53
Type of Cancer			
Rectal, N (%)	16 (69.6%)	21 (67.7%)	0.83
Colon, N (%)	4 (17.4%)	2 (3.2%)	0.26
Anal SCC, N (%)	2 (8.7%)	4 (12.9%)	0.39
Sarcoma, N (%)	1 (4.3%)	2 (6.5%)	0.72
Other[b], N (%)	0 (0%)	3 (9.7%)	0.10
Recurrent Cancer, N (%)	13 (56.5%)	17 (54.8%)	0.82
Chemotherapy, N (%)	22 (95.7%)	28 (84.9%)	0.18
Radiation Therapy, N (%)	21 (91.3%)	28 (84.9%)	0.78
Oncological Surgery			
Abdominoperineal Resection, N (%)	17 (73.9%)	14 (45.2%)	0.04
Pelvic Exenteration, N (%)	5 (20.8%)	13 (41.9%)	0.16
Other[c], N (%)	1 (4.2%)	4 (12.1%)	0.13
Mean Defect Surface Area (cm^2)	48.7	56.2	0.47
Reconstructive Surgery			
Pedicled Gracilis, N (%)	4 (17.4%)	7 (22.6%)	0.51
Pedicled VRAM, N (%)	13 (56.5%)	20 (64.5%)	0.57
Pedicled ALT, N (%)	7 (30.4%)	3 (9.7%)	0.07

BMI: Body Mass Index; CAD: Coronary Artery Disease; COPD: Chronic Obstructive Pulmonary Disease; SCC: Squamous Cell Carcinoma; VRAM: Vertical Rectus Abdominus Myocutaneous Flap; ALT: Anterolateral Thigh Flap.

[a] Clotting disorders included Factor V Leiden trait, Sickle Cell Disease, Lupus, history of pulmonary embolism or venous thrombosis, and prior, unrelated cancer.

[b] Prostate (N = 2) and vulvar squamous cell carcinoma (N = 1).

[c] Other oncological surgery included vaginectomy with vulvectomy and proctectomy (N = 1) and wide local excision (N = 4).

Table 3
ERAS and ambulation data.

	Standard Bedrest (N = 23)	Early Ambulation (N = 31)	P Value
Urinary catheter removal on postoperative day one if no epidural; removal on day two if epidural or pelvic procedure (CAUTI prevention), N (%)	14 (66.7%)	25 (80.6%)	0.19
Discontinue intravenous fluids when tolerating oral intake, N (%)	17 (81.0%)	29 (93.5%)	0.03
Rapid resumption of regular oral intake, N (%)	13 (61.9%)	23 (74.2%)	0.14
Multimodal analgesia (with or without epidural analgesia) delivered by acute pain team (physicians and nurses), N (%)	20 (87.0%)	30 (96.8%)	0.34
Risk-stratified VTE prophylaxis (VTE prevention), N (%)	23 (100%)	31 (100%)	1.00
Ambulatory (JH-HLM = 6–8), N (%)			
Post-Operative Day 0	0 (0%)	2 (6.5%)	0.48
Post-Operative Day 1	1 (4.3%)	18 (58.1%)	<0.0001
Post-Operative Day 2	2 (8.7%)	26 (84.7%)	<0.0001
Post-Operative Day 3	4 (17.4%)	30 (96.8%)	<0.0001

CAUTI: Catheter-Associated Urinary Tract Infection; VTE: Venous Thromboembolism.
JH-HLM: Johns Hopkins – Highest Level of Mobility Scale.
6 = walking 10 + steps, 7 = walking 25 + feet, and 8 = walking 250 + feet.

For minor complications, recurrent cancer (univariate $p = 0.11$), obesity (univariate $p = 0.18$), extirpation by APR (univariate $p = 0.21$), defect size > 48 cm^2 (univariate $p = 0.20$), and reconstruction with VRAM (univariate $p = 0.10$) were included. In this model, early ambulation remained a significant predictor of decreased minor complications (OR 0.16, 95% CI 0.03–0.69). In the model for wound dehiscence, reconstruction with VRAM (univariate $p = 0.06$) and defect size > 48 cm^2 (univariate $p = 0.09$) were included. This again showed that early ambulation offered a significant protective effect (OR 0.17, 95% CI 0.03–0.68).

Discussion

This study was conducted to assess the effect of early ambulation on reconstructive outcomes in patients undergoing oncological colorectal surgery followed by perineal reconstruction with pedicled soft-tissue flaps from the abdomen or thigh. We hypothesized that institution of an early post-operative ambulation scheme would not increase the rate of surgical or medical complications.

The results of this study confirm our hypothesis that early ambulation does not increase the rate of 60-day major complications. Similarly, there was no significant difference in medical complications. Our results were somewhat surprising in that the rate of minor complications was significantly lower in the early ambulation cohort. The multivariable logistic regression analysis confirmed that early ambulation is a non-predictor of major complications and further provides a protective effect against minor complications and wound dehiscence. The ambulation data (Table 3) show the participants in the early ambulation cohort were in fact ambulating significantly more on post-operative days one through three. Based on these results, supervised early ambulation after perineal reconstruction is safe and effective.

There has been substantial disagreement among plastic surgery authorities as to the preferential post-operative ambulation schedule for these patients. A recent review article published by Hollenbeck et al. states that their practice is to allow early

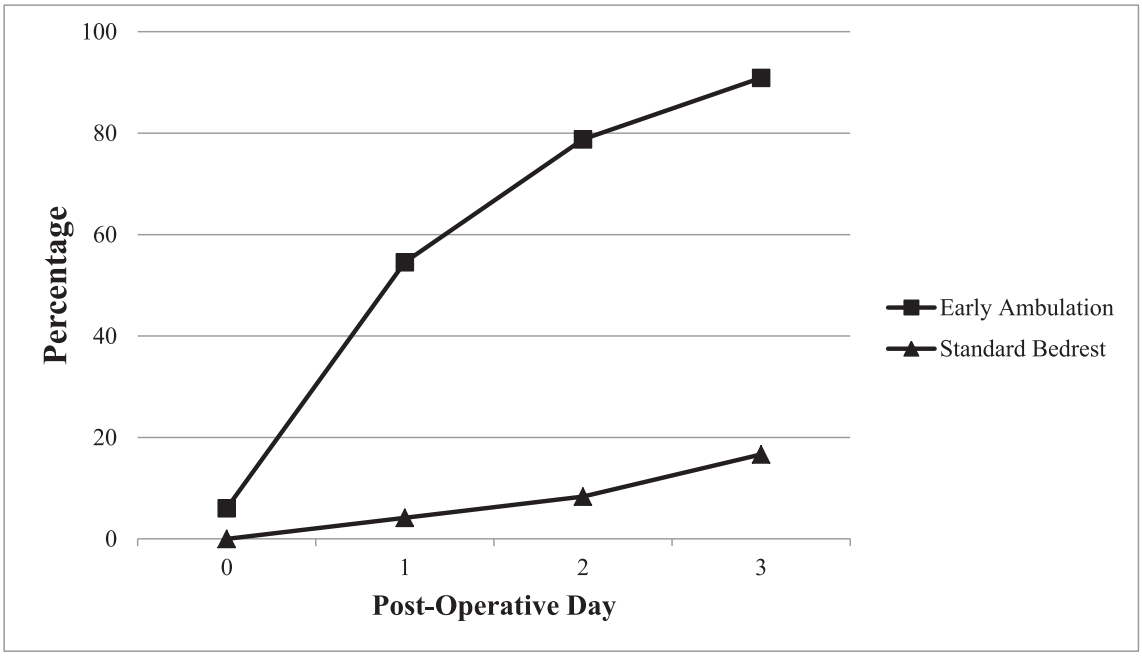

Fig. 1. Percentage of Participants Ambulatory on Post-Operative Days Zero to Three. Ambulatory status corresponds to a Johns Hopkins – Highest Level of Mobility Scale score of any of the following: 6 = walking 10 + steps, 7 = walking 25 + feet, and 8 = walking 250 + feet. Differences on days 1–3 are statistically significant.

Table 4
Outcome variables.

	Standard Bedrest (N = 23)	Early Ambulation (N = 31)	P Value
60-day Major Complication, N (%)	10 (43.5%)	9 (29.0%)	0.26
60-day Reoperation, N (%)	6 (26.1%)	3 (9.7%)	0.11
60-day Readmission, N (%)	8 (34.8%)	5 (16.1%)	0.10
Minor Complication, N (%)	9 (39.1%)	3 (9.7%)	0.02
Pelvic Abscess, N (%)	1 (4.3%)	2 (6.5%)	0.77
Seroma, N (%)	3 (13.0%)	0 (0%)	0.06
Hematoma, N (%)	1 (4.3%)	0 (0%)	0.38
Partial Flap Necrosis, N (%)	1 (4.3%)	1 (3.2%)	0.80
Dehiscence, N (%)	8 (34.8%)	4 (12.9%)	0.06
Wound Infection, N (%)	2 (8.7%)	4 (12.9%)	0.62
Medical Complication[a], N (%)	3 (13.0%)	1 (3.2%)	0.29
Mean LOS[b] (days) (IQR)	13.1 (7–17)	7.9 (5–12)	0.03

LOS: Length of Stay; IQR: Interquartile Range.
[a] Medical complications included pneumonia, pyelonephritis, and stroke in the control arm. There was one case of pneumonia in the experimental arm.
[b] The LOS calculation was made after removing outliers from the data. Outliers were defined as 1.5*IQR < Q1 or 1.5*IQR > Q3. This removed one value (44 days) from the delayed ambulation group and two values (35 and 78 days) from the early ambulation.

ambulation but to prohibit sitting in a chair for at least four weeks.[21] This guidance, however, is given without reference to internal data from that institution or a literature reference. On the other hand, the venerable *Plastic Surgery* textbook series edited by Neligan and Gurtner calls for these patients to be on bedrest for several days, followed by progressive ambulation; they instruct patients to not sit upright for several weeks as well.[22] Despite disagreement between the practice patterns of experts, there has been no published comparison data to support either position.

Numerous outcomes studies have been published regarding perineal reconstruction. In these reports, the post-operative ambulatory protocol is highly variable. One group kept patients on strict bedrest for 10 days after flap surgery.[23] On the other hand, Butler and colleagues allowed patients to ambulate on the first post-operative day.[10] Several other post-operative ambulation schemes exist between these two extremes.[11,12,24] Even within each individual study, patients appear to have merely been free to ambulate beginning on a given post-operative day, as opposed to having a protocol in place that called for standardized, scheduled, and supervised ambulation. This variability is to be expected considering the lack of data to guide best practices.

In our study, participants in the early ambulation cohort had physical therapy orders placed that stipulated planned ambulation. The ambulation data was measured using the Johns Hopkins – Highest Level of Mobility Score. This ordinal scale has been previously published and accepted for use in clinical outcome studies and quality improvement research.[20] It is particularly well suited for identifying patients who were ambulatory versus non-ambulatory. Only the three highest scores – 6 (walking 10 + steps), 7 (walking 25 + feet), and 8 (walking 250 + feet) – correlate to ambulatory states. Thus, identification of truly ambulatory patients was an objective matter in our study and not determined by retrospective interpretation of inpatient physician or nursing notes.

Some of our results were somewhat surprising. In particular, our multivariable logistic regression models show a statistically significant reduction in minor complications and wound dehiscence in the early ambulation cohort. This is contrary to the usual rationale for bed rest, which is that hip flexion, extension, and abduction tends to pull on the perineal inset of the flap and could plausibly promote dehiscence. We believe that the mandatory supervision offered by the early ambulation protocol is likely a major contributing factor explaining these results. Part of the paradigm calls for scheduled physical therapy sessions. These professionals are specifically trained to facilitate ambulation in the safest manner. In their absence, nurses, family members, or patients themselves may inadvertently advocate for ambulation that amounts to over-exertion. Excessively aggressive mobility could promote dehiscence, which may have been the case in the standard bedrest cohort. Moreover, the differential rate of wound dehiscence was the major contributor to the overall minor complications outcome; thus, this high degree of co-linearity between these outcome variables may explain why these two showed a statistically significant difference in the multivariable logistic regression models. In practice, we believe the automatic inclusion of physical therapy orders along with the physiologic benefit of mobility help to explain the positive results seen in the early ambulation cohort.

One possible concern with this study is that the cohorts differed by more than just ambulation status. As Table 1 shows, the ERAS pathway addresses numerous aspects of post-operative care. Many of these tenets were already in practice prior to the implementation of a standardized ERAS algorithm. Table 3 shows that the standard bedrest cohort patients were being treated with similar analgesia regimens, had urinary catheters discontinued promptly, and returned to regular diet as soon as possible. Although this data does not eliminate the possibility of other unmeasured effects enhancing the ability of the early ambulation patients to ambulate successfully, it is a reassuring sign that certain obvious factors (such as improved analgesia or the removal of excess lines and drains) are not the primary drivers of the promising data seen in cases of early ambulation. It is also worth mentioning that the other multidisciplinary aspects of cancer care, such as chemotherapy or radiation treatments, did not undergo institutional changes. We also recognize the inherent limitations of retrospective data and believe prospective studies that successfully control for both operative and post-operative variables are necessary to definitively show the merits of early ambulation in this patient population.

Conclusion

This cohort study before and after the implementation of an enhanced recovery protocol provides data to suggest that supervised early ambulation after flap based perineal soft-tissue reconstruction does not increase major complications, specifically 60-day reoperation or readmission. To the contrary, early ambulation within an ERAS paradigm was associated with a protective benefit against the development of wound complications. These are the first data directly comparing bed rest to early ambulation in this patient population, suggesting that supervised early ambulation can be a useful component for improving outcomes. Large, multi-institutional studies are necessary and warranted.

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None of the authors has a financial interest in any of the products, devices, or drugs mentioned in this manuscript.

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