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A Pilot Randomized Clinical Trial of Early Ambulation after Groin Reconstruction with Sartorius Muscle Flaps

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Background: The use of muscle flaps, such as the sartorius muscle, for groin coverage in high-risk vascular patients has been shown to reduce complication rates. However, it remains unknown whether earlier postoperative ambulation is associated with improved postoperative outcomes for groin muscle flaps following infrainguinal vascular surgery.

Methods: We performed a pilot randomized trial to analyze the effect of early ambulation on postoperative outcomes in patients who had groin reconstruction with sartorius muscle flaps following infrainguinal vascular surgery at our academic institution.

Results: Fourteen patients were randomized to standard ambulation (on postoperative day 6), and 14 patients were randomized to early ambulation (on postoperative day 2). The treatment arms were similar with respect to age, body mass index, risk category, smoking status, and comorbidities. Median length of stay was 6 days in the early group versus 7 days in the standard group. Immediate and long-term physical function and general health were better in the early group. There were slightly more wound complications in the standard (57.1%) versus the early group (42.9%), and the early group had more lymphatic complications (35.7% versus 14.3%).

Conclusions: The decision to ambulate a patient after this surgery continues to be a decision between the vascular and plastic surgeons. However, this pilot trial has shown the safety profile of early ambulation and that it should be considered for specific patients. Additionally, this trial has provided valuable information for performing a larger scale randomized controlled trial to determine the optimal postoperative protocol for patients with these reconstructions. (*Plast Reconstr Surg Glob Open* 2022;10:e4665; doi: 10.1097/GOX.0000000000004665; Published online 21 November 2022.)

INTRODUCTION

Complex groin wounds following open, infrainguinal vascular surgery are associated with significant patient morbidity, prolonged hospitalizations, and health care costs.¹ Complications can involve lymphatic leaks or graft infections, ultimately threatening life and/or limb. Wound

complication rates range from 11% to 44%.¹⁻³ Wound management poses challenges to vascular surgeons, leading to involvement by plastic surgeons.

Muscle flaps, such as sartorius, gracilis, and rectus femoris flaps, for groin coverage in high-risk vascular patients and salvage procedures in infected fields have been shown to effectively reduce complication rates in observational studies.⁴⁻⁹ Well-vascularized muscle flaps can reduce dead space, improve antibiotic delivery, lower bacterial counts, and improve healing time.⁴⁻⁹ Although enhanced recovery with muscle flaps after vascular surgery has been described,^{10,11} minimal research has focused on optimizing

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postoperative care for patients who undergo muscle flaps for groin coverage.

Historically, patients at the University of California San Francisco (UCSF) Medical Center who receive groin muscle flaps after open, infrainguinal vascular surgery are placed on bedrest for 5 days postoperatively. This number was chosen to give the muscle adequate time to heal to the graft bed before ambulation. However, postoperative activity protocols, including bedrest, are not evidence-based.^{5,6,10} In cardiac surgery and intensive care patients, earlier postoperative ambulation reportedly reduces the risk of thromboembolism, improves pulmonary toilet, decreases hospital length of stay (LOS), and reduces deconditioning and the need for rehabilitation.^{12–16} Whether earlier postoperative ambulation is associated with improved postoperative outcomes for groin muscle flaps following infrainguinal vascular surgery is unknown.

We performed a pilot randomized trial to analyze the effect of early ambulation on postoperative outcomes in patients who had groin reconstruction with sartorius flaps following infrainguinal vascular surgery. The goal of this pilot trial was to determine the feasibility and required sample size for a larger trial. Specifically, we examined the effect on surgical complication rates, physical function, hospital LOS, venous thromboembolism, and need for a skilled nursing facility after discharge. We hypothesized that earlier ambulation improves postoperative physical function and decreases hospital LOS and that there would be no difference in wound or surgical complications.

PATIENTS AND METHODS

This was a pilot randomized controlled trial of early (day 2) versus standard (day 6) postoperative ambulation in patients who require groin reconstruction with sartorius flaps following infrainguinal vascular surgery at the UCSF Medical Center. This study was approved by the UCSF institutional review board and registered with Clinicaltrials.gov (ID NCT03477682).

Participants

Written informed consent was obtained from all participants. The vascular and plastic surgeons referred appropriate patients for the study. Inclusion criteria included patients aged 18 years or older, who were ambulatory at baseline and undergoing infrainguinal vascular surgery with unilateral or bilateral rotational sartorius muscle flaps from November 2017 to March 2020.

Preoperatively collected demographic data included prior medical history and smoking status. Each patient's risk of a wound complication was calculated using the Penn Groin Assessment Scale.⁶ Operative data were collected through review of the operative reports. Antibiotic information was collected via chart review of the inpatient stay and the discharge summary.

Study Procedures

The patients were randomized 1:1 into two groups: early ambulation (early) or standard ambulation (standard). Early ambulation was defined as 1 day of bedrest

Takeaways

Question: Is early postoperative ambulation safe in patients who have had groin muscle flaps following infrainguinal vascular surgery?

Findings: Our results showed that immediate and long-term physical function and general health were better in patients who ambulated early. They could also be safely discharged earlier and had fewer wound complications compared with patients who remained on bedrest longer.

Meaning: This pilot trial has shown the safety profile of early ambulation in patients undergoing sartorius flaps for groin reconstruction following infrainguinal vascular surgery, and it should be considered for specific patients.

(ambulate on postoperative day 2). Standard ambulation was defined as 5 days of bedrest (ambulate on postoperative day 6). Groups were assigned using the REDCap randomization module. Study personnel were blinded to the randomization table, which was stratified according to unilateral versus bilateral with permuted blocks of size 4. Once randomized, the primary vascular surgery team was notified, and the patient was placed on strict bedrest for the period (1 day or 5 days) according to their randomization group. Once their bedrest period was over, the inpatient physical and occupational therapy teams assessed the patient and started their standard ambulation protocol and determined safety of discharge. The rest of the inpatient care was at the discretion of the vascular surgery team. Patient demographic and outcome data were collected in the REDCap database.

Surgical Technique

The plastic surgeons provided coverage of the femoral artery reconstruction with a sartorius muscle flap using the surgical technique as originally described by Mathes and Nahai.¹⁷ The wound was dressed with the PREVENA Therapy system and removed before discharge. The first six consecutive patients in this trial received gauze dressings. However, after the trial began, it became standard practice to place a PREVENA on the wound whether or not the patient was enrolled in the study. All patients thereafter received the PREVENA.

Outcome Measures

In this pilot trial, we collected several outcomes to assess feasibility and reliability for use in a larger trial. The primary outcome measures were hospital LOS, physical function, and wound complications. The secondary outcome measures were lymphatic and surgical complications, reoperations, readmissions, discharge to skilled nursing facility (SNF), and thromboembolic events. Physical function was measured with two validated scoring systems: the Activity Measure for Post-Acute Care (AM-PAC) Short Form (SF) and the Short Form Health Survey (SF-36).

The AM-PAC SF was developed to assess activity limitation across postacute care settings.¹⁸ Since our study focused on patient mobility and function, we used the Basic Mobility AM-PAC Inpatient Short Form (Table 1). It

Table 1. Sample of the AM-PAC Short-form Questions

How Much Help from Another Person Does the Patient Currently Need...	Total	A Lot	A Little	None
1. Turning from your back to your side while in a flat bed without using bedrails?			3	
2. Moving from lying on your back to sitting on the side of a flat bed without using bedrails?	1			
3. Moving to and from a bed to a chair (including a wheelchair)?			3	
4. Standing up from a chair using your arms (eg, wheelchair or bedside chair)?			3	
5. To walk in a hospital room?		2		
6. Climbing three to five steps without a railing?	1			

Raw score: 13.
 Standardized *t* score: 33.99.
 Scaled score standard error: 2.51.

has six questions scored from 1 to 4 with a total raw score range of 6–24. A score of 24 indicates the highest level of independent physical function. Raw scores are then converted to a standardized score using a proprietary equation from the creators of AM-PAC.¹⁸ The AM-PAC SF was administered preoperatively on the day of surgery (day 0) and 7 days postoperatively, regardless of randomization group. The mean change in AM-PAC score was measured and reported. If the patient was discharged before postoperative day 7, then the score was obtained via telephone by a trained research assistant.

The SF-36 physical function and general health perceptions domains were also assessed.¹⁹ The maximum score in each domain is 100. The SF-36 is a freely available, public instrument. The patients were asked to complete the SF-36 online or via telephone at 6 weeks postoperatively after their surgery. However, some surveys were collected up to 2 years after surgery.

Medical charts were reviewed by research assistants for follow-up information, including surgical site healing, complications, readmissions, and reoperations after discharge. Using the medical charts, we categorized wound healing into groups according to the providers' assessments. The surgical site healing was placed into five categories of "wound diagnosis": normal healing, delayed healing, cellulitis, abscess, or necrosis. Each patient could have more than one diagnosis. The wound characteristics of this diagnosis were identified via chart review and

included the following: well-approximated/intact, minor/superficial dehiscence, major dehiscence, erythematous, serous drainage, and/or purulent drainage.

Statistical Analysis

We reported results for binary and categorical outcome variables as counts and proportions. For between-group comparisons, we used Fisher exact test. For LOS, we reported the median and interquartile range (IQR) and compared groups using the rank sum test. We used quantile regression to determine the confidence intervals around the difference in medians. For the SF-36, we reported means and standard deviations and compared groups using the *t* test. For the AM-PAC scores, we calculated the difference from baseline to 7 days for each patient, reported the mean changes with standard deviations, and compared groups using the *t* test. We used a two-tailed *P* value less than 0.05 as our definition of statistical significance. Statistical calculations were done using Stata/SE 15.1.

RESULTS

Each treatment arm had 14 patients, and there were no exclusions after randomization. The treatment arms were similar with respect to age, BMI, risk category, smoking status, and comorbidities, but there were fewer men in the early group than in the standard group (Table 2).

Table 2. Clinical Characteristics of Participants Randomized to Early or Standard Ambulation

	Early, N (% or IQR)	Standard, N (% or IQR)	<i>P</i>
Sample size	14	14	
Gender			
Male	6 (42.9)	10 (71.4)	0.252
Female	8 (57.1)	4 (28.6)	
Age, median	67.5 (63–80)	70 (64–71)	0.535
BMI kg/m ² , median	25.7 (23.9–29.1)	29.9 (24.3–31.8)	0.269
PENN groin risk			0.797
Low	7 (50.0)	5 (35.7)	
Intermediate	3 (21.4)	4 (28.6)	
High	4 (28.6)	5 (35.7)	
Smoking status			0.855
Current	2 (14.3)	2 (14.3)	
Former	10 (71.4)	8 (57.1)	
Never	2 (14.3)	4 (28.6)	
Comorbidities			0.596
Hypertension	11 (78.6)	13 (92.9)	1
Diabetes	6 (42.9)	5 (35.7)	1
CAD	6 (42.9)	7 (50.0)	1
PVD	12 (85.7)	11 (78.6)	1
ESRD	0 (0.0)	1 (7.1)	1
Cirrhosis	1 (7.1)	1 (7.1)	1
HIV	1 (7.1)	1 (7.1)	1

CAD, coronary artery disease; ESRD, end-stage renal disease; PVD, peripheral vascular disease.

In terms of operative characteristics by treatment arm, more unilateral sartorius flaps than bilateral flaps were performed. (See table, Supplemental Digital Content 1A, which displays preoperative, intraoperative, and postoperative characteristics of trial participants, <http://links.lww.com/PRSGO/C270>.) Four vascular surgeons and five plastic surgeons were involved in this study. Vascular surgeon A performed most of the vascular procedures and plastic surgeon E performed most of the sartorius flap reconstructions. The most common vascular surgery procedures were endarterectomy and femoral distal bypass. Surgical indications were similar in both treatment arms, except for three unusual indications (infected aortofemoral bypass graft, pelvic tumor, and bypass graft aneurysm) in the early group. The estimated operative blood loss was slightly lower in the early group. All patients had a Jackson-Pratt drain following sartorius flap reconstruction. On average, the drain stayed in 5 days longer in the early group. The distribution of PREVENA Therapy, a negative pressure incision management system, usage was similar between the two groups. Any intravenous and oral inpatient antibiotic usage was similar between the two groups. However, different antibiotics were used, and the duration of antibiotic use varied widely. Cephalexin was prescribed for those who received inpatient oral antibiotics, and treatment duration was 3–6 days. Most patients in each group were discharged with an oral antibiotic—cephalexin, levofloxacin, ciprofloxacin, ampicillin/sulbactam, or doxycycline—for 7–30 days. Prophylactic antibiotics were given until the drains were removed. For patients with longer duration antibiotic treatment, they were prescribed to treat graft or lower extremity. One patient in the early group was discharged with rifampin for 90 days because of a previously infected aortofemoral bypass graft.

The median (IQR) duration of follow-up was 5 weeks in the early group and 3.5 weeks in the standard group. (See table, Supplemental Digital Content 1B, which displays study outcomes for patients randomized to early or standard ambulation, <http://links.lww.com/PRSGO/C270>.) Median (IQR) LOS was 6 days in the early group versus 7 days in the standard group. In the early group, six patients had LOS less than 6 days compared with zero patients in the standard group. Since standard care entailed 5 days of bedrest, none of the patients in the standard group had LOS less than 6 days. A single patient in the early group had an LOS of 23 days due to a pseudomonas urinary tract infection requiring transfer to the intensive care unit. Discharge to an SNF was similar between the two treatment arms.

For the outcomes, preoperative and postoperative AM-PAC scores were only available for 13 of 28 patients (five early and eight standard). The standardized AM-PAC scores are shown in table, Supplemental Digital Content 1B, <http://links.lww.com/PRSGO/C270>, and the mean change in the AM-PAC score was 4.7 points higher in the early group. We obtained the SF-36 for 20 of 28 patients (ten in each group). The mean SF-36 score for physical function was nine points higher in the early group (50.5)

than in the standard group (41.5). However, these findings were not statistically significant.

The early group had fewer wound complications than the standard group. In both groups, delayed healing was equal and always minor except for one in the early group. This included necrosis of the skin and subcutaneous tissue requiring operative debridement and subsequent local wound care. The early group had more lymphatic complications (defined as a lymphatic leak or fistula that was diagnosed clinically), whereas the standard group had higher rates of vascular-specific complications and three more vascular surgery reoperations. The early group had one vascular surgery reoperation and one plastic surgery reoperation. The standard group had no plastic surgery reoperations. The early group had fewer readmissions within 30 days. In one patient in the standard group, a subsegmental pulmonary embolism was incidentally found on a CT scan and was not clinically significant.

DISCUSSION

In this pilot trial of early ambulation versus standard care, we found no evidence of increased wound complications in patients who ambulated early, except for lymphatic complications. The standard group had more vascular surgery complications. Immediate postoperative physical function—measured by the mean change in the AM-PAC score—was better in the early group. Although the collection period for the SF-36 scores varied from 6 weeks to 2 years postoperatively, the SF-36 scores were higher in the early group. Early ambulation allowed for earlier discharge in some patients, though both groups had similar rates of discharge to SNFs compared with home.

Lymphatic complications of the groin wound following infrainguinal revascularization procedures can be quite serious,²⁰ including lymphatic leak, lymphocele, lymphocutaneous fistula, and lymphedema.^{20,21} Adjacent lymphatic vessels can be injured or damaged when the inguinal region is dissected during access to the femoral vessels.^{21,22} Lymph accumulation in the surgical bed can lead to wound breakdown and eventual lymphocutaneous fistula and infection.²² The reported incidence of postoperative lymphatic complications ranges from 2% to 15%.^{23,24} At UCSF, the overall lymphocele rate is 30% with fewer occurring in patients with sartorius flaps than in those with complex layered closures (7% versus 22%).²⁵ Methods for treating lymphatic complications include negative pressure wound therapy (NPWT), sclerosing agents, surgical ligation, muscle flaps, and lymphovenous anastomosis.^{21,26–30} One treatment option is a sartorius flap, which is an argument for performing these flaps.^{20,21} Consistent with our previous study,²⁵ lymphatic complications occurred despite sartorius flap. They were more frequent in the early group. However, one lymphatic leak in the early group was due to a pelvic neoplasm blocking lymphatic drainage; further follow-up information was lacking because the patient was transferred to another facility. Although the difference in lymphatic complications was not statistically significant, it is plausible that early ambulation would increase

the risk of lymphatic leaks in patients where these vessels were unknowingly transected during surgery,^{21,22} and longer bedrest would have allowed the vessels to spontaneously seal. In other words, ambulation and exercise likely encourage lymphatic return, which leads to more flow through the lymphatic vessels, and in the event of an injury, would lead to more leakage or fluid accumulation in the groin. Conservative treatments for lymphatic leaks include antibiotics, local wound care, nutritional support, and bedrest.²⁴ The management of lymphatic complications in our study varied, which is consistent with previous studies.^{21,26–30} However, conservative management with local wound care or prolonged drain use was the most common. Three lymphatic leaks were managed by interventional radiology with sclerosing agents and drains, and only one patient returned to the operating room for surgical ligation.

The overall wound complication rate in our study was quite high in both groups (early 43% versus standard 57%). The reported wound complication rate following infrainguinal vascular surgery without muscle flaps is as high as 40%.^{18,31,32} A previous UCSF study reported a wound breakdown rate of 25% in patients with sartorius muscle flaps.²⁵ In 1988, Samson et al³³ described a classification system for groin infections involving underlying arterial prosthetic grafts without muscle flaps. Samson group 1 indicates an infection that does not extend beyond the dermis, and group 5 is one that surrounds the anastomosis with concurrent bacteremia and/or bleeding.^{31,33} Although we did not use this classification system to categorize the wounds, our category of “delayed healing” is synonymous with Samson group 1. Most of our reported wound complications were due to delayed wound healing, which referred to minor, superficial dehiscence of the skin. The sartorius muscle remained intact for all patients. The most severe complication of superficial wound necrosis occurred in one patient in the early group and was managed with operative debridement and subsequent NPWT. This patient did not have a concurrent lymphatic complication. A lower overall wound and lymphatic complication rate of 15% was reported for muscle flaps to the groin performed at a different institution by a single vascular surgeon over 9 years.³⁴ They do not specify how many patients had delayed healing, which could have been included in the 85% healing rate, whereas we included minor wounds (equivalent to Samson group 1) in our overall wound complication rate. To conclude, though our wound complication rate was high in both groups, they were minor, and the early group had fewer wound complications overall.

The high vascular complication rate (42%) in this trial is consistent with previous findings from UCSF,²⁵ but that study reported on prophylactic flaps only and excluded all patients who had a prior groin operation, active infection, or pseudoaneurysm. In this trial, the reason why more vascular complications occurred in the standard group is unclear. They could be due to random chance because the complications were unrelated to activity: persistent critical limb ischemia requiring

additional bypass graft, osteomyelitis of the foot leading to infection, and graft infection. The one hematoma adjacent to the femoral graft was in the standard group and could also be related to the higher complexity of vascular surgery in the standard group. (See table, **Supplemental Digital Content 1A**, <http://links.lww.com/PRSGO/C270>.) The standard protocol developed by our plastic surgeons has been 5 days of bedrest for patients who undergo groin reconstruction with a sartorius flap following infrainguinal vascular surgery. This likely accounts for the average LOS of 13 days following sartorius flaps at UCSF.²⁵ Thus, another goal of this trial was to determine whether early ambulation led to improved physical function and earlier discharge. Enhanced recovery after surgery³⁵ has influenced multiple surgical specialties, including vascular surgery, and early ambulation is a key postoperative goal in published protocols.^{10,11} However, these protocols do not specify the day of ambulation or whether the patient had a muscle flap. Only one study in cardiac surgery patients analyzed the specific day of ambulation postoperatively.¹³ The authors found that the patients who ambulated within the first 5 days after surgery had improved physical function as measured by distance traveled in a 6-minute walking test.¹³

We measured physical function via two validated scoring systems: the AM-PAC SF and the SF-36 Survey. Because we could not complete preoperative and postoperative AM-PAC scores for all enrolled patients, we reported the mean change in score between the two groups, which was 4.7 points higher in the early group. Thus, of the patients who had both preoperative and postoperative scores, the decline in AM-PAC score was less in the early group. This means that the early group had better postoperative physical function compared with the standard group, which is supported by prior studies that analyze the effects of early ambulation in surgical patients.^{10,11,13} We considered pain control a possible confounder, so we collected the AM-PAC score on postoperative day 7 for both groups. Although no patient in the standard group could be discharged before hospital day 6, six patients in the early group were discharged earlier. The SF-36 scores in the domain of physical function at 6 weeks to 2 years postoperatively also averaged nine points higher in the early group. These findings suggest that early ambulation leads to earlier discharge, and early ambulation improves physical function and overall quality of life in the immediate postoperative period and beyond.

Limitations

This pilot trial had limited power to detect statistically significant, yet clinically meaningful, differences in postoperative outcomes. The follow-up period was relatively short, and we had limited data on our physical function outcome measure. Initially, we used the Barthel Index³⁶ to measure physical function, but we changed that outcome measure to the AM-PAC score during the study because it was more specific. Furthermore, we assumed that all patients would have the maximum AM-PAC score at baseline, but this was incorrect. For these reasons, we reported the mean change in the AM-PAC score because we only had both baseline and follow-up scores for five

patients in the early group and eight in the standard group. We also had variability in the data collection period for the SF-36 surveys. However, this is the only randomized controlled trial of early ambulation after groin reconstruction with a sartorius flap and has important clinical implications.

CONCLUSIONS

In this pilot trial of patients who had groin reconstruction with sartorius muscle flaps following infrainguinal vascular surgery, we hypothesized that earlier ambulation would improve postoperative physical function and decrease hospital LOS, and that there would be no difference in wound or surgical complications. Our results showed that immediate and long-term physical function and general health were better in the early group. Furthermore, patients in the early group could be safely discharged before the standard 5 days of bedrest, and they did not have more wound complications than the standard group. However, the lymphatic complication rate was higher in the early group. This pilot trial shows the safety profile and benefits of early ambulation in vascular surgery patients who have had groin reconstruction with the sartorius flap. Although the decision of when to ambulate after surgery depends on the individual patient and their extenuating circumstances, plastic surgeons should consider ambulating their patients as early as postoperative day 2 following groin reconstruction with a sartorius muscle, as we have shown that it has clear benefits.

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