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Original Article

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# ABSTRACT

*Background:* Although postoperative complications of paramedian forehead flap (PMFF) are generally low, surgical site complications and unplanned reoperation can still occur. Recent literature suggests infection to be the most common complication following PMFF reconstruction. This study sought to determine the patient and preoperative factors associated with surgical site complications and unplanned reoperations at a national level.

*Methods:* Patients who underwent PMFF reconstruction from the ACS-NSQIP 2007 – 2019 database were analyzed to determine composite surgical site morbidity and unplanned return to the operating room. Patient and operative factors were also analyzed

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to assess independent risk factors for surgical site morbidity and unplanned reoperation in the first 30 postoperative days.

*Results:* A total of 1,592 PMFF were analyzed between 2007 and 2019. Of these, 2.7% (43/1592) developed a composite surgical site complication in the first 30 postoperative days. Risk factors for composite surgical site complication included >10% weight loss in the previous 6 months (p<0.05), disseminated cancer (p<0.01), class 4 wounds (dirty/infected) (p<0.01), and operative time greater than 123 min (p<0.01). Based on the univariate analysis, low preoperative albumin and hematocrit were also associated with increased odds of composite surgical site complication. 2.5% (40/1592) of patients underwent unplanned reoperation. Higher ASA class (p<0.05) and class 4 wounds (p<0.05) were associated with unplanned return to the operating room.

*Conclusion:* Significant weight loss, disseminated cancer, prolonged operation time, low preoperative albumin, and hematocrit are associated with higher PMFF composite surgical site complications. Higher ASA and class 4 wound status are associated with an increased risk of unplanned reoperation.

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#### Introduction

One of the most common locations of skin cancer in the head and neck is the nose. With advancement of surgical techniques and the advent of Mohs surgery, nasal skin cancer can usually be removed safely with maximal cosmesis in mind. Despite these advancements, resection of skin cancer of the nose frequently leaves in large skin defects that cannot be closed with local flaps, primary closure, or secondary intention.

The paramedian forehead flap (PMFF) is a type of interpolated flap that is frequently employed in large soft tissue defects of the nose, full thickness defects, total nasal reconstruction, and other complex reconstructions of the nose in the traumatic or oncologic setting. PMFF is generally considered a 2-stage procedure, with the initial stage consisting of harvesting and transferring the flap and a subsequent procedure dividing the vascular pedicle. The flap survival rate of PMFF is above 90%.<sup>1</sup> However, other postoperative complications rates have been reported to be as high as 20%. One of the most common complications after the initial stage is the development of small hematomas at the distal portion of the flap. In addition, ischemia can occur due to the greater rotational stress on the artery when the flap is transposed.<sup>2</sup> PMFF loss in these cases is associated with significant morbidity, often requiring flap removal and repeat tissue transfer.<sup>3,4</sup> Understanding the timing of flap failure and predictors associated with unplanned reoperation is important in mitigating patient morbidity and mortality.

Prior studies have examined preoperative and patient factors that are associated with postoperative surgical site complications. A single center retrospective chart review has demonstrated an increased risk of major postoperative complications including full-thickness nasal defects and smoking.<sup>5</sup> However, the study lacked the ability to detect risk factors for postoperative complications in patients treated at other institutions. Another hospital system-based retrospective case series reported a few incidences of postoperative superficial partial-thickness necrosis that was attributed to excess thinning and trimming of the flap, but further investigation into the technique was not performed.<sup>6</sup>

This study aims to investigate the risk factors associated with complications of PMFF using the ACS-NSQIP de-identified database, which tracks early patient outcomes across the United States.

Primary endpoints will include unplanned return to the operating room and composite surgical site morbidity.

# Methods

## Patient population

Patients who underwent PMFF reconstruction, identified by Current Procedural Terminology (CPT) code 1573, in the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) database from 2007 to 2019, were included in this study.

#### Outcomes

We analyzed the cohort to determine the composite surgical site morbidity and unplanned return to the operating room. We defined surgical site morbidity as a composite outcome of postoperative wound disruption and superficial, deep, or organ space infection. Patient characteristics and operative factors were also analyzed via multivariable logistic regression to assess independent risk factors for surgical site morbidity and unplanned reoperation in the first 30 postoperative days.

# Risk adjustment statistical analysis

We analyzed available clinical characteristics, including patient demographics, intraoperative, and postoperative data, to determine whether they are associated with reoperation using Chi-square tests for categorical variables and t-tests for continuous variables. We used multivariable logistic regression models to evaluate the effect of various risk factors on flap outcomes while controlling for any known potential confounding factors, which are available in the NSQIP database. We excluded any risk factors with >30% missing data in the logistic regression models. Variables with <=30% missing data were generally included with a missing category in the multivariable logistic regression models. All analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC). A *p*-value less than 0.05 was considered statistically significant.

# Results

## Overall cohort

A total of 1592 patients who underwent PMFF reconstruction between 2007 and 2019 were included in our study. The mean age (SD) among patients in the cohort was 66.3 (14.1) years. Of these patients, 55.28% were males and 44.72% were females. Most of our study population was white (89.45%). For composite surgical site complications, 2.7% (43/1592) developed a composite surgical site complication in the first 30 postoperative days.

# Composite surgical site complications

The rates of composite surgical site complications did not vary between patient sex, race, or age (Table 1). Other preoperative variables including diabetes mellitus, current smoking status, severe COPD, hypertension, bleeding disorders, steroid use, INR, platelet count, and ASA classification did not show statistically significant differences in rates of complications.

Disseminated cancer, greater than 10% loss of body weight in the past 6 months, and wound class 4 were associated with a higher risk of surgical site complications. The median operation time in the NSQIP database was 123 min. Those procedures that lasted longer than the median time had higher odds of surgical site complications (OR 2.25, 95% CI 1.19 -4.67) (Table 2). Of these variables, disseminated cancer was most strongly associated with an increased risk of complications, with an odds ratio of 13.91 (95% CI 3.45 – 56.15), followed by wound class 4 dirty/infected, with an odds ratio

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#### Table 1

Clinical Variable	Patients $n = 1592$	Without Complications $n = 1549 (97.2\%)$	With Complications $n = 43$ (2.70%)	Р
Sex				0.353
Male	880	696 (43.7)	16 (1.0)	
Female	712	853 (53.5)	27 (1.7)	
Race				0.872
White	1424	1385 (86.9)	39 (2.4)	
Black	13	13 (0.8)	0 (0)	
Other	12	12 (0.7)	0(0)	
Unknown	143	139 (8.7)	4 (0.2)	
Age	1592	1549 (97.2)	43 (2.70)	0.111
Mean (years)	66.33	62.95	66.42	

## Table 2

Odds Ratio (OR) and 95% Confidence Interval (CI) of Factors Associated with Surgical Site Complications.

	OR	95%CI		p-value
Disseminated Cancer	13.40	3.46	56.96	.0002
>10% Weight Loss in past 6 months pre-operation	9.79	2.00	47.97	.0049
Wound Class 4-Dirty/Infected vs. 1-Clean	12.31	3.98	38.04	.0001
Median Operation Time >123 min vs. <=123 min	2.25	1.19	4.67	.0145

#### Table 3

Mean Preoperative Hematocrit and Albumin Association with Surgical Site Complication\*.

	Overall	Surgical Site Complications	No Surgical Site Complications	p-value
Preoperative hematocrit, N	918	25	893	.004
Mean (SD)	40.44 (4.82)	37.72 (4.41)	40.51 (4.82)	
Median (IQR)	40.80 (37.70, 43.50)	37.80 (36.00, 41.00)	40.90 (37.90, 43.60)	
Median (Range)	40.80 (14.00, 54.10)	37.80 (27.00, 45.50)	40.90 (14.00, 54.10)	
Pre-operative serum albumin, N	378	13	365	.001
Mean (SD)	3.91 (0.52)	3.46 (0.69)	3.93 (0.51)	
Median (IQR)	4.00 (3.70, 4.20)	3.50 (3.10, 4.00)	4.00 (3.70, 4.20)	
Median (Range)	4.00 (1.60, 6.80)	3.50 (2.10, 4.20)	4.00 (1.60, 6.80)	

\* Based on univariate analysis.

of 12.88 (95% CI 4.10 – 40.43) when compared to clean wounds. Dyspnea is associated with an odds ratio of 2.72 although it is based on univariate analysis.

Preoperatively, lower hematocrit, or albumin is associated with increased odds of surgical site complication based on univariate analysis (Table 3).

# Unplanned reoperation

In terms of unplanned reoperation, 2.5% (40/1592) of patients underwent unplanned reoperation related to initial forehead flap reconstruction in the first postoperative month. Like composite surgical site complications, there were no significant association with sex, race, or age. Multivariable analysis demonstrated that higher ASA class (p<0.05), and class 4 wounds (p<0.05) were associated with unplanned return to the operating room. The odds ratio of unplanned reoperation of ASA class 3/4/5 vs. ASA class 1/2 was 2.22 (95% CI 1.09–4.51) vs. 5.36 (95% CI 1.10–26.20), respectively (Table 4).

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#### Table 4

Odds Ratio (OR) and 95% Confidence Interval (CI) of Factors Associated with Unplanned Reoperation.

	OR	95% CI	95% CI	
Wound Class 2-Clean/Contaminated vs. 1-Clean	2.49	1.20	5.20	.0147
Wound Class 3-Contaminated vs. 1-Clean	2.35	0.80	6.90	.1184
Wound Class 4-Dirty/Infected vs. 1-Clean	5.36	1.10	26.20	0.0380
ASA Class 3/4/5 vs. 1/2	2.22	1.09	4.51	.0274

#### Discussion

PMFF is the mainstay option for reconstruction of full thickness defects of the nose. Generally, PMFF has a very good outcome, but its complication rate is not negligible. Prior studies have shown the most common postoperative complication of PMFF is flap infection, followed by bleeding.<sup>1</sup>

A prior study examining preoperative risk factors for PMFF complication using NSQIP similarly demonstrated the strongest risk factor being a dirty infected wound, with an OR of 13.5.<sup>7</sup> The slight difference in OR between our study and theirs could be attributed to the different range of time that was sampled from the NSQIP. Our study sampled NSQIP between 2007 and 2019, while the prior study sampled between 2010 and 2018. This finding is consistent with a prior study by Chen et al., which demonstrated infection to be the most common complication after PMFF surgery.<sup>1</sup>

Interestingly, our study found >10% weight loss in the past 6 months as a significant risk factor for surgical site complication. Although significant malnutrition can lead to surgical site complication through slow wound healing or infection, significant weight loss could be a confounder and a proxy for disseminated cancer.<sup>8</sup> A study by Kmboj et al. have demonstrated a positive association between disseminated cancer and surgical site infection.<sup>9</sup> This is an expected finding as disseminated cancer increases the patient's risk of surgical site complication through coagulopathy and an immunocompromised state.<sup>10</sup> Furthermore, patients with disseminated cancer are undergoing multimodality treatments such as chemoradiation, which can weaken the patients' immune system further and increase their risk of infection.

Prior studies have demonstrated flap infection to be the most common form of PMFF complication, and thus, it is expected that class 4 wounds (dirty infected) would be most strongly associated with flap complication when compared with other wound classes. The CDC has established a classification system composed of four classes of wound statuses, to describe the cleanliness and condition of the wound. A class 4 wound or dirty infected wound is when a surgical or traumatic wound is improperly cared for resulting in bacterial infection of the wound and its surrounding tissues. Typical signs of a class 4 wound include wound erythema, purulence, or in severe cases necrotic tissues.<sup>11</sup> Although the overall rate of flap infection for PMFF is relatively low, it is the most common reason for PMFF complication. PMFF is generally a multistage process, and patients are often discharged home between the initial surgery and subsequent staged surgery. In addition to proper sterile technique and preoperative antibiotic administration, postoperative wound care and monitoring are equally crucial to minimize the risk of flap infection.<sup>12</sup> Generally, the PMFF dressing can be left in place for one week, and the patient is seen 1 to 2 days after the initial surgery to examine the site and to change the dressing, with the pedicle eventually being divided after 2 to 3 weeks. Adequate information and education regarding wound care should be provided to patients to optimize care for their wound. If the patient lacks the ability to care for his or her wound, then home health should be set up for the patient.13

Our data showed an operation time exceeding 123 min was associated with an increased risk of surgical site complication. PMFF is a short procedure, regardless of the stage, and usually lasts less than 1 h, but it can take longer depending on various patient or institution factors including patient anatomy, extent of disease, comorbidities, and the surgeon's familiarity with the procedure.<sup>14</sup> The association between prolonged operation time and surgical site complication has been previously established as prior prospective and retrospective studies have found positive associations between the duration of surgical procedures and complications such as surgical site infection, venous thromboembolism, bleeding, hematoma formation, and necrosis. Specifically, surgical site infection is strongly

associated with prolonged operative time due to prolonged microbial exposure.<sup>15</sup> However, from our data, it is unknown what specifically constituted the surgical site complication as it is not defined in the NSQIP data.

Preoperative albumin and hematocrit have been associated with increased postoperative surgical site complication in prior studies.<sup>16,17</sup> Both factors were only significant on the univariate analysis in our study, likely due to low power. Preoperative albumin can be an indirect measure of patients' nutritional status and highlights the importance of preoperative nutrition. Unfortunately, despite compelling evidence, preoperative nutrition is often glossed over, and postoperative nutrition is instituted only implemented after complications occur. Similarly, preoperative anemia has also been linked to increased odds of postoperative surgical site complications.<sup>18</sup> Both findings suggest that preoperative patient health optimization can be as important as the surgery and its postoperative care, when it comes to overall surgical outcome.

While other works have identified risk factors of surgical site complications following PMFFs using NSQIP data, this study is unique in that it also offers insight into the independent variables associated with unplanned reoperation. Similar to surgical site complications, class 4 wounds were associated with higher rates of unplanned reoperation. Additionally, our study showed that higher ASA scores are associated with increased rates of unplanned reoperation. This finding is consistent with prior studies that have shown that increased ASA scores are associated with higher rates of postoperative complications across various types of surgeries.<sup>19</sup> Higher ASA scores are generally associated with elderly patients with multiple comorbidities or patients who are severely ill. These factors predispose them to postsurgical complications such as surgical site infection, venous thromboembolism, and tissue necrosis.<sup>20,21</sup>

There were several limitations to our study. One of the major limitations is that the NSQIP database only provided information on morbidity and mortality within 30 days after a surgical procedure. Therefore, complications that occur beyond 30 days after the surgical procedure were not included. This can potentially lead to the underestimation of complication rates. Another major limitation of the NSQIP database is the lack of specificity regarding our outcome of interest. The NSQIP allowed us to examine factors that are associated with either postoperative surgical site complication or unplanned reoperation. However, as a de-identified database, it does not provide details regarding the surgical site complications. As a result, the study could not further characterize risk factors that may be associated with a specific type of complication. Similarly for the unplanned reoperation, it was not disclosed what procedures or extent of reoperation took place. The database did not specify the details of the complication that necessitated a reoperation. Future studies could focus on identifying specific complications that were associated with various risk factors through retrospective cohort or cross-sectional study designs. Lastly, there are a few intrinsic limitations of the study design using the NSQIP including retrospective study design, selection bias, and potential confounders that were unaccounted for.

#### Conclusion

Significant weight loss, disseminated cancer, prolonged operation time, low preoperative albumin, and hematocrit are associated with higher PMFF composite surgical site complications. Higher ASA and class 4 wound status are associated with increased risk of unplanned reoperation. To minimize postoperative complications associated with PMFF, it is critical to optimize patient and operative factors associated with surgical site complications and unplanned return to the operating room.

#### **Declaration of Competing Interest**

None declared.

# Funding

None.

# Ethical approval

Not required.

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