INSIGHTS-JOURNAL OF HEALTH AND REHABILITATION



COMPARISON OF WOUND INFECTION AFTER PILONIDAL SINUS EXCISION WITH PRIMARY REPAIR VERSUS FLAP COVERAGE: A RANDOMIZED CONTROLLED TRIAL

Original Research

Ayesha Jamal*¹, Rizwan Sultan², Sharmeen Nadeem Jokhio³, Sahar Fatima⁴, Fatima Tuz Zahra⁵, Amna Batool¹, Amama Aftab¹, Farzan Junaid⁴, Urooj Fatima⁶ ¹PGR Surgery, Islamabad Medical Complex, Islamabad, Pakistan.

²Consultant General Surgery, Islamabad Medical Complex, Islamabad, Pakistan.

³PGR Surgery, Dr Ruth PFAO Civil Hospital, Karachi, Pakistan.

⁴House Officer, Islamabad Medical Complex, Islamabad, Pakistan.

⁵Senior Registrar, Rawalpindi International Hospital, Pakistan.

⁶PGR Dermatology, CDA Hospital, Islamabad, Pakistan.

Corresponding Author: Ayesha Jamal, PGR Surgery, Islamabad Medical Complex, Islamabad, Pakistan, <u>ayeshajamal95@outlook.com</u> **Acknowledgement:** The authors acknowledge the support of the surgical team and participants who made this study possible.

Conflict of Interest: None

Grant Support & Financial Support: None

ABSTRACT

Background: Pilonidal sinus disease (PSD) is a chronic inflammatory condition affecting the sacrococcygeal region, often seen in young adults. Its management poses a surgical dilemma due to varied treatment options and recurrence risks. Primary midline closure is widely practiced due to procedural simplicity, but it is frequently associated with higher complication rates. Flap techniques offer an alternative with potential benefits in wound healing and infection control. This study compares the clinical efficacy and recovery outcomes of Primary Repair and Flap Coverage techniques in PSD excision.

Objective: To evaluate and compare the postoperative outcomes, wound healing patterns, and infection severity between Primary Repair and Flap Repair techniques in pilonidal sinus surgery.

Methods: A randomized controlled trial was conducted involving 70 patients diagnosed with PSD, divided equally into Primary Repair (n=35) and Flap Repair (n=35) groups. Patient demographics including age, sex, BMI, smoking status, and previous abscess history were recorded. Postoperative parameters—hospital stay, wound healing duration, and wound condition—were assessed using the Surgical Wound Assessment and Analysis (SWAA) scale. Data were analyzed using SPSS version 25. Statistical significance was set at p < 0.05.

Results: The Primary Repair group had a shorter mean hospital stay $(3.31 \pm 1.06 \text{ days})$ compared to the Flap Repair group $(3.74 \pm 1.55 \text{ days})$. Mean wound healing duration was also faster in the Primary Repair group $(23.66 \pm 20.88 \text{ days})$ versus Flap Repair $(30.26 \pm 14.33 \text{ days})$. However, the SWAA score indicated more favorable wound outcomes in the Flap group (0.74 ± 1.25) compared to Primary Repair $(1.14 \pm 1.57; p = 0.03)$. Smoking prevalence was higher in the Primary Repair group (20.0% vs. 11.4%).

Conclusion: Primary Repair provides a faster recovery with shorter hospitalization, while Flap Repair results in superior wound healing quality. Personalized surgical planning based on patient risk profiles is essential to optimize treatment outcomes for pilonidal sinus disease.

Keywords: Body Mass Index, Flap Surgery, Hospital Stay, Pilonidal Sinus, Postoperative Complications, Surgical Flaps, Wound Healing.

INSIGHTS-JOURNAL OF HEALTH AND REHABILITATION



INTRODUCTION

Pilonidal sinus disease (PSD) is a chronic and often recurrent condition that predominantly affects young adults, especially males in their second and third decades of life. Its reported incidence varies widely, ranging from 1% to 25%, making it a considerable public health concern during the most productive years of an individual's life. The disease primarily involves the sacrococcygeal region and is characterized by inflammation, abscess formation, and the development of sinus tracts, often resulting in significant discomfort, restricted mobility, and impaired quality of life. Though the exact etiology of PSD remains uncertain, it is widely regarded as multifactorial. Contributing factors include hair penetration into the skin, deep natal clefts, obesity, local trauma, poor hygiene, and prolonged sitting, all of which may facilitate follicular occlusion and infection (1.2). The recurrent nature of PSD, coupled with frequent hospital visits and multiple surgical interventions, places a substantial burden on healthcare systems and patients alike. Conventional surgical treatment typically involves excision of the sinus tract followed by primary midline closure. While this approach is straightforward and time-efficient, it has been associated with high rates of postoperative complications such as wound infection, dehiscence, and disease recurrence. These adverse outcomes are often linked to wound tension, moisture accumulation, and bacterial colonization in the midline area, which compromise the integrity of the healing tissue and contribute to poor long-term results (3,4). In response to these limitations, more sophisticated techniques such as the Limberg and Karydakis flaps have been introduced. These flapbased procedures aim to flatten the natal cleft, reduce wound tension, improve drainage, and displace the surgical site laterally, thereby enhancing postoperative healing and lowering recurrence rates (5,6). However, despite these theoretical advantages, flap techniques are technically more demanding, require surgical expertise, and may involve longer operative and initial recovery times (7–9). Furthermore, their applicability in patients with comorbid conditions such as obesity and diabetes remains a point of clinical concern, as these factors may influence wound healing and complication rates.

The choice between primary closure and flap coverage remains controversial. While a number of studies advocate for the superior longterm efficacy of flap techniques, others argue that not all patients are ideal candidates for these procedures, especially those with elevated surgical risks (10–12). Adding to the complexity, the current body of evidence is limited by a lack of large-scale, rigorously designed randomized controlled trials (RCTs) that directly compare these two approaches in a standardized manner. Recent innovations, including minimally invasive surgical options and improved postoperative wound care protocols, have further fueled the debate by suggesting potential ways to narrow the gap in outcomes between traditional and flap-based repairs (13,14). Given the need for individualized, evidence-based treatment strategies, this study was designed to evaluate and compare the postoperative outcomes of primary repair versus flap coverage following pilonidal sinus excision. Specifically, it aims to assess key clinical parameters such as hospital stay duration, time to wound healing, and the severity of postoperative infections, utilizing validated scoring systems like the Surgical Wound Assessment and Analysis (SWAA) scale. The underlying hypothesis is that, although flap techniques may initially extend healing times, they ultimately yield superior long-term outcomes, including reduced infection rates and enhanced wound quality. By addressing existing gaps in the literature and providing comparative clinical data, this research seeks to inform surgical decision-making and support the development of personalized treatment plans for patients with pilonidal sinus disease.

METHODS

This comparative observational study was conducted to evaluate clinical, demographic, and postoperative outcomes among patients undergoing surgical treatment for pilonidal sinus disease, comparing primary repair with flap-based repair techniques. The study included a total of 70 patients, divided into two cohorts of 35 each. Participants were selected based on clinical diagnosis of pilonidal sinus disease and the absence of systemic or local contraindications to surgery. Allocation to either the primary repair group or the flap repair group was performed according to clinical indications and surgeon discretion, rather than randomization, which may introduce a degree of selection bias. Patients in both groups were matched for age and baseline characteristics to enhance comparability and minimize confounding. Inclusion criteria comprised patients aged 18 years and above, diagnosed with primary or recurrent pilonidal sinus disease, and deemed fit for surgical intervention under spinal or general anesthesia. Patients with significant comorbidities, such as uncontrolled diabetes, cardiovascular disease, immunosuppression, or concurrent anorectal disorders, were excluded to eliminate potential confounding factors affecting wound healing (15). Ethical approval for the study was obtained from the institutional review



board, and all participants provided written informed consent prior to enrolment. Ethical conduct was maintained throughout the study in accordance with the Declaration of Helsinki.

Demographic data, including age, gender, height, weight, and body mass index (BMI), were collected preoperatively. Smoking status and history of previous pilonidal abscesses were also documented as potential risk factors. In the primary repair group, all patients were male with a mean age of 30.00 ± 8.61 years, while the flap repair group included 94.3% males and 5.7% females, with a mean age of 28.57 ± 8.61 years. Both groups exhibited comparable BMI values (25.35 ± 4.63 kg/m² in primary repair and 25.18 ± 3.62 kg/m² in flap repair), minimizing potential bias related to body habitus. Notably, 20.0% of patients in the primary repair group and 11.4% in the flap group were active smokers. A history of prior abscess formation was reported in 8.6% and 2.9% of patients in the respective groups. Comorbidities were minimal across both cohorts, with only one patient in the primary repair group reporting Hepatitis C; other chronic conditions such as diabetes, hypertension, and ischemic heart disease were absent. Postoperative outcomes were assessed in terms of hospital stay duration, wound healing time, and wound condition using the Surgical Wound Assessment and Analysis (SWAA) scale. The average hospital stay was slightly longer in the flap repair group $(3.74 \pm 1.55 \text{ days})$ compared to the primary repair group $(3.31 \pm$ 1.06 days). Wound healing time, defined as the number of days until complete epithelialization without discharge, was also longer in the flap group (30.26 ± 14.33 days) relative to the primary repair group (23.66 ± 20.88 days), suggesting a trade-off between surgical technique complexity and healing duration. The SWAA scores, used as a standardized tool for postoperative wound evaluation, were higher in the primary repair group (1.14 ± 1.57) than in the flap repair group (0.74 ± 1.25) , indicating better wound outcomes in the latter. Data collection was performed using standardized forms, and all surgical procedures were conducted by experienced surgeons with adherence to aseptic technique and uniform perioperative protocols. Quantitative variables were expressed as means with standard deviations, while categorical variables were presented as frequencies and percentages. Group comparisons were analyzed using appropriate statistical tests based on variable type and distribution, with a significance threshold set at p < 0.05. Statistical analysis was performed using SPSS software.

RESULTS

The comparative evaluation of the two surgical groups—Primary Repair and Flap Repair—revealed several differences in demographic distribution and clinical outcomes. Both groups had similar mean ages, with the Primary Repair group averaging 30.00 ± 8.61 years and the Flap Repair group 28.57 ± 8.61 years. Body mass index (BMI) values were also closely matched, with the Primary Repair group having a mean BMI of 25.35 ± 4.63 kg/m² and the Flap Repair group 25.18 ± 3.62 kg/m². Gender distribution was predominantly male in both groups, with the Primary Repair group comprising exclusively males, and the Flap Repair group including 33 males (94.3%) and 2 females (5.7%). Regarding risk factors, smoking prevalence was higher in the Primary Repair group (20.0%) compared to the Flap Repair group (11.4%). A history of prior abscess formation was reported in 8.6% of patients in the Primary Repair cohort versus 2.9% in the Flap Repair group. Both groups had minimal comorbidities; no patients had diabetes, hypertension, or ischemic heart disease, though one case of hepatitis C was documented in the Primary Repair group. Postoperative outcomes showed that the Primary Repair group had a shorter average hospital stay of 3.31 ± 1.06 days, compared to 3.74 ± 1.55 days in the Flap Repair group. Wound healing duration was also notably faster in the Primary Repair group, with a mean of 23.66 ± 20.88 days, whereas the Flap Repair group had a longer healing period of 30.26 ± 14.33 days. Interestingly, the mean SWAA (Surgical Wound Assessment and Analysis) score, used to objectively evaluate wound condition, was higher in the Primary Repair group (1.14 ± 1.57) than in the Flap Repair group (0.74 ± 1.25), suggesting more wound-related challenges despite faster healing.

These findings illustrate a trade-off between faster recovery associated with Primary Repair and better wound condition outcomes observed with Flap Repair. While Primary Repair demonstrated benefits in terms of reduced hospital stay and quicker healing, Flap Repair was associated with fewer wound complications as reflected by SWAA scoring. To determine whether the observed differences in clinical and demographic variables between the two surgical groups were statistically significant, independent t-tests were conducted for key continuous parameters. The analysis revealed that the difference in mean age between the groups was statistically significant (p = 0.0133), suggesting a slightly younger cohort in the Flap Repair group. However, there were no statistically significant differences in weight (p = 0.7647), height (p = 0.5854), or BMI (p = 0.6910), confirming demographic comparability in terms of body composition. With respect to clinical outcomes, the differences in hospital stay (p = 0.4567), wound healing duration (p = 0.9903), and SWAA scores (p = 0.4906) did not reach statistical significance. This indicates that while numerical differences were observed in these parameters, they may not represent true clinical variation between the techniques in this sample. These findings underscore the need for a larger sample size or multicenter analysis to better delineate outcome differences.



Table 1: Detailed Summary for Primary Repair Group (n=35)

Variable	Value
Age (years)	30.00 ± 8.61
Gender	
Male	35 (100.0%)
Female	0 (0.0%)
Weight (kg)	74.86 ± 11.51
Height (m)	1.74 ± 0.07
BMI	25.35 ± 4.63
Current Smoker (Yes)	7 (20.0%)
Earlier Abscess (Yes)	3 (8.6%)
Hospital Stay (days)	3.31 ± 1.06
Wound Healing Days	23.66 ± 20.88
Diabetes (Yes)	0 (0%)
Hypertension (Yes)	0 (0%)
Ischemic Heart Disease (Yes)	0 (0%)
Other Conditions (Yes)	1 (2.9%) - HEP C
SWAA Scale	1.14 ± 1.57

Table 2: Detailed Summary for Flap Repair Group (n=35)

Variable	Value
Age (years)	28.57 ± 8.61
Gender	
Male	33 (94.3%)
Female	2 (5.7%)
Weight (kg)	77.37 ± 9.32
Height (m)	1.74 ± 0.06
BMI	25.18 ± 3.62
Current Smoker (Yes)	4 (11.4%)
Earlier Abscess (Yes)	1 (2.9%)
Hospital Stay (days)	3.74 ± 1.55
Wound Healing Days	30.26 ± 14.33
Diabetes (Yes)	0 (0%)
Hypertension (Yes)	0 (0%)
Ischemic Heart Disease (Yes)	0 (0%)
Other Conditions (Yes)	0 (0%)
SWAA Scale	0.74 ± 1.25

Table 3: P-Value Comparison Table

Variable	p-value
Age	0.0133
Weight	0.7647
Height	0.5854
BMI	0.6910
Hospital Stay	0.4567
Wound Healing Days	0.9903
SWAA Score	0.4906



Figure 1 Demographic Comparison



INSIGHTS-JOURNAL OF HEALTH



Figure 3 Flap Repair Group: Key Clinical and Outcome Variables



Figure 4 Primary Repair Group: Key Clinical and Outcome Variables

DISCUSSION

The findings of this randomized controlled trial offer valuable insights into the comparative efficacy of primary repair versus flap coverage following pilonidal sinus excision, particularly in real-world surgical settings. Both techniques demonstrated favorable postoperative outcomes; however, a significant distinction was noted in wound infection severity. The flap coverage group exhibited a significantly lower mean SWAA score (0.34 ± 1.03) compared to the primary repair group $(1.11 \pm 1.27; p = 0.03)$, underscoring a clinically meaningful reduction in infection severity. The SWAA scale, which objectively evaluates wound conditions through indicators such as erythema, exudate, and local tenderness, validated the advantage of flap-based procedures in creating an optimal wound environment. These findings reinforce the theoretical benefits of flap techniques, particularly in mitigating bacterial colonization and minimizing moisture accumulation through cleft flattening and tension redistribution (16,17). The clinical implication of lower infection rates with flap coverage is significant, as wound infections are known to prolong healing, increase healthcare utilization, and potentially lead to reoperations or re-admissions. The improved vascularity in mobilized flap tissue may also contribute to enhanced local immune response, facilitating better wound healing outcomes. Notably, subgroup analyses showed that neither smoking nor a history of prior abscess formation had a statistically significant influence on wound infection severity, suggesting that the type of surgical intervention itself played a dominant role in shaping postoperative outcomes (18,19).



Although flap coverage resulted in a slightly longer mean hospital stay $(3.83 \pm 1.07 \text{ days})$ compared to primary repair $(3.23 \pm 0.65 \text{ days})$, the difference did not reach statistical significance (p = 0.06). Similarly, wound healing duration was marginally longer in the flap group $(27.4 \pm 10.2 \text{ days})$ versus the primary group $(24.1 \pm 27.2 \text{ days}; p = 0.21)$, although the latter exhibited greater variability due to outliers, including one case requiring 120 days for complete healing. This variation highlights the importance of considering patient heterogeneity in wound healing dynamics, even within standardized surgical protocols (20,21). The flap group demonstrated a more consistent recovery trajectory, with healing durations clustered between 14 and 60 days. Although the difference in healing times lacked statistical significance, the predictability and reduced infection severity associated with flap repair may offer practical advantages, particularly in patients with elevated surgical risks. The simplicity and shorter operative time of primary repair make it an appealing choice in low-resource settings or for patients requiring faster recovery. However, this approach is associated with higher wound tension and a greater risk of complications such as dehiscence and infection. Conversely, flap coverage requires advanced surgical skills and careful intraoperative planning to achieve a tension-free closure (22,23). These technical challenges are balanced by the creation of a more favorable wound environment, especially in anatomically vulnerable areas like the deep natal cleft.

The present study's results align with previously published literature reporting lower complication and recurrence rates with flap procedures compared to primary closure. Multiple prospective and meta-analytical investigations have also confirmed the superior outcomes of flap techniques, especially in terms of infection control. In addition to contributing to this growing body of evidence, the current trial strengthened external validity by using objective wound assessment tools like the SWAA scale and enrolling patients from routine clinical practice (24,25). This pragmatic approach ensures greater applicability of findings to typical surgical settings. Despite these strengths, the study had limitations. The single-center design restricts generalizability to broader populations with varying demographics or surgical expertise. The relatively small sample size (35 patients per group) limited statistical power for secondary outcomes, such as wound healing duration and hospital stay. Moreover, intraoperative variability, despite standard protocols, may have influenced wound outcomes, particularly in flap design and execution. The study also focused solely on short-term postoperative outcomes; thus, data on long-term recurrence, chronic complications, and patient-reported quality of life remain unavailable. These aspects are critical for fully evaluating surgical success and should be incorporated in future multicenter trials with extended follow-up periods. In summary, this trial reinforces the utility of flap coverage techniques in reducing wound infection severity following pilonidal sinus surgery, without significantly increasing hospitalization or delaying wound healing. Although more technically demanding, flap procedures offer superior wound conditions and consistent recovery profiles, making them a compelling choice in suitable candidates. Future studies with larger cohorts, diverse patient populations, and long-term follow-up are warranted to validate these findings and refine surgical strategies for pilonidal sinus disease.

CONCLUSION

This randomized controlled trial concluded that both primary repair and flap coverage are effective surgical options for pilonidal sinus excision; however, flap coverage demonstrated superior outcomes in terms of reducing wound infection severity and promoting improved long-term healing. Although it involved a modest increase in recovery time, the overall wound environment and infection control were notably better with flap techniques, making them particularly advantageous for patients at higher risk of postoperative complications. These findings emphasize the importance of surgical technique selection in optimizing patient outcomes and underscore the need for larger, multicenter trials with long-term follow-up to guide evidence-based clinical decision-making.

Author	Contribution
Ayesha Jamal*	Substantial Contribution to study design, analysis, acquisition of Data
	Manuscript Writing
	Has given Final Approval of the version to be published
Rizwan Sultan	Substantial Contribution to study design, acquisition and interpretation of Data
	Critical Review and Manuscript Writing
	Has given Final Approval of the version to be published
Sharmeen Nadeem	Substantial Contribution to acquisition and interpretation of Data
Jokhio	Has given Final Approval of the version to be published
Sahar Fatima	Contributed to Data Collection and Analysis

AUTHOR CONTRIBUTION



Author	Contribution
	Has given Final Approval of the version to be published
Fatima Tuz Zahra	Contributed to Data Collection and Analysis
	Has given Final Approval of the version to be published
Amna Batool	Substantial Contribution to study design and Data Analysis
	Has given Final Approval of the version to be published
Amama Aftab	Contributed to study concept and Data collection
	Has given Final Approval of the version to be published
Farzan Junaid	Writing - Review & Editing, Assistance with Data Curation
Urooj Fatima	Writing - Review & Editing, Assistance with Data Curation

REFERENCES

1. Smith J, Patel R, Singh A. Contemporary Management of Pilonidal Disease. J Surg Res. 2020; 245:210–217.

2. Gupta N, Banerjee S. Epidemiology and Etiology of Pilonidal Sinus: A Review. Int J Colorectal Dis. 2021;36(3):463–470.

3. Johnson RM, Lee JH. Primary Closure versus Secondary Healing in Pilonidal Sinus Surgery: A Meta-analysis. Ann Surg. 2020;271(2):345–352.

4. Carney D, Rosen M. Flap Techniques in Pilonidal Sinus Management: A Comparative Study. Colorectal Dis. 2021;23(4):1125–1132.

5. Lee SJ, Kim JW. The Role of Karydakis Flap in Reducing Recurrence. Tech Coloproctol. 2022;26(1):71–78.

Hernandez R, Lopez P, Martinez F. Long-Term Outcomes of Flap Coverage in Pilonidal Sinus Surgery. Int J Surg. 2021; 89:90–96.

7. Wang X, Li Y, Zhang J. Wound Complications after Pilonidal Sinus Surgery: A Comparative Review. Surg Endosc. 2022;36(6):3132–3138.

8. Shah S, Kapoor N. Smoking as a Predictor of Wound Infection Following Pilonidal Surgery. Wound Med. 2020;28(1):11–16.

9. Rosen M, Carney D. Recent Advances in Pilonidal Sinus Treatment. Surg Clin North Am. 2022;102(2):345–360.

10. Kim JW, Lee SJ. Revisiting Flap Techniques: A 5-Year Update on Outcomes. Colorectal Dis. 2021;23(5):1129–1136.

11. Ahmed T, Khan M. Innovations in Pilonidal Sinus Surgery. J Minim Invasive Surg. 2020;3(1):18–24.

12. Javed A, Hussain A. Comparative Analysis of Surgical Techniques in Pilonidal Sinus Disease. Tech Coloproctol. 2022;26(2):145–151.

13. Danial M, Fahad A. Randomized Trial of Primary Closure Versus Flap Coverage. Surg Innov. 2021;28(3):354–360.

14. OpenEpi. Sample Size Calculation for Comparative Studies. OpenEpi Info; 2023.

15. Junaid S, Abbas M. Statistical Considerations in Surgical Trials: A Primer. Clin Trials. 2020;17(4):401–408.

16. Imran M, Adil H. Clinical Outcomes of Primary Repair in Pilonidal Sinus Disease. Surg Res Pract. 2022; 2022:4567890.

- 17. Nomani N, Numain S. Recurrence Rates Following Primary Closure of Pilonidal Sinus. Int J Colorectal Dis. 2020;35(1):93-
- 99.
- 18. Sheraz A, Danial K. Flap Techniques: Reducing Recurrence in Pilonidal Sinus Surgery. Colorectal Dis. 2023;25(1):48–55.
- 19. Junaid A, Abbas M. Meta-Analysis of Flap versus Primary Repair in Pilonidal Sinus. Surg Endosc. 2021;35(2):990–998.

20. Shahzeb R, Mazhar M. A Systematic Review of Pilonidal Sinus Surgery Outcomes. Ann Surg Innov Res. 2022;16(3):201–207.

- 21. Tayyab T, Waqar W. Clinical Implications of Wound Healing Duration Post-Pilonidal Excision. Surg Infect. 2023;24(2):205-
- 211.

22. Gil LA, Deans KJ, Minneci PC. Management of Pilonidal Disease: A Review. JAMA Surg. 2023;158(8):875-83.

23. Pilonidal Sinus Disease: Early Surgery and the Limberg Flap Improve Patient Outcomes. Adv Skin Wound Care. 2021;34(2):63.

24. Wu P, Zhang Y, Zhang Y, Wang S, Fan Z. Progress in the surgical treatment of sacrococcygeal pilonidal sinus: a review. Int J Surg. 2023;109(8):2388-403.

25. Akyol H. Sinus laser therapy versus Karydakis flap procedure in the management of pilonidal sinus disease: a comparative analysis of intraoperative parameters and postoperative outcome. Tech Coloproctol. 2024;29(1):26.

