

## Fistula in Ano – Comparison Between Fistulectomy with Primary Sphincter Reconstruction (FPSR) Vs Core Out Fistulectomy with Sphincter Reconstruction

Pratik Pandurang Panjarkar<sup>1</sup>, Prasad Uppanlawar<sup>2</sup>, Pranav Rameshwar Ukey<sup>3</sup>, Raju Wamanrao Gore<sup>4</sup>, Vidhey Tirpude<sup>5</sup>

<sup>1</sup>Junior Resident, Department of Surgery, GMC Gondia, Maharashtra, India

<sup>2</sup>Associate Professor and Head of Department, Department of Surgery GMC, Gondia, Maharashtra, India

<sup>3</sup>Senior Resident, Department of Surgery, GMC, Gondia, India

<sup>4</sup>Associate Professor, Department of General Surgery, GMC, Gondia, Maharashtra, India

<sup>5</sup>Assistant Professor, Department of General Surgery, GMC, Gondia, Maharashtra, India

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Corresponding Author: Dr. Raju Wamanrao Gore

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### Abstract

**Background:** Fistula in ano, a common and often debilitating condition, represents a significant burden in proctology. It is characterized by an abnormal connection between the anal canal and the perianal skin, typically resulting from an anorectal abscess that fails to heal adequately.

**Objective:** To examine the two prominent surgical approaches: Fistulectomy with Primary Sphincter Reconstruction (FPSR) and Core Out Fistulectomy with Sphincter Reconstruction.

**Methods:** This Comparative Observational study was conducted at in the Department of Surgery among all patients with high complex trans-sphincteric anal fistula admitted to the tertiary care hospital and eligible for surgical treatment, who agreed to participate in the study.

**Result:** Both FPSR and CORING were effective in treating fistula in ano, with no significant differences in recurrence rates, incontinence, or wound dehiscence between the two techniques. FPSR was associated with longer operative times (mean  $45 \pm 3.22$  minutes), extended wound healing periods (mean  $8.20 \pm 0.96$  weeks), and higher immediate postoperative pain (mean VAS score  $4.5 \pm 0.77$ ) compared to CORING. However, both procedures showed low long-term complication rates, indicating their effectiveness and safety.

**Conclusion:** Both FPSR and CORING are viable surgical options for managing high complex trans-sphincteric anal fistula, with similar efficacy in preventing recurrence and maintaining continence. FPSR, while associated with increased operative time and pain, did not significantly differ from CORING in terms of long-term outcomes.

**Keywords:** Fistula In Ano, Fistulectomy, Primary Sphincter Reconstruction, Core Out Fistulectomy, Sphincter Reconstruction

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### Introduction

Fistula-in-ano results from the obstruction of the glands, located chiefly at the dentate line, by debris and their subsequent infection. This condition not only causes discomfort and pain but can also lead to recurrent infections, impacting the quality of life and posing challenges in management.<sup>[1]</sup> It could also be due to previous surgeries, trauma, malignancy, diseases like Crohn's, tuberculosis, HIV infections, etc.

The global incidence of fistula in ano is 8.6 per 100,000 per year, of which 26–38% develop from previous perianal abscesses.<sup>[2]</sup> There are many

surgical options available as not a single technique is foolproof. Conventionally successful techniques, like laying open the tract (fistulotomy) and coring out the tract (fistulectomy) and cutting seton placement, are fraught with complications ranging from recurrences to incontinence.<sup>[3,4,5]</sup> To overcome these complications, newer sphincter-saving procedures are fast evolving.

Despite advancements in surgical techniques, the treatment of fistula in ano remains complex due to the delicate balance required to eradicate the disease while preserving the anal sphincter

function. [6]

The primary aim of fistula treatment is to achieve complete healing while minimizing the risk of recurrence and maintaining continence. Traditional surgical options, such as fistulotomy, have been effective in many cases but carry a risk of sphincter damage, leading to potential incontinence. [7] More advanced techniques, including various forms of fistulectomy with sphincter reconstruction, have been developed to address these concerns. [8] Present study examines the two prominent surgical approaches: Fistulectomy with Primary Sphincter

**Study Population: The study population included**

Reconstruction (FPSR) and Core Out Fistulectomy with Sphincter Reconstruction.

**Material and Methods:** This Comparative Observational study was conducted at in the Department of Surgery among all patients with high complex trans-sphincteric anal fistula admitted to the tertiary care hospital and eligible for surgical treatment, who agreed to participate in the study. The study protocol received approval from the ethical committee for research studies in a clinical setting at the medical institution under appropriate supervision and guidance.

Inclusion Criteria	Exclusion Criteria
1. Patients with high complex trans- sphincteric anal fistula (defined as fistulae involving more than 50% of the external anal sphincter).	1. Patients with simple anal fistula. 2. Patients with comorbidities and chronic illnesses affecting the healing process, such as immune-compromising diseases and chronic inflammatory bowel diseases. 3. Patients diagnosed with acute anal sepsis.

**Formula Used:** Formula for sample size collection using software Source. Source: Lwanga SK, Lameshaw S.[9]

$$N = \frac{Z_{1-\alpha/2}^2 * P * (1 - P)}{d^2}$$

Variable used for sample size calculation: Mean and standard deviation of primary healing rate in patients operated with Fistulectomy by primary sphincter reconstruction (FPSR).

Sample size: Estimation of Population Proportion with absolute precision		
<b>P</b>	Your guess of Population P (any value < 1)	0.9
<b>1-α</b>	Confidence level set by you	0.95
<b>Z</b>	Z value associated with confidence	1.959963985
<b>d</b>	Absolute precision (Value less than P)	0.09
<b>N</b>	Minimum sample size	43

**Sampling technique:** Simple random sampling.

**Detailed Study Plan Preoperative Assessment:**

Preoperative assessment and evaluation for fistula were performed through a comprehensive clinical examination, MRI fistulogram, and transanal ultrasound (TUS). All patients provided informed consent before the operation, acknowledging the operative steps and potential complications. Bowel preparation with a rectal enema was conducted the night before surgery.

**Operative Technique:** Patients were anesthetized with general anesthesia and positioned in the lithotomy position. The skin was draped, and the external fistula orifice was identified. Probing of the fistula tract was performed with identification of the fistulous tract and internal orifice by injecting diluted methylene blue into the tract. The fistula was laid open, and fistulectomy was conducted with the aid of diathermy cautery.

Primary repair of the sphincter, without overlap, was performed using Vicryl 2/0 with proper hemostasis achieved through coagulation diathermy. Local anesthetic was injected for postoperative pain control. The duration of the surgery was recorded, and all excised tissue was sent for histopathological examination.

**Postoperative Follow-Up and Assessment**

**Immediate Postoperative Care:** All patients received antibiotics and proper pain management during the postoperative period. Perianal cleansing was done with a sitz bath after each bowel motion. Upon discharge, patients were instructed to continue sitz baths every eight hours daily and after every bowel motion.

**Follow-Up Schedule:** Follow-up visits were scheduled every two weeks for the first two months, then monthly for one year. Clinical assessments for recurrence and anal incontinence

were performed during these visits. After one year, a comprehensive assessment for fistula recurrence and anal continence was conducted using clinical examination, MRI fistulogram, and TUS. The Wexner score was used to evaluate continence.

**Methods of Data Collection:** Institutional Ethics Committee approval was obtained, and valid informed and written consent was taken from all patients. Data were collected using a structured proforma.

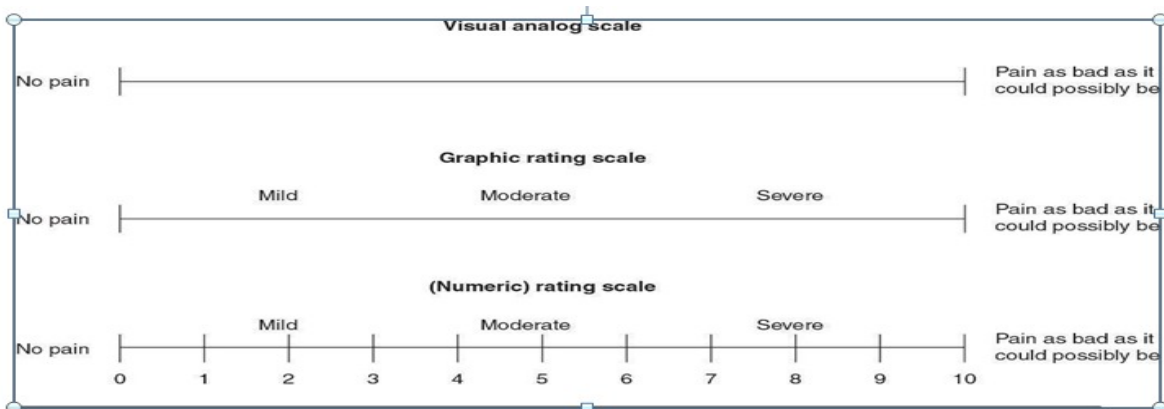
**Continence Score:**

Frequency	Solid	Liquid	Gas	Wears Pad	Lifestyle Alteration
Never	0	0	0	0	0
Rarely	1	1	1	1	1
Sometimes	2	2	2	2	2
Usually	3	3	3	3	3
Always	4	4	4	4	4

The Wexner Score was used to evaluate continence:

0 – Perfect Continence, 20 – Complete Incontinence Postoperative pain score-

**Visual Analogue Score:**



**Visual Analogue Score**

**Statistical Analysis:** Data were collected using a structured proforma, entered into an MS Excel sheet, and analyzed using SPSS 24.0 version IBM USA. Qualitative data were expressed in terms of proportions, while quantitative data were expressed in terms of mean and standard deviation. Associations between two qualitative variables were analyzed using Chi-square/Fisher’s exact test. A p-value of <0.05 was considered statistically significant, while a p-value of <0.001 was considered highly significant.

**Results**

The majority of the participants fall within the age groups of 40-49 years (28.33%) and 30-39 years (26.67%). Participants aged 20-29 years comprise 21.67% of the total, while those aged 50-59 years make up 11.67%. The age groups 60-69 years and

≥70 years account for 10% and 1.67% of the participants, respectively. The total number of cases is 60, representing 100%.

The majority of the cases were male, with 53 cases (88.33%, n=53), while females accounted for 7 cases (11.67%, n=7).

The data indicates that 43 patients (71.67%) did not report any pain, while 17 patients (28.33%) reported experiencing pain (n=17).

Of the total patients, 41 (68.33%) were having discharge, while 19 (31.67%) were not. This data indicates that a significant majority of patients were having perianal discharge.

The majority of patients, 55 out of 60 (91.67%), had no history of perianal surgery. In contrast, a small proportion, 5 patients (8.33%), reported a history of perianal surgery (n=60).

**Table 1: Number of external openings.**

NOEO	No. of Cases	Percentage
1	48	80%
2	10	16.67%
3	2	3.33%
Total	60	100%

Out of the total sample (n=60), 48 cases (80%) had one external opening. Two external openings were observed in 10 cases (16.67%), while three external openings were noted in 2 cases (3.33%). This distribution highlights that the majority of cases (80%) have a single external opening, with a smaller proportion exhibiting two or three openings.

**Table 2: Position of external opening.**

POEO	No. of Cases	Percentage
Posterior	48	80%
Anterior	12	20%
Total	60	100%

Out of the total cases, 48 cases (80%) had a posterior position of the external opening (n=48), while 12 cases (20%) had an anterior position (n=12). This indicates that the majority of the external openings were located posteriorly, with a smaller proportion located anteriorly.

Out of the total number of cases, 11.67% were palpated at 12 o'clock, 8.33% at 1 o'clock, 58.33% at 6 o'clock, and 16.67% at 7 o'clock. Additionally, 5% of cases were not palpable. This indicates that the internal opening is most frequently located at the 6 o'clock position.

Out of the total cases, 60 were examined using proctoscopy, representing 100% of the cases. This indicates that proctoscopy was employed for all cases to visualize the internal opening.

Out of the total cases analyzed, 60 cases were classified as Trans-sphincteric, representing 100% of the cases. This indicates that all the cases in this study were identified as Trans-sphincteric on the Magnetic Resonance Fistulogram.

All 60 cases (100%) were classified as high. This indicates that every case in the study exhibited a high level of fistula.

**Table 3: Operative Procedure.**

OP	No. of Cases	Percentage
FPSR	30	50%
CORING	30	50%
Total	60	100%

The table shows that 30 cases (50%, n=30) underwent the FPSR procedure, while an equal number of 30 cases (50%, n=30) were subjected to the CORING procedure. The selection of the

patients for surgery was done by simple random sampling. This distribution indicates that both procedures were performed with equal frequency among the cases.

**Table 4: Comparison of Operative Procedure with Duration of Surgery (in minutes).**

OP	DOS	P-Value
	Mean ± SD	
FPSR	45 ± 3.22	<0.001
CORING	32.50 ± 3.15	

The mean duration for FPSR is 45 ± 3.22 minutes, while for CORING it is 32.50 ± 3.15 minutes. The difference between these two procedures is statistically significant, with a p-value of less than

0.001. This indicates that FPSR requires significantly more time on average compared to CORING.

**Table 5: Comparison of Operative Procedure with Wound healing time (in weeks).**

OP	WHT	P-Value
	Mean ± SD	
FPSR	8.20 ± 0.96	<0.001
CORING	7.23 ± 0.77	

The mean wound healing time for patients undergoing FPSR was 8.20 weeks with a standard deviation of 0.96, while those undergoing CORING had a mean wound healing time of 7.23 weeks with a standard deviation of 0.77. The p-value for this

comparison is less than 0.001, indicating a statistically significant difference in wound healing time between the two procedures. This suggests that the FPSR procedure results in a longer wound healing time compared to CORING.

**Table 6: Comparison of Operative Procedure with Postoperative Pain (VAS Scale).**

OP	POP	P-Value
	Mean ± SD	
FPSR	4.5 ± 0.77	<0.001
CORING	2.93 ± 0.73	

For the FPSR procedure, the mean pain score was 4.5 ± 0.77, which is significantly higher than the mean pain score of 2.93 ± 0.73 for the CORING procedure (p < 0.001). This indicates that FPSR is

associated with greater postoperative pain in immediate post operative period (within 2 days) compared to CORING.

**Table 7: Comparison of Operative Procedure with Incontinence.**

INCONT	FPSR	CORING	P-Value
Yes	1	0	0.313
No	29	30	
Total	30	30	

Among the patients who underwent FPSR, 1 experienced incontinence to flatus (Wexner score 1) which spontaneously resolved in 3 months, while none of the patients who underwent CORING had incontinence. The majority of patients in both groups did not experience incontinence, with 29 patients in the FPSR group and 30 in the CORING group being unaffected. The difference in incontinence occurrence between the two procedures is not statistically significant (p=0.313).

which aligns with the findings of previous studies. For instance, Awad PB et al. (2023) found mean ages of 46.65 and 45.85 years<sup>[10]</sup> and Hassan BHA et al. (2024) reported a mean postoperative age of 41.5 years for their study groups<sup>[11]</sup>.

Out of the total cases analyzed, 4 patients with wound dehiscence had undergone FPSR, and 3 patients had undergone CORING, compared to 26 and 27 patients without wound dehiscence, respectively. The p-value for the comparison is 0.687, indicating that there is no statistically significant difference between the two operative procedures concerning the occurrence of wound dehiscence. This suggests that the type of operative procedure (FPSR vs. CORING) does not significantly influence the risk of wound dehiscence in this study.

Regarding gender distribution, the current study found a significant male preponderance, with 88.33% of cases being male. This finding is consistent with other research. Baakza DA. (2020) noted a male predominance of 89.1%, and Nirmala AMS et al. observed 80% males<sup>[12]</sup>.

Among patients who experienced a recurrence, 2 underwent FPSR and 4 underwent Coring. In contrast, among those who did not experience a recurrence, 28 underwent FPSR, and 26 underwent Coring. The p-value of 0.389 indicates that there is no statistically significant difference in recurrence rates between the two operative procedures.

In the present study, 28.33% of patients reported pain, which is consistent with findings from Ayyar PV et al., who observed pain in 35% of their fistula in ano patients<sup>[13]</sup>. Pain is a common symptom due to the inflammation or infection of the fistulous tract, reflecting the symptomatic nature of the condition. Comparatively, Awad PB et al. (2023) assessed postoperative pain using the Visual Analogue Scale (VAS) and found that a significant portion of patients in both groups reported moderate to severe pain, indicating that pain is a prevalent concern both pre- and post-operatively in fistula in ano cases<sup>[10]</sup>.

**Discussion**

Regarding discharge, the present study found that 68.33% of patients experienced perianal discharge, a characteristic feature of fistula in ano. This finding aligns with Gecim et al. (2017) and other studies such as those by Ayyar PV et al., who reported discharge as the most common presenting symptom in 88.3% of cases<sup>[13]</sup>.

The present study observed that the majority of fistula in ano patients were within the age groups of 40-49 years (28.33%) and 30-39 years (26.67%),

In the present study, 91.67% of patients had no previous history of perianal surgery, indicating that most were first-time cases. This aligns with

findings from Awad PB et al. (2023), where most patients also had no prior history of perianal surgery, suggesting these were primarily first-time cases<sup>[10]</sup>.

Regarding the number of external openings, the study found that 80% of cases had a single external opening, which is consistent with the findings of Murad-Regadas et al. (2016), who reported that the majority of fistula in ano cases typically present with a single external opening<sup>[14]</sup>. This observation is crucial as multiple external openings can complicate surgical intervention and increase the likelihood of recurrence.

The posterior position of the external opening was the most common (80%), which aligns with known anatomical considerations of fistula in ano, where posterior openings are more frequent. The per rectal examination revealed that the internal opening is most frequently palpated at the 6 o'clock position (58.33%), a finding similar to those reported by Ratto et al. (2019)<sup>[15]</sup>.

In the present study, proctoscopy was employed for visualizing the internal openings in all cases, highlighting its reliability and utility in diagnosing fistula in ano. This approach ensures a consistent and thorough examination of the internal opening, which is crucial for planning effective surgical intervention.

Additionally, the uniform classification of all cases as trans-sphincteric on Magnetic Resonance Fistulogram (MRF) underscores the diagnostic accuracy of this imaging modality. The use of MRF aligns with findings from Buchanan et al. (2018), where MRF proved effective in accurately identifying the type and extent of fistula tracts<sup>[16]</sup>.

In the present study, the operative procedures were evenly distributed between FPSR and CORING, reflecting a balanced approach to treatment. The mean duration for FPSR was significantly longer at  $45 \pm 3.22$  minutes compared to  $32.50 \pm 3.15$  minutes for CORING, suggesting that FPSR is more time-consuming. This observation aligns with findings from Limura and Giordano (2015), who also noted that procedures involving primary sphincter reconstruction, such as FPSR, generally require more operative time due to the complexity of reconstructing the sphincter mechanism<sup>[17]</sup>.

Comparatively, Hassan BHA et al. (2024) reported a considerably longer mean operative time of 90.3 minutes (SD  $\pm$  11.9), indicating variability in procedural duration based on different surgical techniques or patient conditions<sup>[11]</sup>. Baakza DA (2021) found that the mean operation time for fistula procedures was approximately 33.14 minutes, with the majority of cases taking between 31-60 minutes, which is closer to the CORING time observed in the present study<sup>[18]</sup>.

These comparisons suggest that while FPSR generally requires more time due to its complexity, CORING can achieve similar outcomes with less time. The variability across studies emphasizes the importance of tailoring the choice of procedure to the individual patient, considering factors such as the extent of the disease, patient anatomy, and the surgeon's experience.

In the present study, patients who underwent FPSR had a significantly longer wound healing time, averaging  $8.20 \pm 0.96$  weeks, compared to those undergoing CORING, with an average healing time of  $7.23 \pm 0.77$  weeks. The extended healing period associated with FPSR is likely due to more extensive tissue dissection and the complexity of sphincter reconstruction, which requires more time for proper recovery. This finding is consistent with Awad PB et al. (2023), who observed that patients managed by modified LIFT (group I) had a faster wound healing time, averaging 4.67 weeks, compared to those who underwent fistulotomy with primary sphincter reconstruction (group II), which had a mean healing time of 6.05 weeks<sup>[10]</sup>.

Both studies highlight the impact of the extent of surgical intervention on wound healing duration, with more invasive procedures involving muscle repair leading to longer recovery times. This underscores the need to balance the surgical approach's benefits against the potential for prolonged healing, particularly in cases where quicker recovery is advantageous for patient quality of life. The findings suggest that while FPSR may be necessary for complex cases, procedures like CORING or modified LIFT may be preferable for reducing healing time and minimizing post-operative recovery periods.

In the present study, patients who underwent FPSR reported higher levels of immediate postoperative pain, with a VAS score of  $4.5 \pm 0.77$ , compared to those undergoing CORING, who had a VAS score of  $2.93 \pm 0.73$ . This observation is consistent with Ellis et al. (2017), who noted that more extensive reconstructive procedures tend to be associated with increased postoperative pain due to greater tissue manipulation and repair<sup>[19]</sup>.

Similarly, Awad PB et al. (2023)<sup>[10]</sup> assessed postoperative pain using the VAS scale and found that a higher percentage of patients in group II (fistulotomy with primary sphincter reconstruction) experienced moderate to severe pain. Specifically, 55% reported moderate pain (VAS 4-6), and 10% reported severe pain (VAS 7-9). In contrast, group I (modified LIFT) had 50% of patients reporting moderate pain and only 5% experiencing severe pain. Although the p-value was not statistically significant ( $p = 0.275$ ), the trend indicates that more invasive procedures result in greater pain levels<sup>[10]</sup>.

This evidence highlights the importance of considering postoperative pain management strategies when choosing the surgical approach for treating fistula in ano, aiming to minimize discomfort and improve patient recovery experience.

In the present study, among the patients who underwent FPSR, one experienced incontinence to flatus (Wexner score 1) which spontaneously resolved in 3 months, while none of the patients who underwent CORING had incontinence, indicating a low overall risk of sphincter impairment. Incontinence was measured clinically by Wexner score. Additionally, wound dehiscence was observed in a similar number of cases for both FPSR (4 cases) and CORING (3 cases), demonstrating no significant difference in wound integrity between the two surgical techniques. These findings align with those from studies such as Adegbola et al. (2019), which also documented low incidences of incontinence and wound complications in fistula surgery, suggesting that these procedures are generally safe concerning sphincter preservation and wound integrity<sup>[20]</sup>.

Other studies, such as those by Ratto C et al. and Lasheen AE et al., reported higher rates of transient and permanent incontinence, as well as superficial wound infections<sup>[15, 21]</sup>. Lasheen AE et al. found that transient incontinence was common, affecting 53% of patients postoperatively, although this did not result in permanent impairment. These differences may be attributed to varying patient demographics, surgical techniques, and postoperative care protocols.

Overall, the present study's results support the notion that both FPSR and CORING are associated with low rates of incontinence and wound complications, making them viable options for treating fistula in ano. Prior patient counseling should be done for possible incontinence. However, the slightly higher immediate postoperative pain and prolonged healing time associated with FPSR suggest that patient selection and surgical approach should be carefully considered to optimize outcomes

In the present study, recurrence was observed in 2 cases following FPSR and 4 cases following CORING, reflecting a slightly higher recurrence rate with the CORING procedure, though this difference was not statistically significant (Table 18). These findings are consistent with the results of a meta-analysis by Ommer et al. (2020), which indicated similar efficacy in preventing recurrence across various surgical approaches for fistula in ano, highlighting that both FPSR and CORING are effective treatments with comparable outcomes in terms of recurrence rates<sup>[22]</sup>.

Overall, the present study's findings on recurrence

rates after FPSR and CORING align with the broader literature, suggesting that both surgical techniques offer effective long-term management of fistula in ano, with no significant difference in recurrence rates. The probability of recurrence with CORING increases because the original source of sepsis is not removed if the internal opening is not found. Therefore, it is necessary to find and resolve the internal opening during anal fistula surgery. This information is crucial for clinical decision-making, particularly in selecting the most appropriate surgical approach based on patient-specific factors and the complexity of the fistula.

The findings of this study indicate that while FPSR is associated with longer operative times, increased wound healing duration, and higher postoperative pain, it does not significantly differ from CORING in terms of recurrence, incontinence, and wound dehiscence rates. Both procedures show effectiveness in treating trans-sphincteric fistula in ano, with no significant long-term adverse outcomes. Future studies should focus on long-term follow-ups to further evaluate the recurrence rates and quality of life outcomes in patients undergoing these procedures.

### Conclusion

This comparative observational study has highlighted the clinical outcomes associated with two surgical techniques—fistulectomy with primary sphincter reconstruction (FPSR) and core-out fistulectomy with sphincter reconstruction (CORING)—in the management of high complex trans-sphincteric anal fistula.

- 1) Both FPSR and CORING were found to be effective in the treatment of this condition, showing no significant difference in terms of recurrence.
- 2) FPSR was associated with extended wound healing periods compared to CORING.
- 3) There is no significant difference in terms of incontinence.
- 4) FPSR was associated with higher immediate postoperative pain compared to CORING.
- 5) FPSR was associated with longer operative time compared to CORING.
- 6) There is no significant difference in terms of wound dehiscence rates.

These findings suggest that either procedure can be selected based on individual patient needs and surgeon expertise without compromising long-term outcomes.

While FPSR was associated with longer operative times, extended wound healing periods, and higher immediate postoperative pain compared to CORING, these differences did not translate into significant long-term complications. The increased healing time and postoperative discomfort

associated with FPSR may be justified in cases where sphincter preservation is critical. Conversely, CORING offers a less invasive alternative with quicker recovery, making it a preferable option for patients where a less complex procedure is indicated.

The consistency of the present study's findings with existing literature reinforces the reliability of these surgical approaches in managing complex anal fistulae. Both FPSR and CORING maintain low rates of recurrence and minimal impact on continence, supporting their continued use in clinical practice. Future research should focus on long-term follow-up to assess patient quality of life, recurrence, and other potential complications post-surgery. These insights will further aid in refining surgical approaches to ensure optimal patient outcomes.

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