RESEARCH PAPER

"ACCURACY OF FROZEN SECTION DIAGNOSIS IN COMPARISON TO HISTOPATHOLOGICAL DIAGNOSIS"

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Abstract:

Introduction:
Frozen section (FS) is an intraoperative diagnostic method used for rapid pathological evaluation to assist surgical decision-making. Its performance needs periodic assessment against the gold standard formalin-fixed paraffin-embedded histopathology (HPE) to ensure reliability and quality.

Aims and Objectives:
To evaluate intraoperative FS diagnoses and determine their diagnostic accuracy in comparison with final HPE, including assessment of concordance and discordance rates.

Materials and Methods:
A cross-sectional study was conducted on 100 FS cases from October 2023 to May 2025 in the Department of Pathology, MMIMSR, Mullana. FS findings were correlated with final HPE. Key parameters assessed included turn-around time, sensitivity, specificity, accuracy, PPV, NPV, concordance/discordance rates, and Cohen's kappa agreement.

Results:
The majority of patients were in the 41–60 years age group (47%), with a female predominance (73%). Most requests originated from the Surgery department (51%), and the main indication was differentiation of benign and malignant lesions (70%). A definitive FS diagnosis was rendered in 90% of cases, with a mean turn-around time of 20.5 minutes.

Compared with HPE, FS showed a sensitivity of 71.8%, specificity of 93.9%, accuracy of 84.1%, PPV of 90.3%, and NPV of 80.7%. Overall concordance was 87%, while discordance was 13%. False-negative cases (76.9%) were more frequent than false positives (23.1%). The main causes of discordance were sampling error (46.2%), interpretative error (38.5%), and technical artefacts (15.3%). The kappa value ($\kappa = 0.74$) indicated good agreement between FS and HPE.

Conclusion:
Frozen section demonstrates good overall agreement with final histopathology, with strong specificity and predictive value. However, relatively lower sensitivity and a higher proportion of false-negative results limit its diagnostic performance, mainly due to sampling-related issues. Regular quality audits and improved tissue sampling strategies are essential to enhance diagnostic accuracy.

Keywords: Frozen section, intraoperative diagnosis, histopathology, diagnostic accuracy, concordance, sampling error

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INTRODUCTION

Frozen section (FS) is a rapid diagnostic technique that enables intraoperative microscopic evaluation

of surgically obtained tissue specimens, providing timely pathological information to guide surgical management. The development of frozen section has been closely linked to the evolution of surgical pathology, allowing pathologists to deliver real-time diagnoses that can significantly influence the course and extent of surgery [1]. Since its introduction in the late nineteenth century and subsequent refinement during the early twentieth century, frozen section has become an established tool for intraoperative consultation and decision-making [2].

The technique involves rapid freezing of fresh tissue, followed by preparation of thin sections for immediate microscopic examination. Unlike conventional paraffin-embedded histopathology, which requires several hours of processing, frozen section provides diagnostic information within a short turnaround time, thereby facilitating prompt surgical decisions [3].

Frozen section is widely used for intraoperative assessment of neoplastic and non-neoplastic lesions, evaluation of surgical margins, lymph node status, tissue adequacy, and confirmation of pathological processes that may influence further management. Its role is particularly important in surgical oncology, where intraoperative findings often determine the extent of resection and staging procedures. Applications have been well established in breast, gynecological, and other oncological surgeries requiring immediate pathological assessment [4].

Despite its clinical utility, frozen section interpretation remains challenging because of technical and diagnostic limitations. Freezing artifacts, suboptimal morphological preservation, sampling errors, tissue-specific constraints, and observer variability can affect diagnostic accuracy and lead to discordance with final histopathological examination [5]. Therefore, careful interpretation and awareness of these limitations are essential for optimal utilization of the technique.

Although advances in imaging modalities and preoperative biopsy techniques have improved diagnostic capabilities, frozen section continues to play a crucial role in situations requiring immediate intraoperative decision-making, particularly in the assessment of tumor margins, staging of malignancies, and confirmation of tissue adequacy [6]. Its value remains especially relevant in resource-constrained healthcare settings, where rapid and cost-effective intraoperative consultation is often necessary.

Frozen section has demonstrated high diagnostic performance in previous studies, with reported sensitivity ranging from approximately 85% to 96%, specificity from 94.5% to 99.8%, and overall concordance with permanent histopathological sections between 92% and 98.3%. However, reported discordance rates of 1.7%–4.5% underscore the need for continuous quality assessment and evaluation of its diagnostic reliability [7]. Therefore, the present study was undertaken to assess the accuracy of frozen section diagnosis by comparing intraoperative frozen section findings with final histopathological diagnosis and to evaluate its utility in routine surgical practice.

REVIEW OF LITERATURE

Frozen section (FS) examination is an established intraoperative diagnostic technique that provides rapid pathological assessment to guide surgical management. Its principal applications include determination of the nature of lesions, evaluation of surgical margins, assessment of lymph node involvement, and confirmation of tissue adequacy during surgery [8,9]. Despite advances in preoperative imaging and biopsy techniques, frozen section remains an indispensable tool for real-time surgical decision-making, particularly in oncological practice [6].

Several studies have demonstrated high diagnostic accuracy of frozen section when compared with final histopathological examination. Reported sensitivity ranges from 85% to 96%, specificity from 94.5% to 99.8%, and overall concordance rates from 92% to 98.3%, highlighting the reliability of this technique in routine surgical pathology practice [7]. Nevertheless, occasional discordance between frozen section and permanent section diagnoses has been reported, with discordance rates ranging from 1.7% to 4.5% [7].

The diagnostic performance of frozen section varies according to the organ system and nature of the lesion being evaluated. High levels of accuracy have been reported in breast pathology, particularly for margin assessment and sentinel lymph node evaluation, with overall accuracy ranging from 92% to 100% [10-12]. Similarly, studies involving central nervous system lesions have demonstrated diagnostic accuracies exceeding 97%, supporting its value in neurosurgical practice [13]. In ovarian tumors, frozen section has shown high sensitivity and specificity for distinguishing benign from malignant lesions, although diagnostic challenges remain in borderline and mucinous tumors because of tumour heterogeneity and sampling limitations [14].

Despite its proven utility, frozen section interpretation is subject to several technical and diagnostic limitations. Freezing artifacts, suboptimal morphological preservation, inadequate

sampling, and tissue-specific constraints may compromise diagnostic accuracy [15]. Sampling error remains one of the most important causes of discordance because only a limited portion of the specimen is examined intraoperatively [15]. In addition, reactive and inflammatory changes may mimic malignancy, while certain low-grade neoplasms, lymphomas, and borderline lesions often pose significant interpretative difficulties [16,17].

Turnaround time is another important quality indicator in frozen section practice. The College of American Pathologists recommends reporting the majority of frozen section diagnoses within 20 minutes, while current NABL guidelines suggest a turnaround time of 20–30 minutes [18-20]. Maintaining rapid reporting without compromising diagnostic accuracy remains a key challenge, particularly in tertiary care settings handling complex specimens [21].

Although frozen section continues to demonstrate high accuracy and clinical utility, diagnostic discrepancies still occur because of technical limitations, interpretative challenges, and sampling-related factors. Therefore, periodic institutional audits comparing frozen section diagnoses with final histopathological diagnoses are essential for quality assurance and for identifying areas that require improvement in diagnostic practice.

Several studies have demonstrated the high diagnostic reliability of frozen section when compared with permanent histopathological examination. Reported sensitivity and specificity range from 84.6%–96% and 94.5%–99.8%, respectively, with concordance rates between 92% and 98.3% and discordance rates of 1.7%–4.5%.[22.23.24.]

Overall diagnostic accuracy in published studies has generally ranged from 87% to 97%, while turnaround times have varied from approximately 15–20 minutes to over 30 minutes depending on case complexity and institutional practices [18-21].

Early large-scale investigations consistently reported excellent performance of frozen section diagnosis. Dankwa and Davies reported an overall diagnostic accuracy of 96.5% in 1,000 frozen section cases, with clinically significant errors occurring in only 1.3% of cases, primarily due to false-negative interpretations and morphological misinterpretation [25]. Similarly, Kaufman et al. observed an overall accuracy of 97.1% in 586 intraoperative consultations, identifying sampling error as the principal cause of false-negative diagnoses, particularly in gastrointestinal and thyroid lesions [26]. In a larger series of 4,434 frozen section biopsies, Hwang et al. reported a diagnostic accuracy of 97.97%, with low false-positive, false-negative, and deferred diagnosis rates. Diagnostic discrepancies were mainly attributed to sampling errors, interpretative difficulties, and inadequate clinical information [27].

The potential benefit of combining frozen section with complementary diagnostic techniques has also been highlighted. Mair demonstrated that the combined use of frozen section and cytological preparations improved intraoperative diagnostic accuracy to 99.5% for distinguishing benign from malignant lesions, emphasizing the complementary nature of these approaches [28].

Evidence from high-volume pathology centers further supports the reliability of frozen section. Ferreiro et al. reviewed 24,880 cases and reported an overall accuracy of 97.8%, with clinically significant errors accounting for only 0.1% of cases. Most discrepancies were related to unavoidable sampling limitations rather than technical deficiencies [7]. However, studies evaluating surgical margin assessment have shown that despite high concordance between frozen and permanent sections for individual specimens, frozen section may be less reliable in predicting the final margin status of the entire resection specimen because of sampling limitations. Ord and Aisner reported a 99% concordance rate for individual margin samples, yet several positive margins identified on final histopathology were not detected intraoperatively [29].

Collectively, these studies demonstrate that frozen section is a highly accurate and clinically valuable intraoperative diagnostic modality. Nevertheless, diagnostic discordance may occur because of sampling errors, tissue heterogeneity, technical limitations, and interpretative challenges, underscoring the need for continuous quality assessment and correlation with final histopathological findings [25-29]

Several studies have evaluated the diagnostic performance of frozen section across different organ systems and clinical settings. In head and neck malignancies, frozen section has demonstrated excellent concordance with permanent histopathology for sampled tissue; however, its ability to predict final resection margin status is limited by sampling constraints. Studies by DiNardo et al. and Ribeiro et al. reported concordance rates exceeding 98%, while highlighting that positive margins may still be missed on final histopathological examination because only selected areas are assessed intraoperatively [30,31].

Large institutional audits have consistently reported high diagnostic accuracy of frozen section,

generally ranging from 91% to 98%. Studies by Khoo, White and Trotter, Abbasi et al., Chbani et al., Vimal et al., Zinzala et al., and Trisal et al. demonstrated concordance rates above 95%, confirming frozen section as a reliable intraoperative diagnostic modality [32-39]. Across these studies, false-negative diagnoses were more common than false-positive diagnoses and were primarily attributed to sampling limitations, tissue heterogeneity, freezing artifacts, and interpretative difficulties.

The accuracy of frozen section varies according to tissue type and diagnostic indication. Higher diagnostic performance has been reported in thyroid, breast, lymph node, and central nervous system lesions, whereas borderline ovarian tumors, follicular thyroid lesions, and certain low-grade neoplasms remain diagnostically challenging [40-41]. Reviews by Jaafar and Taxy emphasized that frozen section should be used selectively for situations in which the diagnosis will directly influence intraoperative management, rather than as a substitute for permanent histopathological examination [7,42].

Quality assurance studies have further demonstrated the importance of continuous monitoring of frozen section performance. Raab et al. reported that long-term participation in structured quality improvement programs was associated with reduced discordance and deferral rates [43]. In addition to diagnostic accuracy, turnaround time remains a critical quality indicator. Recent studies have shown that specimen complexity, requirement for additional sections or special stains, multiple specimen submissions, and consultation among pathologists may significantly influence reporting time.

Overall, the published literature demonstrates that frozen section is a highly accurate and clinically valuable technique for intraoperative diagnosis. Nevertheless, diagnostic discrepancies continue to occur because of sampling errors, technical limitations, interpretative challenges, and lesion-specific factors. Regular institutional audits comparing frozen section findings with final histopathological diagnosis remain essential for maintaining quality standards and improving diagnostic performance [43].

Aim and Objective:

To evaluate intraoperative FS diagnoses and determine their diagnostic accuracy in comparison with final HPE, including assessment of concordance and discordance rates.

MATERIALS AND METHODS

Study Design and Setting

A cross-sectional study was conducted in the Department of Pathology, Maharishi Markandeshwar Institute of Medical Sciences and Research (MMIMSR), Mullana, Ambala, from October 2023 to May 2025.

Study Population

All specimens received for intraoperative frozen section examination from various surgical departments during the study period were included. Consecutive sampling was employed, and a minimum sample size of 96 cases was calculated based on an expected frozen section diagnostic accuracy of 90%, 95% confidence level, and 6% margin of error. A total of 100 cases were included in the study.

Data Collection

Clinical, demographic, laboratory, radiological, and pathological data were collected from both prospective and retrospective records. Information regarding indication for frozen section, specimen type, gross findings, turnaround time, frozen section diagnosis, and final histopathological diagnosis was recorded using a structured data collection form.

Frozen Section Procedure

Fresh tissue specimens were examined intraoperatively using a Leica CM 1860 UV cryostat. Representative tissue sections were selected after gross examination and frozen at −15°C to −18°C. Sections of approximately 10–12 μm thickness were prepared, stained with rapid hematoxylin and eosin (H&E), and evaluated microscopically. Provisional diagnoses were communicated immediately to the operating surgeon, and turnaround time was recorded.

Following frozen section reporting, all specimens were fixed in 10% neutral buffered formalin, processed routinely, and examined on permanent paraffin-embedded H&E-stained sections. Final histopathological diagnosis served as the reference standard.

Outcome Measures

Frozen section diagnoses were compared with final histopathological diagnoses to determine:

- Diagnostic accuracy
- Sensitivity
- Specificity
- Concordance rate
- Discordance rate

All discordant cases were reviewed to identify the underlying causes of discrepancy.

Ethical Considerations

The study was approved by the Institutional Ethics Committee of MMIMSR, Mullana, Ambala (IEC-3263; dated 18.02.2025). The study was conducted in accordance with the ethical principles of the Declaration of Helsinki.

Statistical Analysis

Data were analyzed using SPSS version 29.0. Descriptive statistics were expressed as frequencies and percentages. Frozen section diagnoses were compared with final histopathological diagnoses, which served as the gold standard, to calculate sensitivity, specificity, diagnostic accuracy, concordance, and discordance rates.

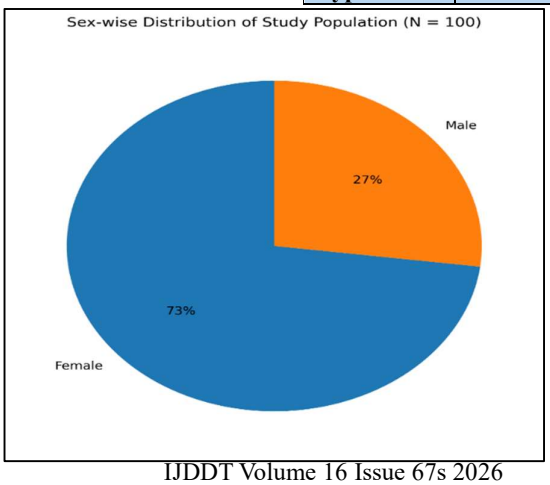
RESULTS:

A total of 100 cases were evaluated in the present study with reference to demographic characteristics, departmental and site distribution, and correlation between intraoperative frozen section findings and final histopathological diagnosis

The age distribution showed that most patients belonged to the 41–60 years group (47%), followed by 21–40 years (33%) and >60 years (18%), while the least number of cases were in the ≤20 years group (2%), indicating that frozen section was predominantly utilized in middle-aged and adult patients.

The sex distribution showed a clear female predominance, with females comprising 73% of cases and males 27% as shown in figure 1. This likely reflects the higher frequency of gynecological and breast specimens requiring intraoperative frozen section evaluation. Overall, the pattern highlights the important role of frozen section in guiding surgical decision-making, particularly in female-predominant oncologic and reproductive system conditions.

Figure1: Gender- Wise Distribution of Study Population N=100



The departmental distribution of frozen section cases was highest in Surgery (51%), followed by Gynecology (33%), with fewer cases from Oncosurgery (11%) and other departments (5%). This pattern reflects predominant use in general surgical and gynecological procedures, where intraoperative decisions regarding tumor status, margins, and diagnosis are most critical.

As highlighted in Table 1 our study found gynecological cases were most frequent (34%), followed by lymph nodes (16%) and breast (15%), with smaller contributions from GI/HPB, head & neck, endocrine, soft tissue/bone, and genitourinary systems. Biopsies formed the largest specimen group (42%), followed by gynecological resections (29%) and margin/breast excisions (17%). Organ-wise analysis again confirmed predominance of gynecological, lymph node, breast, and GI/HPB cases. Overall, the data indicate that frozen section is mainly utilized in gynecologic and oncologic settings, with a major share of biopsy and limited resection specimens, supporting its role in rapid intraoperative decision-making and surgical guidance.

Table 1: **Distribution of Cases by Site Group, Specimen Type, and Organ/System (N = 100)**

Category Type	Subcategory	N	%

Site Group	Gynecologic	34	34
	Lymph node	16	16
	Breast	15	15
	Gastrointestinal & HPB	12	12
	Head and neck (including oral cavity)	9	9
	Soft tissue and bone	5	5
	Endocrine	5	5
	Genitourinary (non-gynecologic)	4	4
Specimen Group	Biopsy	42	42
	Gynecologic resection	29	29
	Breast / margin excision	17	17
	Major resection*	12	12
Organ/System	Gynecologic	34	34
	Breast	15	15
	Lymph node#	16	16
	GI/HPB	13	13
	Head & neck##	13	13
	Soft tissue & bone	5	5
	Genitourinary (non-gynecologic)	4	4
Total		**100**	**100**

In our study we found that the main indication for frozen section was differentiation between benign and malignant lesions (70%), followed by margin assessment (14%) and metastasis evaluation (12%), with tissue identification being least common (4%). Diagnostic categories were dominated by non-neoplastic/other tissue (34%) and malignant cases (28%), followed by benign diagnoses (23%). Inconclusive (10%), inflammatory (4%), and borderline (1%) cases were less frequent as shown in Table 2A and 2B. Overall, it highlights the primary role of frozen section in rapid intraoperative assessment of malignancy and surgical margins, supporting real-time operative decisions.

Table 2A. Indications for frozen section

Indication for frozen section	Frequency	Percentage (%)
Benign vs malignant	70	70
Margin status	14	14
Metastasis	12	12
Tissue identification	4	4

Table 2B. Distribution of frozen section diagnostic categories

This table summarizes the distribution of frozen section diagnostic categories. It reflects the spectrum of intraoperative pathological interpretations.

Frozen Section Diagnostic Category	Frequency	Percentage (%)
Malignant/Positive	28	28
Benign/Negative	23	23
Borderline	1	1
Inflammatory	4	4
Inconclusive/Deferred	10	10
Non-neoplastic/Other tissue diagnosis	34	34
Total	100	100

Talking about the distribution of frozen across organ systems, Non-malignant lesions predominated in gynecologic and head & neck cases, whereas malignant diagnoses were most frequent in GI/HPB, lymph node, and breast specimens, reflecting their greater oncological significance. Indeterminate diagnoses were uncommon overall but occurred more often in gynecologic cases, indicating greater diagnostic complexity. Similarly non-malignant diagnoses were the most common across all age groups, particularly among patients aged 41–60 years and 21–40 years. Malignant diagnoses were also most frequently observed in the 41–60 years age group, indicating a higher overall disease burden in middle-aged individuals.

Most frozen section reports were issued within 21–25 minutes (37%), followed by 16–20 minutes (30%) and ≤15 minutes (20%), while only 13% required 26–30 minutes. No case exceeded 30 minutes as shown in Table 3. These findings indicate efficient laboratory workflow, with the majority of diagnoses delivered within the recommended intraoperative time frame.

Table 3. Turn-around time overview

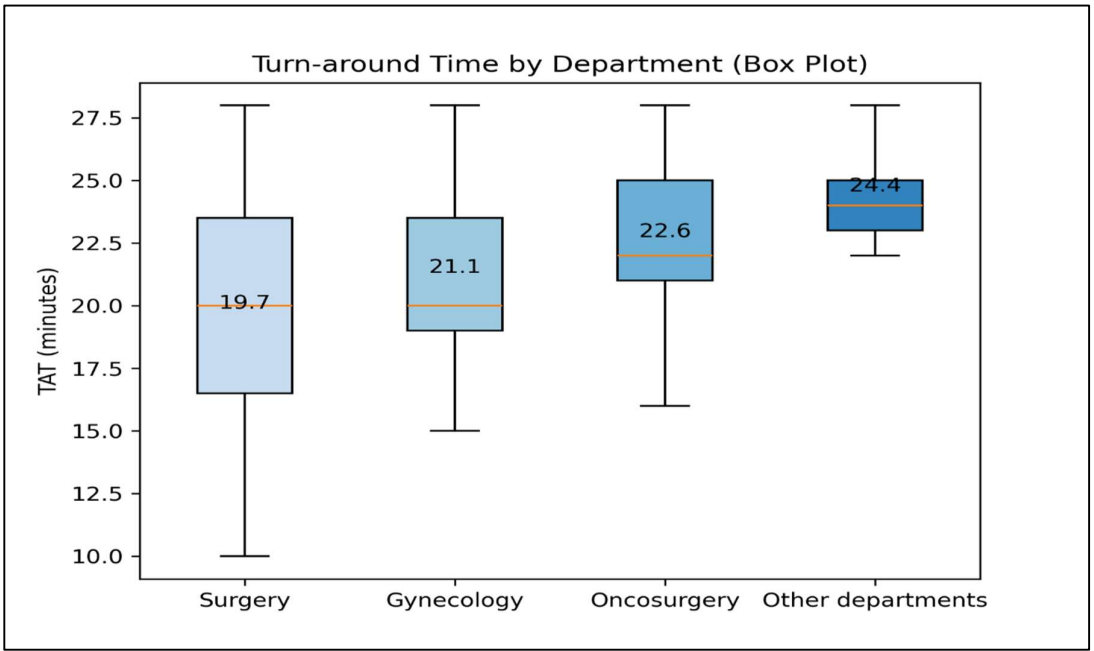
A) Overall TAT summary		
Overall TAT summary	**Value**	
Mean TAT (minutes)	20.5	
Median TAT (minutes)	20.5	
SD	4.3	
Minimum	10	
Maximum	28	
B) TAT category distribution		
TAT category (minutes)	**N**	**%**
<=15	20	20
16-20	30	30
21-25	37	37
26-30	13	13
>30	0	0

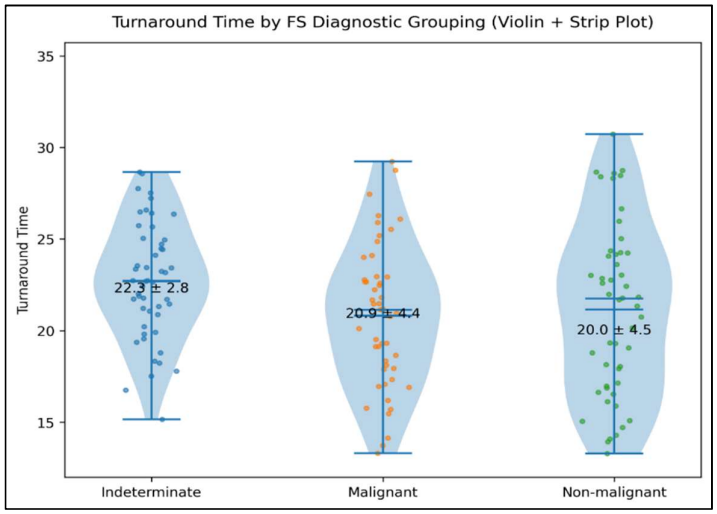
The box plot as shown in figure 2 shows that the median turnaround time (TAT) was lowest in **Surgery (19.7 minutes)**, followed by **Gynecology (21.1 minutes)** and **Oncosurgery (22.6 minutes)**, while **other departments had the highest median TAT (24.4 minutes)**. Despite these differences, most cases across all departments were reported within the acceptable intraoperative range of 15–25 minutes, reflecting efficient frozen section services.

Figure 2: **Turn-around Time (TAT) Distribution by Department (Box Plot) (N =**

The distribution of turnaround time varied slightly across frozen section diagnostic categories. **Indeterminate cases had the highest mean TAT (22.3 ± 2.8 minutes)**, followed by **malignant (20.9 ± 4.4 minutes)** and **non-malignant cases (20.0 ± 4.5 minutes) as shown in Figure 3**. The longer reporting time for indeterminate cases likely reflects additional diagnostic evaluation and interpretative complexity.

Figure 3: **Turn-around Time (TAT) by Frozen Section Diagnostic Grouping (Violin + Strip Plot) (N = 100)**

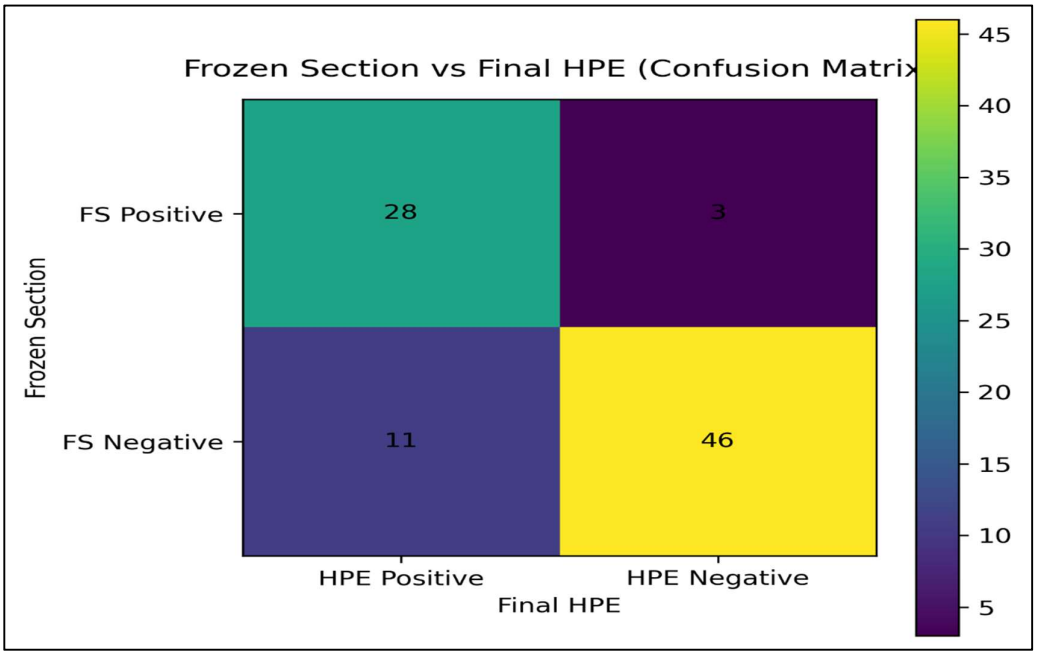




emphasizing the importance of final histopathological confirmation.

Figure 4. Comparison of Frozen Section Diagnosis with Final Histopathological Examination (HPE)

The confusion matrix demonstrates good agreement between frozen section (FS) and final histopathological examination (HPE). Of the 100 cases, **28 were true positives** and **46 were true negatives**, while **3 were false positives** and **11 were false negatives as shown in Figure 4**. The higher number of correctly classified cases indicates good diagnostic reliability of frozen section. However, the presence of false-negative cases highlights the potential for missed lesions due to sampling or interpretative limitations,



In our study we found 90% of cases received a definitive frozen section diagnosis, while only **10% were inconclusive**, indicating high intraoperative diagnostic efficiency. Figure 12B demonstrates **87% concordance** and **13% discordance** between frozen section and final histopathology. These findings support the reliability of frozen section as a rapid diagnostic tool for intraoperative decision-making, while reinforcing the need for final histopathological confirmation.

Our study revealed higher concordance between frozen section and final histopathology in **benign cases (93.6%)** than in **malignant cases (81.1%)**, indicating greater diagnostic accuracy for non-malignant lesions as shown in Figure 4A. Figure 4B demonstrates high concordance across organ systems, ranging from **80% to 100%**, with the highest agreement in **head & neck and genitourinary cases (100%)**, followed by **lymph node (93.8%)** and **breast (93.3%)** specimens. Overall, frozen section showed strong diagnostic reliability across different tissues, although slightly lower concordance was observed in malignant and more complex lesions.

Table4A. Concordance by Diagnostic Category (N = 100)

Diagnosis Category	**Concordant**	**Discordant**	**Concordance Rate (%)**	**p-value**
Benign	44	3	93.6	
Malignant	43	10	81.1	
Total	87	13	87	p = 0.02
Test: Chi-square → p = 0.02 (significant)*				

Table 4B. Concordance by Organ/System (N = 100)

Organ/System	**Concordant**	**Discordant**	**Concordance Rate (%)**	**p-value**
Gynecologic	30	4	88.2	
Breast	14	1	93.3	
Lymph node[#]	15	1	93.8	
GI/HPB	11	2	84.6	
Head & neck[##]	13	0	100	
Soft tissue & bone	4	1	80	
Genitourinary	4	0	100	
Total	**91**	**9**	**91**	p = 0.997
Test: Chi-square test of independence → $\chi^2 = 0.32$, df = 5, p = 0.997 (NS)				

Our study concluded that the majority of discrepancies were false negatives (76.9%), while false positives were less common (23.1%), indicating a tendency toward underdiagnosis rather than overdiagnosis.

Among the causes of discordance, sampling error was the most frequent (46.2%), followed by interpretative error (38.5%) and technical artefacts (15.3%).

Overall, the findings suggest that most diagnostic errors arise from inadequate or non-representative tissue sampling, with additional contribution from interpretative and technical limitations, highlighting the need for careful sampling and cautious intraoperative evaluation to improve FS accuracy and reduce discordance.

DISCUSSION:

Frozen section (FS) is a well-established intraoperative diagnostic tool that enables rapid microscopic evaluation of fresh tissue to guide immediate surgical decisions, including assessment of lesion type, margins, lymph nodes, and tissue adequacy. Its clinical value is particularly important in oncologic surgery where intraoperative decisions directly influence extent of resection [8,9].

Despite its utility, formalin-fixed paraffin-embedded histopathology remains the gold standard due to superior morphology and availability of ancillary techniques [44,45]. Frozen section is limited by freezing artefacts, sampling constraints, and interpretative challenges, making correlation with final histopathology essential for evaluating diagnostic performance [46].

Several studies have consistently demonstrated high diagnostic accuracy of frozen section across different organ systems. Ashwin et al.[47] reported

an overall accuracy of 97% with high sensitivity and specificity, whereas Hatami et al. [48] demonstrated a concordance rate of 97.96% between frozen and permanent sections,supporting its reliability in intraoperative diagnosis These findings reinforce that, when appropriately utilized, frozen section provides reliable real-time diagnostic support during surgery.

However, discordance is mainly attributed to sampling and interpretative errors, emphasizing the need for careful grossing and clinicopathological correlation [49]. Regular audit of FS performance is therefore essential for quality improvement, especially in tertiary care settings [50].

The present study was undertaken to evaluate the diagnostic utility of frozen section by comparing intraoperative diagnoses with final histopathological findings and assessing concordance, discordance, and overall accuracy.

Demographic and Clinical Profile

In the present study, FS was predominantly utilized in middle-aged and adult patients, with highest frequency in the 41–60 years group (47%) and female predominance (73%), reflecting the high proportion of gynecological and breast specimens. Similar age and sex distributions have been reported by Shukla et al. (2025) [51] and Kikaniya et al. (2025), [52] supporting the influence of case mix on FS utilization.Surgery (51%) and Gynecology (33%) were the main requesting departments, with gynecological, lymph node, and breast specimens forming the major workload, consistent with published literature.

The mean turnaround time (TAT) in our study was 20.5 minutes, with all cases reported within 30 minutes, indicating acceptable intraoperative efficiency. Comparable TAT and diagnostic performance have been reported by Buch et al. (2024) [53] and Alswayyed et al. (2026) [54] , confirming FS as a rapid and reliable modality. Slight prolongation of TAT in indeterminate cases reflected diagnostic difficulty rather than departmental variation, consistent with findings of Rima et al. (2022) [55] and Ingole et al. (2024)[56].

Overall diagnostic performance showed accuracy of 84.1%, sensitivity of 71.8%, and specificity of 93.9%, indicating strong ability to confirm benign lesions but relatively lower sensitivity for malignancy. Concordance was 87% with 13% discordance, comparable to published studies where sampling and interpretative errors were the main causes of discrepancy [56-58]. This highlights that FS is reliable for intraoperative guidance but not a substitute for final histopathology.

Concordance was significantly higher for benign lesions (93.6%) than malignant lesions (81.1%) ($p = 0.02$), indicating greater reliability in excluding malignancy than confirming it. Organ-wise, concordance ranged from 80% to 100% but showed no significant variation ($p = 0.997$), suggesting broadly consistent performance across systems. False-negative cases (76.9%) were the predominant discordance type, mainly due to sampling and interpretative errors, consistent with previous studies [54,56].

The Cohen's kappa value of 0.74 indicated substantial agreement between FS and final histopathology. Similar studies have reported higher kappa values (0.79–0.93), but consistently confirm good diagnostic agreement when adequate sampling and interpretation are ensured8 [59-60].

Overall, the study confirms that frozen section is a reliable intraoperative diagnostic tool with high specificity and good agreement with final histopathology. However, limitations such as sampling error and reduced sensitivity in malignant lesions necessitate its use as an adjunct rather than a replacement for permanent section diagnosis.

CONCLUSION:

This study evaluated the diagnostic performance of intraoperative frozen section (FS) in comparison with formalin-fixed paraffin-embedded histopathology in a tertiary care setting. Frozen section demonstrated good overall diagnostic performance with substantial agreement with final histopathology ($\kappa = 0.74$) and an overall accuracy of 84.1%, indicating its usefulness as a reliable intraoperative diagnostic tool.

The technique showed high specificity (93.9%) and positive predictive value (90.3%), supporting its strength in confirming malignant diagnoses intraoperatively. However, comparatively lower sensitivity (71.8%) and negative predictive value (80.7%) highlight an important limitation, particularly in excluding malignancy, with a measurable false-negative rate. This emphasizes that negative frozen section results should be interpreted cautiously and always correlated with permanent section findings.

Overall concordance between frozen and final histopathology was 87%, with discordance primarily attributed to sampling error, interpretative challenges, and technical artifacts. These findings reinforce that the accuracy of frozen section is highly dependent on adequate tissue sampling and close clinicopathological correlation.

The mean turnaround time of 20.5 minutes indicates efficient intraoperative workflow within

acceptable standards, supporting the role of frozen section in guiding timely surgical decision-making.

In conclusion, frozen section remains a valuable adjunct to surgical pathology, particularly for intraoperative decision-making. However, it should not replace definitive histopathological examination. Continuous quality improvement, meticulous sampling, and effective communication between surgeon and pathologist are essential to further enhance diagnostic accuracy and reduce discordance.

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