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Opinion

Computational Pathology as a Mechanistic Discipline: From Morphology to Molecular Data

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Abstract

Pathology is undergoing a shift from morpho-molecular interpretation toward the computational integration of molecular mechanisms encoded in tissue architecture. Here, we argue that such morphology-driven molecular inference may enable biomarker prediction and potentially generate therapeutic insights directly from routine histology. This paradigm has important clinical implications for quantitative biomarker testing, patient stratification, and the design of digital biomarker-based clinical trials. At the same time, we emphasize that most current artificial intelligence (AI) models remain correlative, with clinical impact still dependent on rigorous validation, integration into workflows, and ethical governance. Addressing these open challenges will be essential for computational pathology to mature into a clinically meaningful discipline.

Keywords: pathology; biomarkers; artificial intelligence; deep learning

1. Introduction

Pathology has always been a discipline of morpho-molecular interpretation to inform the clinical management of patients [1–3]. Then came the digital pathology, a revolution that allowed the tissue slide to be seen in new ways: shared, quantified, and computationally processed [4]. Yet digital slides, also referred to as whole-slide images (WSI), are still a derivative of the physical ones, not their replacement; as such, they inherently reflect pre-analytical and analytical variability related to tissue handling, fixation, processing, staining, and scanning, limitations that continue to define the boundaries of computational pathology. The evolution of this field exposes a paradox of modern molecular profiling, that put morphology on one side, molecular biology on the other [5,6]. Hence, we can sequence the DNA in a matter of hours, decode its mutational landscape, and reconstruct molecular pathways in detail, but these data are often generated outside their native morphological context [7,8]. As a result, critical biological information embedded in tissue architecture, spatial organization, and tumor–microenvironment interactions is frequently lost or interpreted in parallel rather than in concert with morphology. The current frontier lies in bridging that divide. It is not digitalization *per se* that is redefining pathology, but the integration of morphologic, biologic, and clinical data through computation [9].

2. From Digital Slides to Quantitative Mechanistic Pathology

The first wave of digital pathology (a wave that is still very much ongoing) has been about visibility: converting slides into images and microscopes into monitors [10]. It has enabled remote consultation, standardization, and a new level of collaboration across pathologists, molecular biologists, and clinical counterparts worldwide [11,12]. However, its ambition has been mainly infrastructural, aimed at reproducing the analog workflow in a digital environment rather than transforming it [13]. The real shift began when WSIs became data, when artificial intelligence (AI) emerged as the analytical layer capable of learning from patterns that no human could quantify alone [14]. Today, deep learning (DL) architectures (e.g., convolutional neural networks and vision transformers) are demonstrating the ability to infer diagnostic, prognostic, and even molecular mechanisms directly from histology [15–17]. What began as a technological advance has matured into a scientific discipline, grounded in reproducible, data-driven evidence: computational pathology. The goal is no longer automation or replacement but augmentation of the pathologist's eye, amplifying biological insight, detecting subtle cues, and linking morphology to mechanism [18]. In particular, AI demonstrates clear utility in high-throughput screening and reproducible quantification tasks, whereas the nuanced interpretation of rare morphological patterns and complex differential diagnoses remains critically dependent on expert pathologist judgment [19].

A fundamental concept of computational pathology is that morphology is a molecular epiphenomenon of disease [16,20,21]. Every contour, texture, and spatial relationship on a tissue slide encompasses biological information, signaling pathways, mutational effects, and microenvironmental interactions [5,22]. New DL tools are now beginning to translate into this language. By linking WSIs to genomic and proteomic profiles, mechanistically informed inference models can identify patterns that correlate with specific mutations, expression programs, or therapeutic targets [23]. These systems learn to associate microscopic architecture with molecular characteristics, bridging the gap between what we see and what drives it [24–27]. Possible clinical applications of these types of approach include triage to prioritize molecular testing and task-oriented molecular predictors [28]. It should be noted, however, that emerging spatial transcriptomic and proteomic technologies have the strong potential to act as mechanistic anchors, confirming, refining, and biologically grounding AI-derived inferences by linking digital morphology to spatially resolved molecular states within the tissue [29,30]. However, despite these advances, prospective, pre-registered, multi-institutional evaluations remain scarce, and their systematic implementation should be considered a priority. Importantly, the promise of mechanistically informed inference should not be overinterpreted: current models remain vulnerable to domain shift and limited generalizability across laboratories and populations, to dataset bias (including cohort enrichment, confounding, and imperfect ground-truth labels), and to the scarcity of rigorously designed multi-center external validation studies [31]. Therefore, such claims derived from WSI-based AI should be treated as hypothesis-generating unless supported by independent validation and biologically grounded anchoring (e.g., matched spatial-omics data) [32,33].

For all its clinical utilities, traditional immunohistochemistry (IHC) remains an uneasy balance between biology and morphology subjectivity [34]. Threshold-based scoring systems (whether for membrane, cytoplasmic, or nuclear markers) often struggle with reproducibility and interobserver variability. Small differences in staining intensity or interpretation can alter clinical categorization, creating uncertainty precisely where precision is most needed [35,36]. Digital pathology offers a way out of this interpretive bottleneck. For example, the Quantitative Continuous Scoring (QCS) approach for Trophoblast Cell Surface Antigen 2 (TROP2), based on the Normalized Membrane Ratio (NMR), exemplifies how DL quantification can transform subjective IHC scoring into continuous, reproducible data [37–41]. Biologically, TROP2 is a transmembrane glycoprotein involved in calcium signal transduction, cell proliferation, and epithelial–mesenchymal transition [42]. Its overexpression in solid tumors, including non-small cell lung cancer and breast cancer, makes it an effective target for novel antibody–drug conjugates (ADCs) [43–45]. By translating IHC staining patterns into numerical distributions rather than categorical bins, QCS approach mitigates interobserver variability inherent in traditional IHC scoring. Its correlation with clinical outcomes in prospective trials, such as TROPION-Lung01, highlights the role of computational pathology in advancing biomarker standardization and precision oncology [46]. Beyond TROP2, any biomarker (theoretically) can be redefined within a quantitative continuum using DL biology-aware models. Despite this promise, algorithm generalizability across laboratories, scanners, staining protocols, and pre-analytical variables remains a major challenge, requiring rigorous validation (both clinical and analytical) [47,48]. In addition, the transition from continuous scores to clinically actionable decision thresholds introduce new questions regarding cutoff definition. Taken together, computational pathology is poised to influence clinical outcomes not through isolated algorithms, but through its integration into end-to-end diagnostic and therapeutic workflows.

3. Conclusion

We stand at the threshold of mechanistic pathology, a new paradigm in which digital slides and molecular profiles converge within a single computational ecosystem. Pathology once unified structure and function; the digital and molecular revolutions, for a time, divided them. Today, computational pathology has the potential to reunite them. This is both an opportunity and a responsibility that carries regulatory implications. Ethical governance, data stewardship, and inclusive validation strategies should therefore be considered integral components of mechanistically informed inference, alongside technical and clinical innovation. Key implementation challenges extend beyond technical performance and include (i) algorithmic bias and fairness across demographic and socio-economic strata, (ii) interpretability and explainability to support clinical accountability and error analysis, and (iii) equitable access to computational pathology infrastructure (WSI scanners, storage, compute, and digital workflows), which may otherwise widen disparities between high-resource academic centers and low-resource healthcare settings. These issues should be addressed through established ethical and governance frameworks for AI in healthcare, including principles of transparency, accountability, privacy, and human oversight [49]. The responsible adoption of computational pathology requires addressing data bias and representativeness, algorithmic fairness, model interpretability (explainability), equitable access to enabling infrastructure, data ownership and patient rights, and transparent definition of intended clinical use with human oversight. In addition, continuous post-deployment monitoring is essential to detect performance drift, ensure fairness across populations, and maintain safety in real-world clinical settings. In conclusion, laboratories, academic institutions, and industry must now work together to embrace this convergent era by develop-

ing open, rigorously validated AI models for quantitative biomarker assessment, embedding computational pathology pipelines into prospective, biomarker-driven clinical trials, and investing in dedicated training programs for a new generation of "computational pathologists".

Author Contributions

NF and KV contributed equally to this work, including manuscript conception, drafting, and critical revision. Both authors read and approved the final manuscript. Both authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

Not applicable.

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Conflict of Interest

The authors declare no conflict of interest.

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