Will Artificial Intelligence replace histopathology in the future?

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Introduction

The question of whether machines can think was first asked in 1950 by Alan Turing (Turing, 1950). Artificial intelligence (AI) can be defined as the capability of a computer to perform tasks associated with human intelligence. These tasks may include pattern recognition, decision-making and complex analysis (Xu *et al.*, 2021). Healthcare has emerged as a particularly active domain for AI development. In September 2021, Turing's theoretical question found concrete expression when the FDA granted marketing authorisation for the first AI system in pathology called Paige Prostate Detect (FDA, 2021). This approval was based on evidence that this AI could enhance prostate cancer detection beyond the capabilities of unassisted pathologists (Raciti *et al.*, 2020). Such AI applications became feasible only through the digital enhancement of histopathological practice (Aeffner *et al.*, 2019).

Histopathology, the microscopic examination of diseased tissue for clinical diagnosis, has undergone substantial transformation over recent decades (Aeffner *et al.*, 2019). While historically an observational discipline relying on manual microscopy since the 16th century, the field has recently embraced digital analytical methods (Musumeci, 2014). Whole slide scanners which became commercially available in the early 2000s allowed tissue samples to be converted into high-resolution digital images (Kumar, Gupta and Gupta, 2020). These digital images could then be stored, shared and analysed on computer platforms (Aeffner *et al.*, 2019). The analysis of

histopathological images with the assistance of computer-based technologies such as AI is termed computational pathology (Rau *et al.*, 2024).

Artificial intelligence in histopathology

This digital transformation has created a substantial foundation for AI development in histopathology. After the United States and China, the United Kingdom (UK) has been reported to be the third largest artificial intelligence market in the world valued at £72.3 billion (*UK Government*, 2024). Investment into histopathology AI has been significant. For example, in 2020 the UK government invested £50 million pounds of funding for PathLAKE (Pathology Image Data Lake for Analytics Knowledge and Education), a consortium that aims to develop a large pool of annotated whole slide images (WSIs) (*UK Government*, 2020). The application of AI to histopathology can be understood through three interconnected dimensions that together define how these systems operate (see Figure 1).

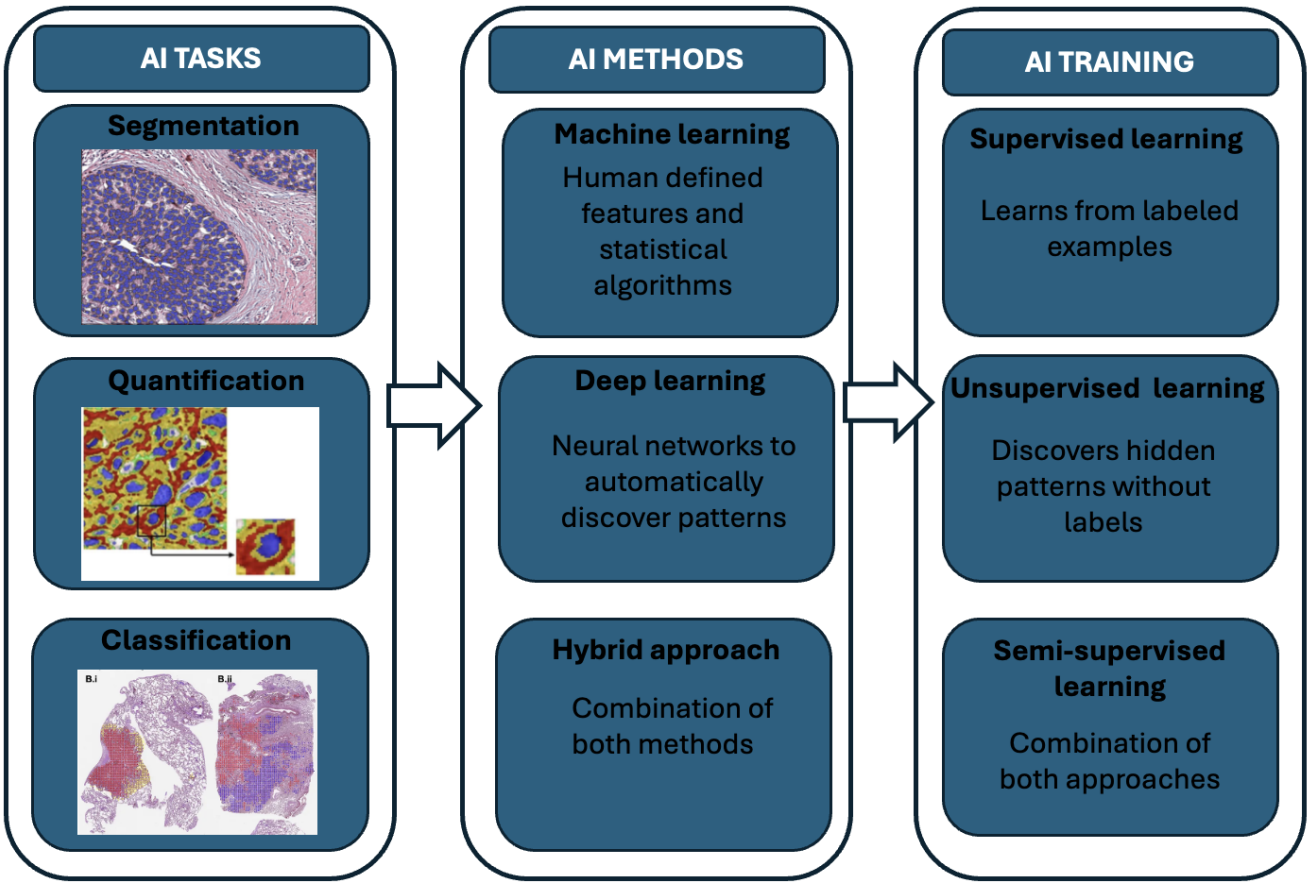

Figure 1: Overview of AI applications, methods, and training approaches in digital pathology. The diagram illustrates three key AI components: tasks, methods, and training. Image examples sourced from (Ram *et al.*, 2021), (Guerrero, 2021) and (Wei, 2019). Definitions adapted from (Komura, Ochi and Ishikawa, 2025). Diagram created by Izieduwa Akhionbare on Microsoft Powerpoint.

As illustrated in figure 1, AI systems in histopathology are designed to perform three primary tasks. Segmentation involves delineating structures such as cellular structures or regions of tissue. Quantification includes the counting and measuring features such as cell populations or biomarker expression levels. Classification categorises tissue regions or assigns diagnostic labels to histological patterns (Komura, Ochi and Ishikawa, 2025). These tasks are accomplished through different methodological approaches. These approaches include machine learning algorithms that recognise patterns based on human-defined features and statistical

methods, and deep learning systems that employ neural networks to automatically discover complex patterns from raw image data. A hybrid approach combining both methods is increasingly common in practice. The development of these AI systems relies on training paradigms. These include supervised learning where algorithms learn from labelled examples and unsupervised learning where systems discover hidden patterns in unlabelled datasets. There is also semi-supervised learning which combines both approaches to maximize learning efficiency while minimizing the need for extensive manual annotation (Cooper, Ji and Krishnan, 2023).

An increasing number of laboratories are implementing AI decision support tools particularly in a research setting. Current commercially available tools can be categorised into two main domains. Table 1 demonstrates examples of companies that provide these algorithms.

Table 1: Commercially available algorithms. Information from (Rigby, Vidya and Shaaban, 2025).

Biomarker algorithm companies (prognostic/predictive)	**Diagnostic algorithm companies**
Aiforia	Aiforia
Mindpeak	Ibex
Visiopharm	Paige

Biomarker algorithm vendors specialise in quantification of predictive or prognostic markers through digital image analysis. These systems help to score biomarkers such as the oestrogen receptor (ER), progesterone receptor (PR), Human Epidermal Growth Factor Receptor 2 (HER2) or Programmed Death-Ligand 1 (PD-L1). In

addition, these may also perform automated cell counting tasks. Diagnostic algorithm vendors focus on pattern recognition for diagnosis such as cancer detection (Moxley-Wyles and Colling, 2024).

Man vs algorithm: Diagnostic AI

To consider whether artificial intelligence can replace histopathologists it is important to consider the scope of histopathological practice. Histopathologists perform many roles including tissue diagnosis, multidisciplinary team meeting discussions, laboratory management, research and protocol development, report writing, and workload management (Pathologists, 2025). Of these diverse responsibilities, AI has primarily targeted the technical aspects that involve pattern recognition and digital image analysis. Diagnostic interpretation with AI which is the process of identifying and classifying tissue abnormalities, has received particular attention in the literature (Komura, Ochi and Ishikawa, 2025). This focus makes sense as diagnostic interpretation represents one of the most pattern-recognition dependent aspects of pathological practice (Ma *et al.*, 2025). Within this, cancer detection has been a particular focus in the literature given its clinical importance and the potential consequences of diagnostic errors (S. Alshuhri *et al.*, 2024). This has naturally raised the question of whether AI could achieve performance comparable to, or even surpass, that of trained histopathologists in diagnostic tasks.

One of the most influential attempts to answer this question was the CAMELYON16 challenge, a landmark study by Benjordi *et al.* (2017). This study compared the discriminative accuracy of AI and histopathologists in detecting the presence of metastasis in resected sentinel lymph nodes in women with breast cancer (Bejnordi *et*

al., 2017). Sentinel lymph nodes are the first site of potential metastatic spread and play an important role in breast cancer staging and thus clinical treatment (*NICE*, 2018). Benjordi *et al.* (2017) evaluated 32 algorithms that were submitted as part of a challenge competition (CAMELYON16). Table 2 demonstrates a summary of the methods and results of the study.

Table 2: Summary of CAMELYON16 methods and results. Collated from (Bejnordi *et al.*, 2017).

Training dataset	110 WSIs with metastases, 160 WSIs without metastases (from the Netherlands)
Testing dataset	129 WSIs (49 metastatic, 80 non-metastatic)
Number of Pathologists	11 pathologists assessed the test set under time pressure
AI (best performing) vs Pathologist Performance	AI: Best algorithm AUC 0.994 (95% CI: 0.983–0.999) Pathologists: Mean AUC 0.810 (Range: 0.738–0.884) P < .001

Abbreviations: WSI = Whole Slide Image; AUC = Area Under the Curve.

As demonstrated in Table 2, the best performing algorithm reached an Area under the curve (AUC) of 0.994 (95% CI: 0.983–0.999; P < .001), exceeding the performance of pathologists assessed under time constraints 0.810 (Range: 0.738–0.884; P < .001).

The AUC is a measure of diagnostic accuracy, where 1.0 represents perfect discrimination and 0.5 represents random chance performance (Çorbacıoğlu and Aksel, 2023).

Although these results suggest a superiority of the best AI algorithm to the pathologists, they warrant a careful interpretation. Arguably one of the biggest limitations was the artificial time constraint placed on the pathologists. In the clinical environment, pathologists often review different tissue levels, request immunohistochemical staining in equivocal cases and utilise clinical information to aid diagnosis (Gavrielides *et al.*, 2021; Li, Bui and Pantanowitz, 2022). Therefore, it may be argued that this methodological choice may have provided more advantage to AI algorithm. Indeed, this study highlighted the challenges of creating AI algorithms that are clinically translatable into routine digital pathology workflows. While this algorithm performed well under controlled conditions the limitations discussed above meant that its results could not be directly applied to real-world clinical practice.

By contrast, Paige prostate detect which was the first FDA-approved algorithm for clinical histopathology was developed with these real-world considerations in mind. Paige prostate detect was designed for prostate cancer detection on needle biopsies (Raciti *et al.*, 2020). Unlike CAMELYON16, Paige prostate detect was built to integrate into the pathologist's workflow, augmenting diagnostic decisions rather than replacing human judgment. How this AI integrates into histopathology workflow is demonstrated in Figure 2.

Figure 2: Paige prostate detect AI workflow. Diagram taken from (Canadian Agency for Drugs and Technologies in Health, 2024).

One of the key studies that provided evidence for the FDA approval of Paige prostate detect was a study by Raciti et al (2020). The aim of this of this trial was to compare the diagnostic accuracy of pathologists reviewing haematoxylin and eosin stained WSIs of prostatic biopsies with and without Paige AI assistance. Paige AI assistance included detecting the presence of cancer and highlighting areas of highest cancer likelihood. Three pathologists assessed 304 prostate needle biopsies over eight hours, categorising them as benign or cancerous. After one month, the same pathologists re-evaluated the cases using Paige AI assistance. The results demonstrated significant improvements in diagnostic performance as demonstrated in Table 3.

Table 3: Pathologist performance with and without Paige AI. Table taken from (Raciti *et al.*, 2020)

	Pathologist 1		Pathologist 2		Pathologist 3		Average	
	Sens	Spec	Sens	Spec	Sens	Spec	Sens	Spec
−Paige Prostate Alpha	66.7%	100.0%	87.1%	95.0%	67.7%	95.0%	73.8%*	96.6%
+Paige Prostate Alpha	84.9%	98.6%	93.5%	96.4%	91.4%	90.6%	90.0%*	95.2%
Change	+18.3%	−1.4%	+6.5%	+1.4%	+23.7%	−4.3%	16.1%	−1.4%

*= $p<0.001$

With Paige AI assistance, average sensitivity increased from 73.8% to 90% (p<0.001), while specificity was not statistically significant (96.6% vs 95.2%, p=0.33) (Table 3). Furthermore, the AI assistance was most beneficial for detecting small, well-differentiated cancers that closely mimic benign prostate tissue, arguably the cases most likely to be missed in clinical practice (Figure 3).

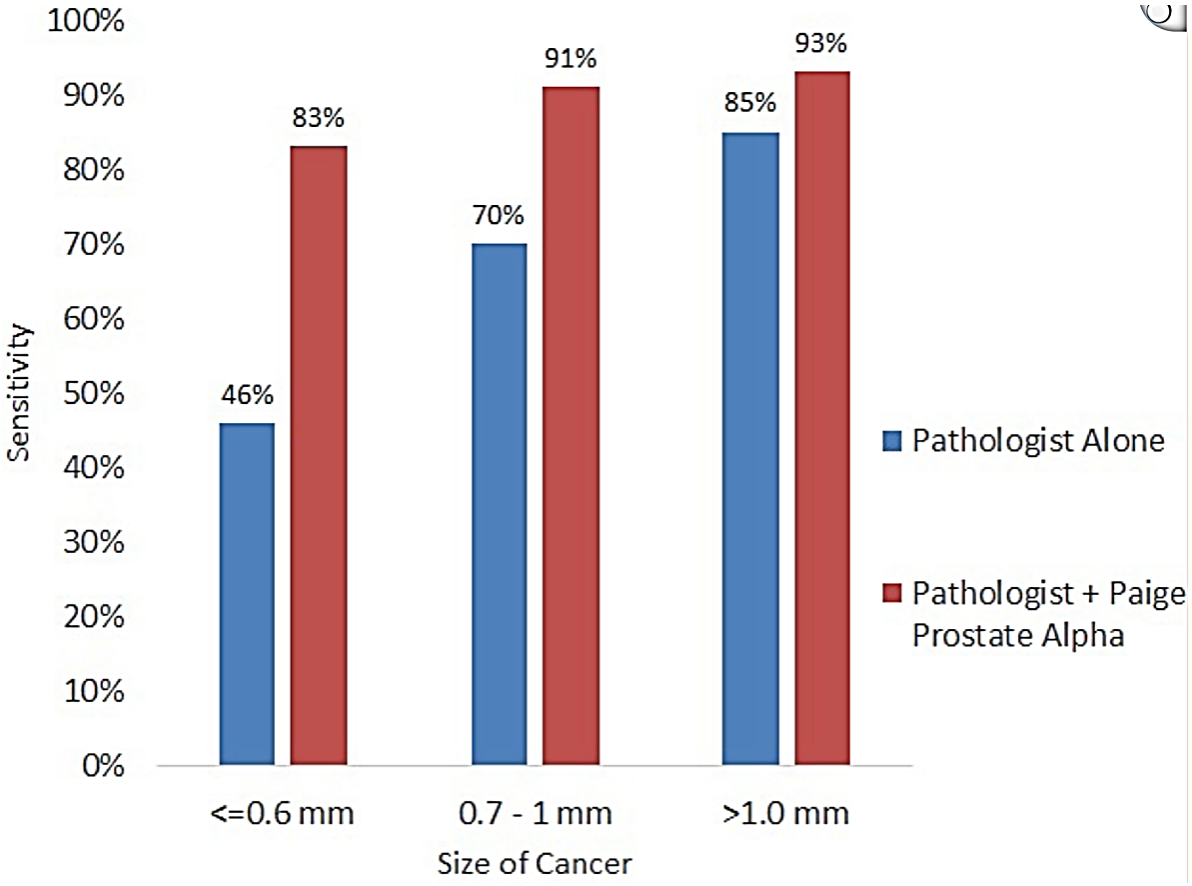

Figure 3: Mean sensitivity across different tumour size categories. Graph taken from (Raciti *et al.*, 2020).

Additionally, pathologists were significantly faster when using AI assistance, particularly for cancer-positive WSIs (13 seconds faster, P < 0.001).

Benefits of AI augmentation in histopathology diagnostics

The potential benefits of AI integration extend beyond increased diagnostic accuracy. A recent prospective study by Flach *et al*. (2025) aimed to investigate whether Paige AI assisted workflow reduced the need for IHC use. This study demonstrated that AI assistance reduced the risk of IHC use per detected prostate cancer case at both the patient level (RR, 0.55; 95% CI, 0.39 to 0.72) and slide level (RR, 0.41; 95% CI, 0.29 to 0.52). Cost reductions on IHC were estimated €1,700 for the trial, at €50 per IHC stain. Additionally, pathologists reported higher confidence in their diagnoses when using AI assistance. Nearly 80% of slides achieving confident or high confidence levels compared to just over half in the control arm ($P < 0.001$) . In contrast to the Raciti et al. (2020) study, Flach et al. (2025) found no significant difference in time efficiency. The median time of assessment for each haematoxylin and eosin slide demonstrated no significant difference between the pathologists with and without AI assistance (139 seconds *v* 112 seconds; $P = 0.2$) .

The potential benefits of AI integration extend beyond prostate cancer detection. In colorectal cancer, there has been evidence that AI assistance can significantly improve the detection of lymph node metastases (Khan *et al.*, 2023). Similarly, in lung cancer diagnostics, AI-assisted workflows have also demonstrated promise (Davri *et al.*, 2023). Furthermore, a study by Sandbank et al. (2022) aimed to develop and validate an AI-based quality control system for breast biopsy review. The AI algorithm demonstrated strong performance with AUCs of 0.99 for invasive carcinoma detection (specificity 93.57%, sensitivity 95.51%) and 0.98 for ductal carcinoma in situ detection (specificity 93.79%, sensitivity 93.20%) (Sandbank *et al.*, 2022).

While early AI studies like CAMELYON16 suggested the possibility of AI achieving superior diagnostic performance to pathologists under controlled conditions, current

clinical implementation trends favour augmentation over replacement. The FDA approval of systems like Paige prostate detect demonstrate that likely the most practical and effective approach, at least in the near future, involves AI working alongside pathologists rather than replacing them. However, there are specific domains within histopathology where replacement rather than augmentation may be more of a reality in the future.

Man vs algorithm: Biomarker analysis (predictive and prognostic)

Biomarker analysis highlights a key area of application of AI in histopathology. AI can help with both predictive and prognostic biomarker assessment. Predictive AI can help to determine which patients will respond to certain treatments through the quantification of predictive biomarkers. Prognostic AI can help to give an indication of patient outcome regardless of treatment through biomarker quantification also (Ballman, 2015; Aeffner *et al.*, 2019).

Unlike diagnostic AI, biomarker quantification represents an area where AI has greater potential to automate manual processes. Traditional biomarker scoring such as for ER, PR, HER2, Ki-67, and PD-L1 expression rely on visual assessment. This can be subjective and prone to inter-observer variability. AI systems offer the potential for more objective and reproducible biomarker quantification (Aeffner *et al.*, 2019).

Furthermore, several AI systems have achieved clinical validation as demonstrated in Figure 1. For example, Aiforia has received CE-IVD marking (European regulatory approval) for the assistance of PD-L1 quantification in non-small cell lung cancer

patients; with the first NHS Trust signing a contract for this model through the PathLAKE Plus consortium in 2023 (Aiforia, 2023).

The limitations and challenges of integrating AI into clinical workflows in the future

Despite the potential of integrating AI into histopathology, there are numerous implementation barriers that exist that may make widespread adoption difficult in the future. One significant obstacle is the lack of annotated datasets for the training of robust algorithms for different diseases. Obtaining detailed annotations for WSIs can be time-consuming, requiring input from expert pathologists. Although researchers have developed alternative approaches such as weakly supervised and self-supervised learning that reduce annotation needs (see Figure 1) these methods often involve greater computational complexity (Abdelsamea *et al.*, 2022).

Although there is a potential for cost savings through AI-augmented diagnostic workflows as demonstrated by the Flach et al. (2025) study; implementation requires significant upfront investment. Initial costs include WSI scanners, digital storage infrastructure and ongoing expenses for AI decision support services. For example, integrating Paige AI into a laboratory management system has implementation costs starting at £15,000 (NICE, 2021). Currently, there is little evidence from NHS-based studies to demonstrate clear long-term cost and productivity benefits from digital histopathology implementation. Furthermore, the increasing histopathology workload may make economic benefits difficult to measure in practice (Bonert *et al.*, 2021).

The 'black box' problem highlights a potential barrier to widespread AI adoption. Deep learning algorithms (see figure 1) in particular may not be able to adequately explain how they reach their diagnostic conclusions. This has the potential to create scepticism among clinicians and regulatory bodies (Shafi and Parwani, 2023). For AI methods to be widely adopted in medical research or clinical practice, they need to be reproducible so that clinicians and regulators can have confidence in their use. This highlights the need for transparent and explainable AI systems before confident and widespread clinical implementation can occur (Faa, Fraschini and Barberini, 2024).

Conclusion

The question Alan Turing posed in 1950 of whether machines can think, finds a nuanced answer in modern histopathology. Based on the evidence presented, AI likely will not replace histopathologists but may transform how they practice. In diagnostic applications, studies from CAMELYON16 to real-world implementations like Paige AI demonstrate that augmentation, not replacement may deliver the greatest clinical benefit. AI has the potential to enhance human diagnostic accuracy and efficiency while preserving the critical role of histopathologist expertise. In biomarker quantification, AI shows stronger replacement potential through objective measurement that addresses subjective variability in manual scoring.

The broader professional responsibilities such as multidisciplinary team meetings, laboratory management and research development remain largely human endeavours. While implementation barriers including dataset limitations, substantial costs, and algorithmic explainability challenges may moderate adoption timelines, significant investments like PathLAKE demonstrate this transformation is actively underway.

In summary, it is likely the future lies in a human-AI partnership where algorithms augment diagnostic decision-making and automate biomarker scoring. While histopathologists focus on complex interpretation, clinical correlation, and the multifaceted responsibilities that define modern pathological practice.

Word count: 2670

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