AI-assisted mitosis counting in breast cancer. A large-scale validation study.

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Introduction

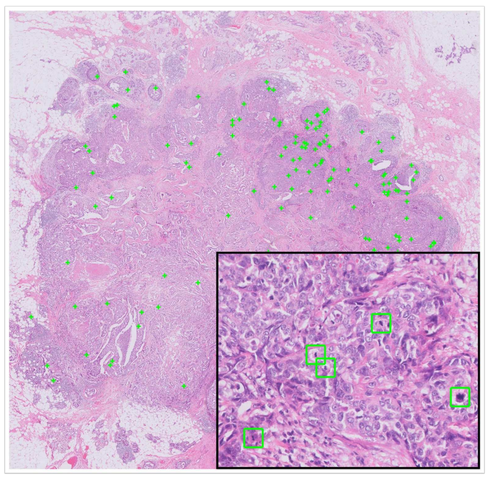

Figure 1: Aiosyn Mitosis Breast, output as seen by participants in the study

Expectations for artificial intelligence (AI) in pathology are very high, yet only a few studies attempted to quantify its impact in clinical practice.

Mitosis counting in breast cancer is a tedious, time-consuming and error-prone task.

We designed a large-scale, international study to quantify the impact of an AI device (Aiosyn Mitosis Breast) aiming at detecting mitoses in breast cancer slides in pathology practice (Fig. 1)

Material and Methods

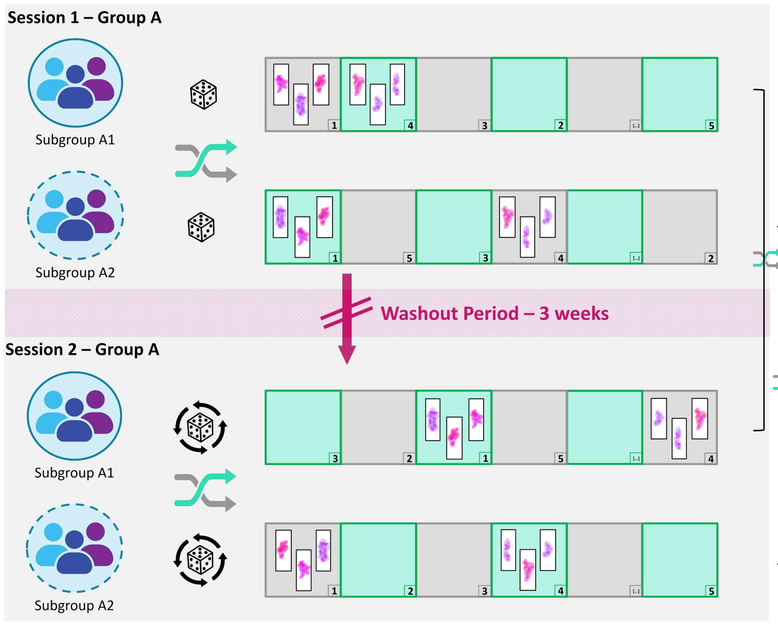

Figure 2: Study workflow.
Data shown for group A only (likewise for group B, on a different set of 105 slides).
Crossover on reading modality in each phase for subgroups A1 and A2. Reading modality alternates every 10 slides for each reader (**green** : AI-assisted, **grey** : unassisted). Randomization (🎲) of slide order for each participant and in each phase.

28 participants

9 countries

Various degrees of experience in breast pathology

Split-plot design

- 2 groups
- **210 slides**
- 105 per group
- read without and with AI-assistance

Results

Primary endpoints:

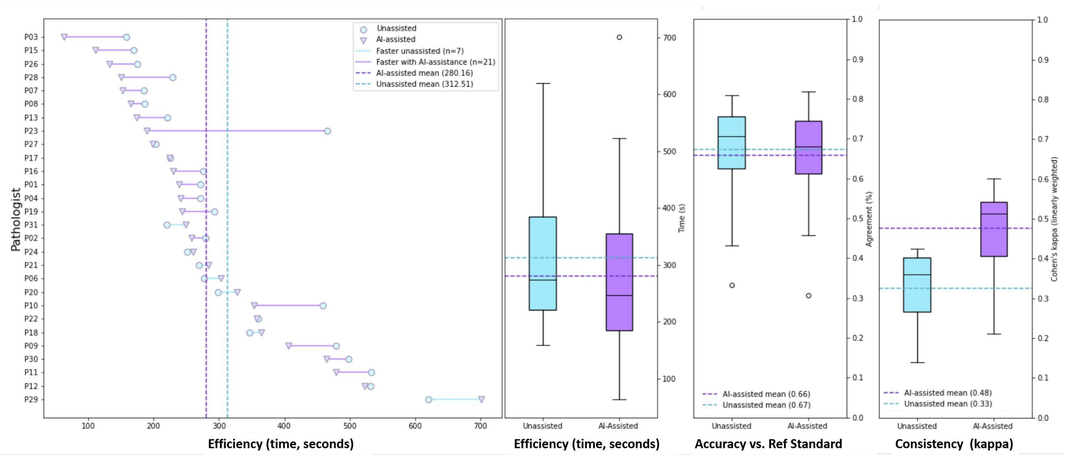

Figure 3: Graphical representation of the main results on efficiency, accuracy, and consistency.

	Unassisted	AI-assisted	p-value
Accuracy (score, %)	67.37 [63.26, 72.07]	65.87 [61.64, 70.64]	<0.01*[1]
Efficiency (time, seconds)	312.5 [264.1, 357.4]	280.2 [226.9, 328.6]	<0.01*[2]
Consistency (score, avg. linear kappa)	0.33 [0.3, 0.35]	0.48 [0.46, 0.50]	<0.01*[3]

Table 1: Main results summary

1. Generalized mixed-model (agreement~modality+(1/Cases/User)), non inferiority testing (delta: 10%).
2. Linear mixed-model (time~modality+(1/Cases/User)), superiority testing.
3. Wilcoxon signed-rank test (interobserver variability per case, per modality), superiority testing.

Homogeneity in hotspot selection:

- Overlap analysis: Normalized ratio of the union of areas of all users divided by the sum of all areas (per case) - **More overlap in the AI-assisted modality** (p<0.01)

User experience survey:

- Users would like to use this AI device in practice: 90%

- AI helped them locate the highest mitotic density area: 90%

- AI made them feel:
  - **Faster: 86%**
  - More accurate: 62%
  - More confident: 67%

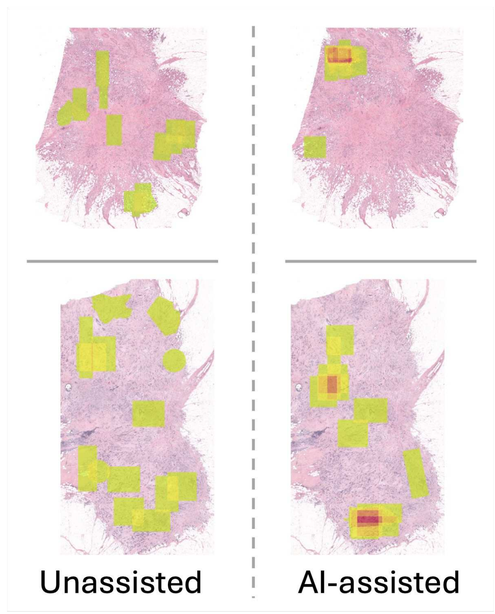

Figure 4: Homogeneity in hotspot selection.
Counting areas of the pathologist. Overlap is presented as a heatmap from green (no overlap) to red (max overlap observed across the two reading modalities).

Discussion and Conclusion

Results of our study show that the use of the AI induces:

- **A significant time gain of 10.35% overall (~32 sec/case)**, and a 15.54% productivity increase in resections.
- **A significant decrease in interobserver variability (in scores and area selection)**
- **No significant decrease in the score accuracy** compared to reference standard.

Pathologists welcomed the AI algorithm, with 90% declaring they would use it in clinical practice.

Strengths of the study:

Large scale and robust study setup designed to limit biases and interactions.

Limitations:

Platform-agnostic tools might have lowered overall efficiency in both modalities.

Readily-available AI can play a significant role in pathology practice across countries, not only by decreasing time consumption for tedious tasks, but also by improving interobserver reproducibility and, therefore, patient care.

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