

Imaging AI/Radiomics decision support improves physicians' stratification of indeterminate nodules: An MRMC study

Anil Vachani¹, Pierre Massion², Reginald Munden³, Fergus Gleeson⁴, Christina Bellinger⁵, Travis Dotson⁵, Lutz Freitag⁶, Noah Waterfield Price⁶, Quentin Chometon⁶, Vaclav Potesil⁶, Timor Kadir⁶

1 University of Pennsylvania, Philadelphia, Pennsylvania

2 Vanderbilt University Medical Center, Nashville, Tennessee

3 Department of Radiology, Wake Forest Baptist Health, Winston Salem, North Carolina

4 Oxford University Hospitals NHS Foundation Trust, Oxford, United Kingdom

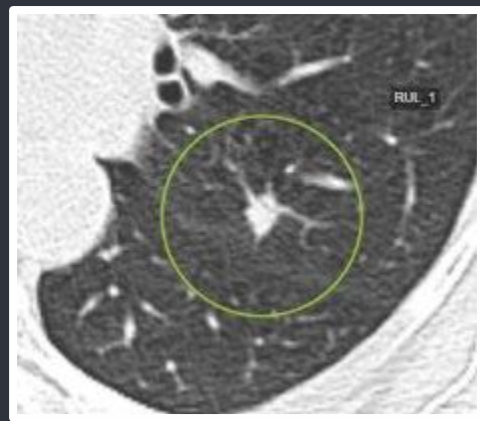
5 Department of Pulmonary/Critical Care, Wake Forest School of Medicine, Winston-Salem, North Carolina

6 Optellum Ltd., Oxford, United Kingdom



Lung Cancer Prediction (LCP) digital biomarker

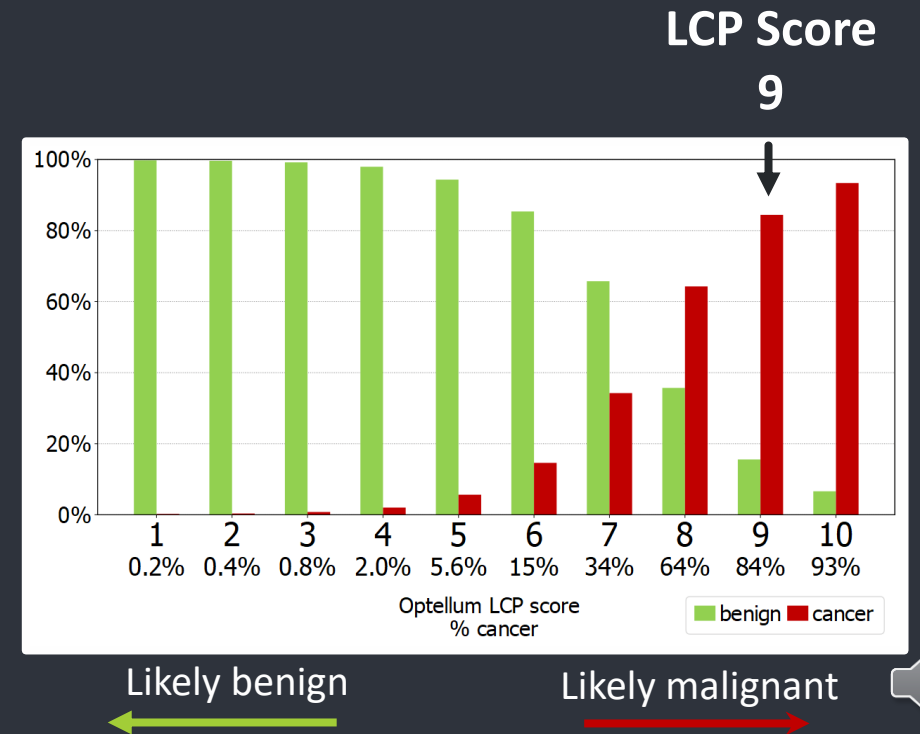
- Imaging AI/Radiomics-based biomarker – computed from CT images only.
- Software package developed by Optellum Ltd (Oxford, UK).
- Trained on more than 70,000 patient scans with known nodule diagnosis (cancer vs. benign).
- Model produces a score between 1 (benign) and 10 (malignant) for a nodule of interest.



Nodule of interest marked in CT image



AI-based digital biomarker



Study design: Multi-case Multi-reader study

- 300 cases: Solid and semi-solid nodules, 150 cancer and 150 benign, 5-30mm in diameter.
- 12 readers: 6 radiologists and 6 pulmonologists.
- Two sequential reads of each case: blinded and unblinded to the AI score.
- For each case, **likelihood of malignancy** and **clinical recommendation** (blinded and unblinded).

The screenshot displays the Optellum software interface. On the left, a CT scan image shows a nodule with a score of 10. A callout box says "click anywhere to activate". In the center, a bar chart titled "Optellum Score" shows the percentage of cancer for scores 1 through 10. The x-axis is "LCP-CNN score (% cancer)" and the y-axis is "Percentage Cancer". The legend indicates green for Benign and red for Cancer. The text "Score is being calculated..." is at the bottom of the chart. On the right, the "Case Assessment" panel shows "No Score" and "With Score" options. The "With Score" option is selected, showing a "Likelihood of Malignancy" slider set to 50 and a "Next Appropriate Action" dropdown menu.

LCP-CNN score	Benign (%)	Cancer (%)
1	100.0	0.0
2	100.0	0.0
3	100.0	0.0
4	99.0	1.0
5	98.0	2.0
6	95.0	5.0
7	85.0	15.0
8	65.0	35.0
9	20.0	80.0
10	5.0	95.0

Likelihood of malignancy:
1 to 100

Clinical recommendation:

- No action
- Long term CT follow-up
- Short term CT follow-up
- PET-CT/Biopsy
- Surgical resection/other treatment



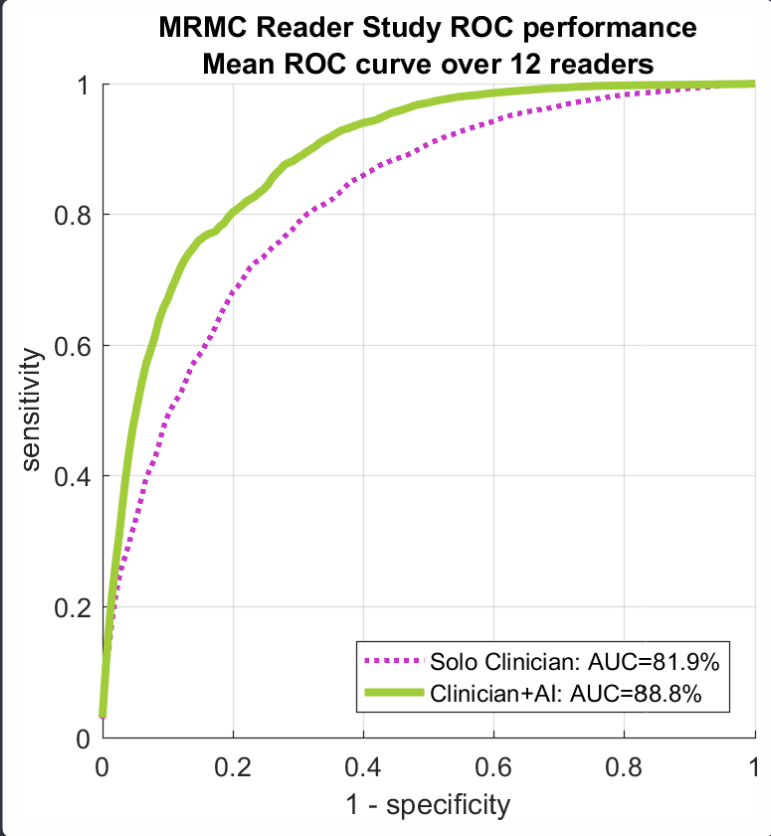
Results: Overall

Primary endpoint: Change in AUC

- Mean AUCs averaged over the 12 readers:
 - Pre-AI: 81.9% (95%CI 80.5-83.3%)
 - Post-AI: 88.8% (95%CI 87.7-89.8%)
- Mean effect size: 6.85 AUC points (95%CI 4.29-9.41%, p<.001)

Secondary endpoints:

- **Clinical recommendation:** Overall 26% of decisions improved when assisted by the AI.
- **Inter-reader consistency:** Variation in assessment reduced from 16.65 pp to 11.07 pp when assisted by the AI.

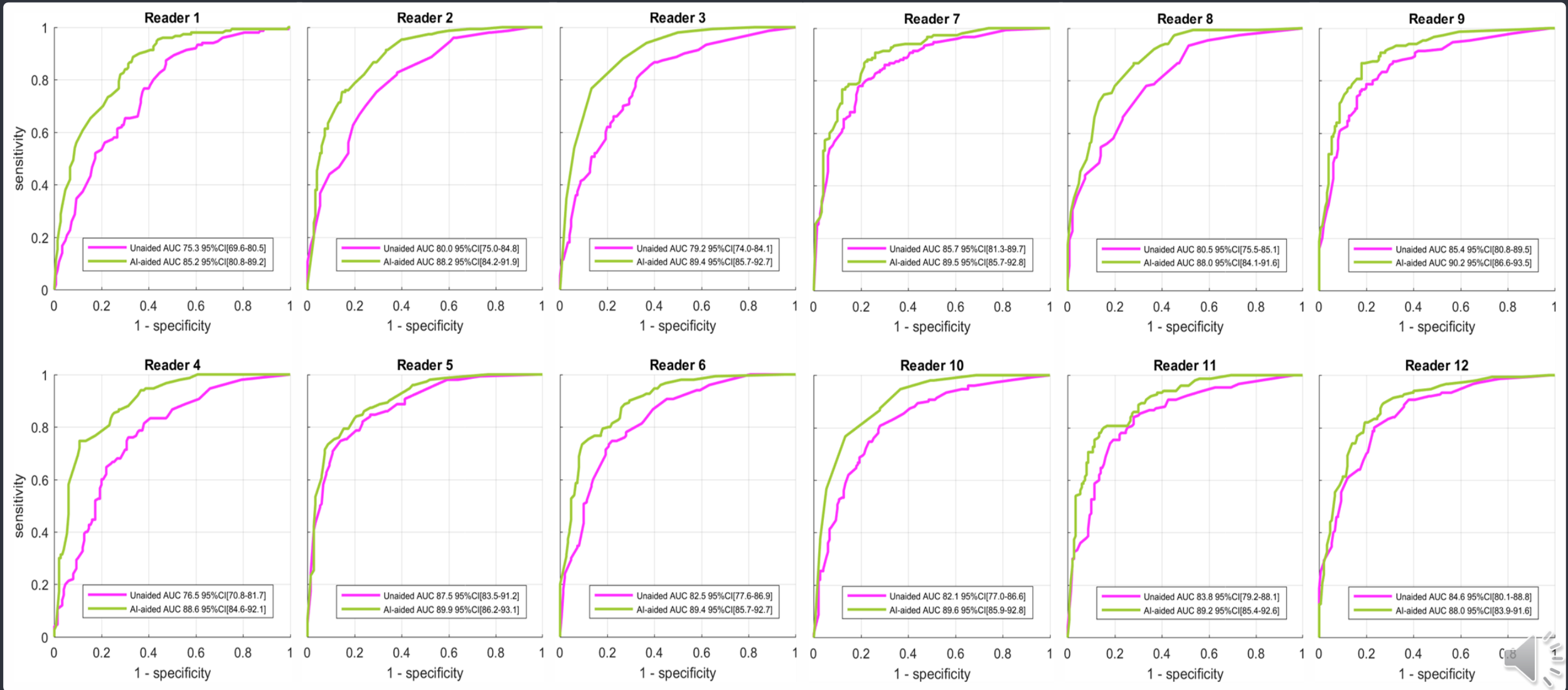
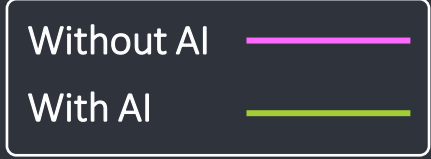


LoM Threshold	Sensitivity			Specificity		
	Unassisted	Assisted	P	Unassisted	Assisted	P
5%	94.06	97.89	< .001	37.44	42.28	.001
65%	55.67	65.00	< .001	86.50	89.28	.001



Results: Individual reader ROC performance

- The individual assessments of all readers were improved when assisted by the AI.



Conclusions

- The LCP digital biomarker helped all participant radiologists and pulmonologists improve their performance in categorising IPNs as benign or malignant.
- Overall AUC, sensitivity, and specificity were significantly improved by using the LCP score.
- The LCP digital biomarker improved the clinical decision-making of all readers.
- The LCP digital biomarker improved readers' consistency.

