Changes in the Detection of Clinically Relevant White Matter Lesions in MS Using FDA-Cleared Automated Software

Kelly Leyden MRes[1], Anisha Keshavan PhD[1], Victor Gehman PhD[1], Michael Iv MD[1,2]

[1]Octave Bioscience, Menlo Park, CA, United States of America
[2]Stanford University, CA, United States of America

DISCLOSURE

Kelly Leyden, MRes
Product Lead - MRI Insights
Employee of **Octave Bioscience**

Anisha Keshavan, PhD
Senior Data Scientist
Employee of **Octave Bioscience**

Michael Iv, MD
Neuroradiologist
Octave Bioscience
Clinical Associate Professor of Radiology
Stanford University

Contribution to this study was as a paid consultant, and was
not part of his Stanford University duties or responsibilities

Victor Gehman, PhD
Principal Data Scientist
Employee of **Octave Bioscience**

Improving lesion burden detection in patients with multiple sclerosis (MS)

- Outside of gadolinium enhancing T1 lesions, disease activity in MS is often characterized by new, enlarging, and shrinking T2 lesions on MRI.

- Use of institution-specific semi-automated software can improve white matter lesion detection, which can influence neurologists' clinical decision-making.[1]

- Commercially available FDA-cleared automated software can potentially provide similar benefits but with the added advantage of being widely available in the United States.
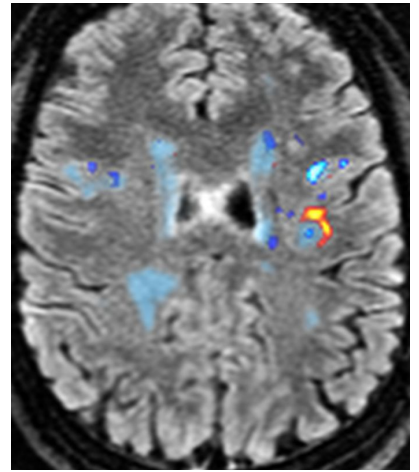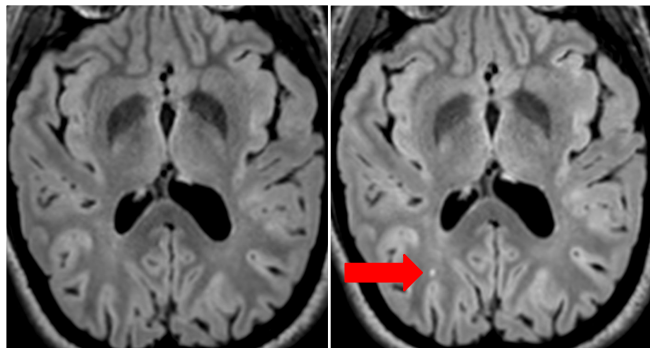
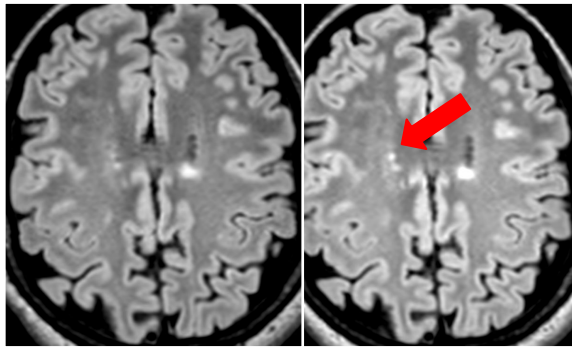[1] Van Heerden J et al. *AJNR*, 2015

Improved white matter lesion detection with FDA-cleared automated software?

- To compare and characterize the detection of **clinically relevant** white matter lesions on MRI without and with the use of a commercially available FDA-cleared automated software package.
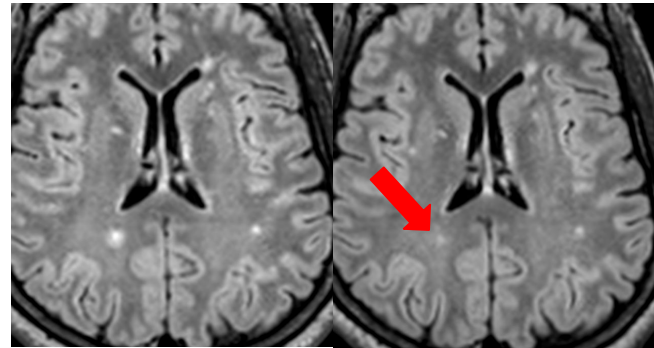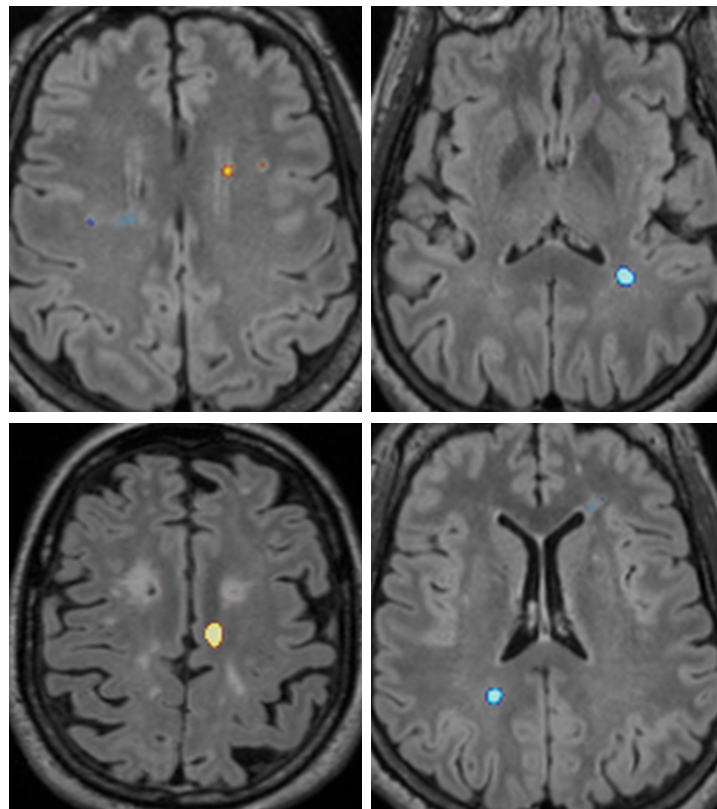
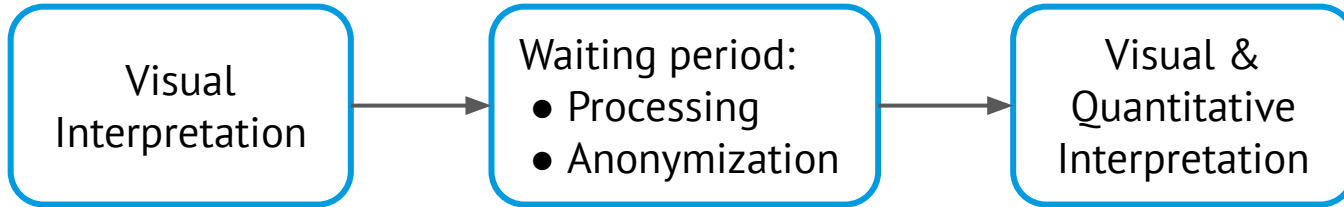**New T2 Lesion** **Enlarging T2 Lesion** **Shrinking T2 Lesion**

Image acquisition and post-processing

- Retrospective study w/ subject selection from anonymized dataset between 2013-2019

- 2 MRIs/patient: 3D T1 and 3D T2 FLAIR

- 3D T1 and 3D T2 FLAIR images processed using FDA-cleared software (LesionQuant 3.0.1) to produce:

  - **Co-registered, color-coded map highlighting lesion changes between MRI comparisons**

    - **Hot (red/yellow): new or enlarging lesion**

    - **Cold (blue): shrinking lesion**

Comparison of radiology findings

Visual Interpretation	→	Waiting period: ● Processing ● Anonymization	→	Visual & Quantitative Interpretation

- Using only visual interpretation, a board-certified neuroradiologist reported the number of new, enlarging, and shrinking T2 lesions.

- To avoid recall bias, the second interpretation with the aid of the software package (including processed data and the color-coded head map) was performed after a one-month waiting period.

- Lesion differences were compared with paired t-tests.

- Agreement was assessed with Bland-Altman analysis.

Detection of MS lesions without and with software use

- 52 MS patients who had 2 brain MRIs (mean MRI time interval: 12 months)

- In **23 patients (44%),** new or enlarging lesions were found with the software that were missed or misidentified on visual inspection alone, yielding on average **2 more new or enlarging lesions per patient**.

- *Good agreement* between both methods, but the use of software resulted in **detection of more lesions in patients with high lesion burden** (mean difference: 0.7; 95% limits of agreement: -2.9, 4.2)
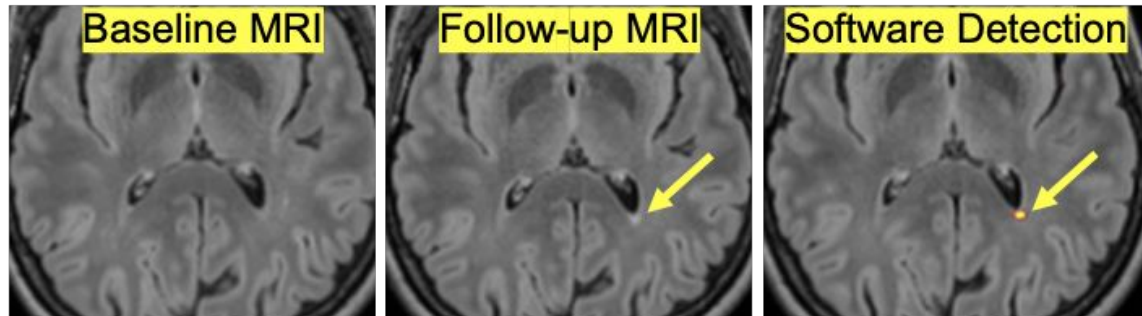
Comparison of Lesion Counts

	W/O software	W/ software	% difference
New	67	82	**20.1%** P=0.11
Enlarging	13	32	**84.4%** P=0.02*
Shrinking	14	15	**6.9%** P=0.57

RESULTS

Examples:
Lesions missed with visual inspection only
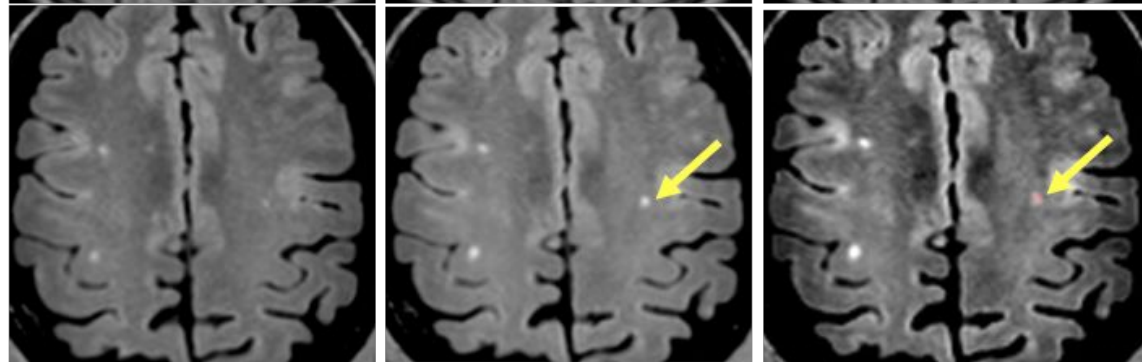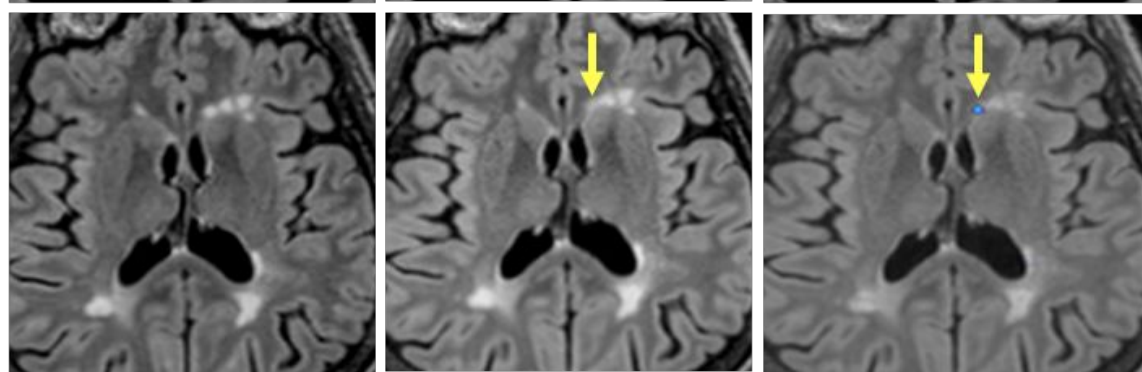
Software detects more clinically relevant MS lesions

- Use of FDA-cleared automated software improved the detection of MS WMLs, especially of enlarging T2 lesions in patients with **high lesion burden**.

- In nearly half of patients, the number of T2 lesion differences detected with the software was different from the routine evaluation, suggesting an **opportunity to improve reporting of disease activity and impact clinical outcomes**.

Assess impact on clinical decision-making

- Evaluate additional metrics such as T1 WM hypointensities and brain volumes

- Assess MS Neurologists' satisfaction and assess potential change in treatment decision-making based on improved neuroimaging findings

Questions or comments?
Corresponding Author: kleyden@octavebio.com

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