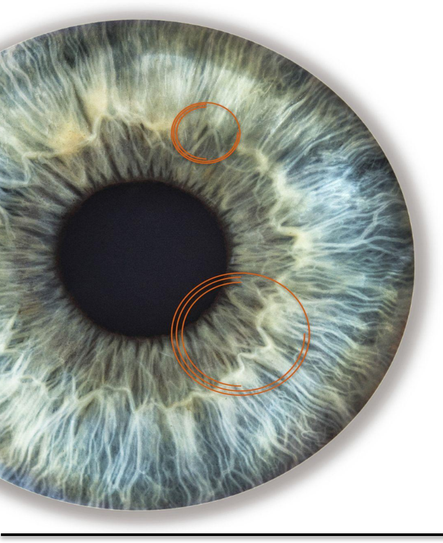

Screening for Memory Concerns in Optometry Settings to Facilitate Early Detection of Alzheimer's Disease: Measuring the Utility of the RetiSpec Scan

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INTRODUCTION

- ~6.7M (10.7%) Americans age 65 and older are living with Alzheimer's disease (AD) in 2023. As the size of the U.S. population 65+ continues to grow, so will the numbers and proportion of Americans with Alzheimer's or other dementias.[1] Current AD diagnostic solutions, such as Positron Emission Tomography scans and Cerebrospinal Fluid analysis, are impractical for scalable and accessible early detection.
- The launch of new AD therapies in 2023 has led to an urgent and unmet need for accessible diagnostics.
- Optometry may serve as an entry point to increase AD screening; Optometrists routinely identify signs of neurological conditions (e.g., papilledema can indicate brain tumor) and facilitate referrals.
- Research shows that retinal hyperspectral imaging can detect AD biomarkers given its shared developmental/biological similarities to the brain.[2,3] RetiSpec's Artificial Intelligence (AI)-based retinal imaging solution may enable an affordable and non-invasive way to enhance real-time clinical decision support at the point-of-care.

To address the raising AD cases and need for screening, utilizing the RetiSpec scan in optometry settings may provide an opportunity to enable actionable information for healthcare providers as well as a pathway to accelerate access to disease-modifying AD treatments.

METHODS

- Single-group, cross-sectional study to assess community-based settings to increase rates of cognitive assessment and biomarker testing (RetiSpec scan) in adults aged 55+ with a memory concern
  - Aim 1: to assess the feasibility of a community-based AD screening program in partnership with optometry clinics to increase rates of cognitive and retinal assessment
  - Aim 2: to evaluate risks, benefits, facilitators, and barriers to these settings to increase rates of cognitive and retinal assessment
- Dual entry screening: local Alzheimer Society chapter for cognitive screening or optometry clinics for a RetiSpec scan, plus a brief survey on scan experience (Figure 2)
- RetiSpec scan: participants were seated comfortably at a RetiSpec Retinal Imaging System comprised of a commercially available standard fundus camera (Topcon TRC-NW8) and hyperspectral sensor (Cubert FireflEYE 185) (Figure 1 - left). Bilateral retinal images were acquired over ~10 mins. Dilation drops administered (per standard clinic practices) for adequate pupil size to ensure high quality imaging.
- RetiSpec AI analysis: ensemble convolutional neural network model of 3D spectral-spatial architecture that scrutinizes multiple retinal regions (Figure 1 - center)
- Utilization focused evaluation: to explore the risks, benefits, facilitators, and barriers to these settings from the perspective of frontline providers
- All study activities took place in Toronto, Ontario, Canada

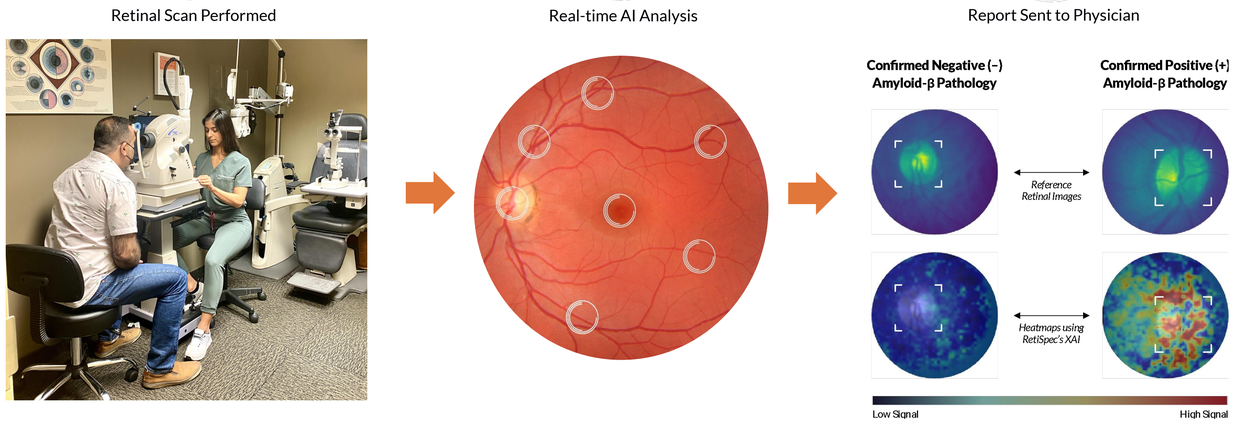

Figure 1: RetiSpec's AI-based Retinal Imaging Solution - system set-up (left), followed by AI analysis (center) and reporting (right)

RESULTS

Aim 1:

- Retinal scans (a) and cognitive tests (b) integrated well into existing clinical workflows (Figure 2)
  - (a) 99 retinal scan performed (80% of enrollment – Figure 2)
  - (a) 29% of cognitive test referrals originated from optometry compared to the study target of 10%
  - (b) 13.8/month compared to 1.8/month in the 12-month pre-study period

Aim 2: *(preliminary results as analysis still underway)*

- Facilitators: effective training, staff buy-in, clear communication pathways with primary care, financial coverage for screening
- Barriers: stigma, lack of electronic health record sharing between optometry and primary care

- Screening rates were higher in optometry settings (60% – Figure 2)
- 35% of participants enrolled were from minority groups (including Black, Asian, Latino, Hispanic, Armenian, & Mixed-Race Ethnicities) (Table 1)
- Results from the RetiSpec survey were highly favorable, with positive experiences, willingness to repeat particularly if the cost was covered and unanimous interest in sharing scan results with PCP (Table 2)

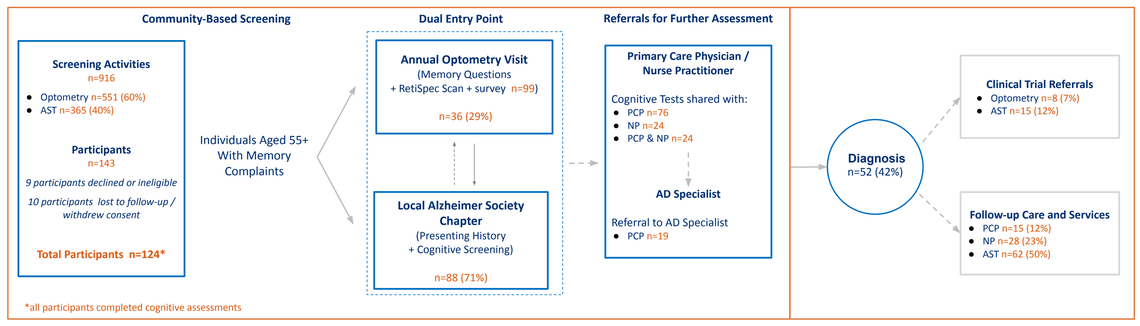

Figure 2: Clinical Workflow of Study

Point of Entry:	Optometry N (%)	Alzheimer Society N (%)	Total N (%)
Total # of Participants	36 (29.03)	88 (70.97)	124 (100)
Age Mean (SD) (Range)	72.08 (6.42) (55-87)	75.17 (6.53) (55-89)	74.26 (6.99) (55-89)
Sex			
Male	14 (11.29)	31 (25.00)	45 (36.29)
Female	22 (17.74)	57 (45.97)	79 (63.71)
Ethnicity			
Caucasian	20 (16.13)	55 (44.35)	75 (60.48)
Black	0	7 (5.65)	7 (5.65)
Hispanic	0	2 (1.61)	2 (1.61)
Asian (East, South, Southeast, West/Arab)	8 (6.45)	7 (5.65)	15 (12.10)
Mixed Race	1 (0.81)	7 (5.65)	8 (6.45)
Other	2 (1.61)	7 (5.65)	9 (7.26)
Did not disclose	2 (1.61)	0	2 (1.61)
Highest Level of Education			
Some highschool or less	1 (0.81)	4 (3.23)	5 (4.03)
Highschool graduate or GED	5 (4.03)	7 (5.65)	12 (9.68)
Some college, associate's degree or technical training	6 (4.84)	23 (18.55)	29 (23.39)
University or college graduate (Bachelor's degree)	11 (8.87)	32 (25.81)	43 (34.68)
Graduate school degree (Master's, professional, doctorate)	13 (10.48)	22 (17.74)	35 (28.23)
Employment Status			
Working full or part time (paid)	10 (8.06)	15 (12.10)	25 (20.16)
Retired or not currently employed	26 (20.97)	72 (58.06)	98 (79.03)
Homemaker	0	1 (0.81)	1 (0.81)
Marital Status			
Single, Dating or Never Married	3 (2.42)	23 (18.55)	26 (20.97)
Married or Common-Law	22 (17.74)	44 (35.48)	66 (53.23)
Separated or Divorced	5 (4.03)	10 (8.06)	15 (12.10)
Widowed	6 (4.84)	11 (8.87)	17 (13.71)

Table 1: Participant Demographic Characteristics

Questions	Average Score*
The RetiSpec scan was difficult to do	Strongly disagree 1.76
Was initially nervous/afraid to do the RetiSpec scan	Strongly disagree 1.83
The duration of the RetiSpec scan was longer than expected	Disagree 2.32
The duration of the RetiSpec scan was reasonable	Agree 4.13
The RetiSpec scan was comfortable for the eyes	Agree 4.17
The RetiSpec seating position and posture were comfortable	Agree 4.21
Level of satisfaction with the RetiSpec scan experience	Agree 4.24
Willingness to undergo a RetiSpec scan again	Agree 4.44
Willingness to undergo RetiSpec scan if covered by OHIP	Agree 4.63
Interested in providing RetiSpec scan results to clinician	Strongly agree 5.0

Table 2: Participant Feedback from RetiSpec Scan

SUMMARY

- Optometry clinics are a promising venue for AD screening with effective training and staff buy-in.
- Participants found the imaging experience to be positive and would repeat it again.
- High interest to share results with their PCP demonstrates that brain health is top of mind for many individuals.
- Screening in a multicultural city achieved an ethnically diverse population, supporting generalizable results.

CONCLUSIONS

The findings from this study demonstrate that RetiSpec's AI-based retinal scan seamlessly integrate into existing clinic workflows and may offer a pragmatic, affordable, and scalable way to increase Alzheimer's screening rates in the community.

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For more info on RetiSpec's technology: