Usability and Quality of Retinal Images Captured by a Self-Operated, Home-based OCT System

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Financial Disclosures

- Consultant to Allergan
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- Consultant to Beyeonics
- Consultant to Forsightlabs
- Consultant to Notal Vision
- Consultant to Novartis
- Consultant to Roche

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Disclosure

The presentation discusses medical devices not clear for clinical use by the FDA.

Summary
Potential impact of Home OCT monitoring

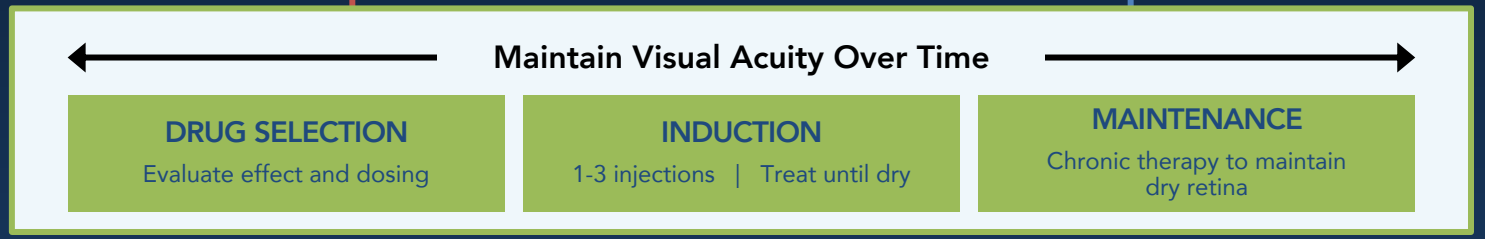
- Information generated by tele-connected OCT in our patients' homes has the potential to support current retinal disease management and any future evolution which may occur in:
  - Monitoring patterns
  - Drug selection and dosing
  - Patient outcomes

Home OCT for Personalizing eAMD Management

AT HOME OCT MONITORING **TO** Catch and treat wet days **AS SOON** as they happen **BY** Providing patients and physicians with unique **INTER-VISIT DISEASE KNOWLEDGE**

THE BENEFITS

- Avoiding under treatment and improving visual acuity outcomes
- Reducing treatment burden, increasing patient satisfaction and reducing cost



COVID-19 pandemic highlights the need for remote patient monitoring

Requirements for a Home OCT System

1. Patients must be able to self-image on OCT device
2. Analysis of daily images must be automated and accurate
3. Device must be low cost but deliver high image quality
4. Patient compliance must be monitored by remote clinic

We evaluated two of the requirements

1. Patients must be able to self-image on OCT device

3. Device must be low cost but deliver high image quality

Objective

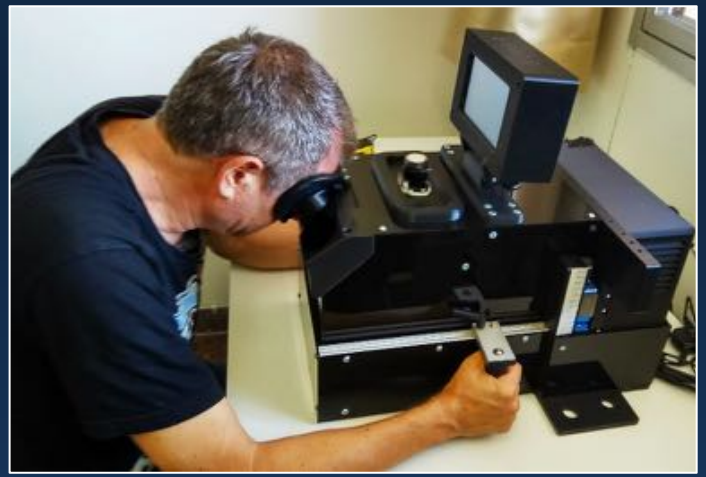
- Evaluate self-operability of Notal OCT by elderly patients with AMD
- Comparison of investigator image assessment for disease activity between Notal OCT and commercial in-office OCT devices

Study Design

- Prospective IRB approved clinical trial
- Consecutive eyes with dry and wet AMD and VA ≥ 20/400
- Non-dilated subjects were imaged on a commercial OCT (Cirrus or Spectralis)
- Following a 2-minute video tutorial, subjects self-operated the Notal OCT to capture OCT images of their own eyes
- Images from the Notal OCT were compared to commercial OCT images by a masked reader for presence of intra- and/or subretinal fluid in the central 10˚ of the macula

Investigational OCT Devices

- Field of view:
  central 10 deg. (3 mm x 3 mm)
- Scan pattern:
  88 B-scans with 34 µm spacing



Prototype V2.5

Commercial form factor V3

Study Population

	V2.5	V3	Total
No. of subjects enrolled & analyzed	264	45	309
Mean Age	79	81	
Number of eyes	469	69	538
Number of Notal OCT scans	469	336	805

Patient Characteristics by Ability to Self-image

	V2.5			V3		
	Completed self-imaging	Could not complete self-imaging	Total / p-value	Completed self-imaging	Could not complete self-imaging	Total / p-value
N (%) - patients	264 (91%)	26 (9%)	290	45 (100%)	0	
N (%) - eyes	469 (88%)	62 (12%)	531	69 (93%)	5 (7%)	74
VA, Mean (SD)	0.54 (0.28)	0.38 (0.27)	<0.001	0.62 (0.30)	0.41 (0.31)	0.13
Mean VA Snellen equivalent	20/40	20/50		20/33	20/49	
VA, Median (IQR)	0.5 (0.3,0.8)	0.3 (0.1,0.6)		0.67 (0.35,0.8)	0.3 (0.2-0.68)	
Median VA Snellen equivalent	20/40	20/63		20/30	20/66	

Eye Characteristics for Success of Self-imaging

Diagnosis		
AMD stage	V2.5	V3
Early	8.1%	8.7%
Intermediate	25.8%	23.2%
Neovascular	66.1%	68.1%

Visual acuity		
	V2.5	V3
>20/40	62%	70%
<20/40-20/80	21%	21%
<20/80-20/160	9%	0%
<20/160-20/320	6%	10%
<20/320-20/400	2%	0%

Subjective Experience with Notal OCT V2.5 (n=146)

	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
The demonstration (movie) was helpful	65%	33%	1%	1%	0%
The tutorial session was clear	69%	29%	2%	0%	0%
I understand the tasks I must do to scan my eye	62%	32%	4%	1%	1%
The tasks I had to do to scan my eye were easy to perform	64%	33%	2%	1%	1%
Resting between the sessions helped me to complete the test	44%	43%	9%	3%	0%
Testing duration was short	66%	31%	0%	1%	1%
I felt comfortable during the test (posture, head rest)	67%	31%	0%	1%	1%
I didn't feel that my eyes are getting tired or burning during the test	64%	33%	1%	1%	0%
The viewer's mask was comfortable while performing the test	65%	32%	2%	0%	1%
The handles of the device were helpful to position myself	56%	36%	9%	0%	0%

Of the 146 respondents, 96% of users "strongly agree" or "agree" with statements on the simplicity and comfort of the Notal OCT V2.5

Subjective Experience with Home OCT V3 (n=37)

	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
The demonstration (movie) was helpful	54%	35%	3%	8%	0%
The tutorial session was clear	65%	35%	0%	0%	0%
I understand the tasks I must do to scan my eye	57%	35%	8%	0%	0%
The tasks I had to do to scan my eye were easy to perform	49%	46%	5%	0%	0%
Resting between the sessions helped me to complete the test	41%	46%	14%	0%	0%
Testing duration was short	57%	35%	8%	0%	0%
I felt comfortable during the test (posture, head rest)	57%	30%	5%	5%	3%
I didn't feel that my eyes are getting tired or burning during the test	57%	32%	5%	5%	0%
The viewer's mask was comfortable while performing the test	62%	27%	3%	8%	0%
The handles of the device were helpful to position myself	62%	30%	3%	5%	0%

Of the 37 respondents, 91% of users "strongly agree" or "agree" with statements on the simplicity and comfort of the Notal OCT V3.0

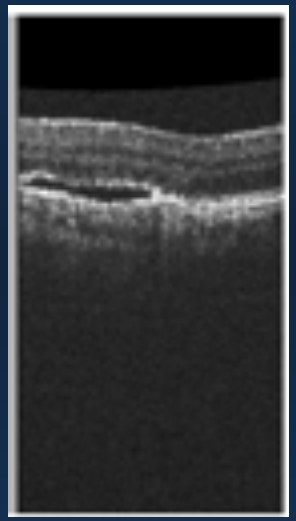
Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) of V2.5 with Commercial OCT

V2.5	Commercial OCT			PPA and NPA
	Fluid	No Fluid	Total	(95% CI per binomial distribution)
Presence of Fluid				
Fluid	213	9	222	PPA: 213/217 = 98% (95.3%, 99.5%)
No Fluid	4	237	241	NPA: 237/246 = 96% (93.2%, 98.3%)
Total	217	246	463	
Sub-retinal Fluid				
Fluid	152	13	165	PPA: 152/163 = 93% (88.2%, 96.6%)
No Fluid	11	287	298	NPA: 287/300 = 96% (92.7%, 97.7%)
Total	163	300	463	
Intra-retinal Fluid				
Fluid	89	9	98	PPA: 89/98 = 91% (83.3%, 95.7%)
No Fluid	9	356	365	NPA: 356/365 = 98% (95.4%, 98.9%)
Total	98	365	463	

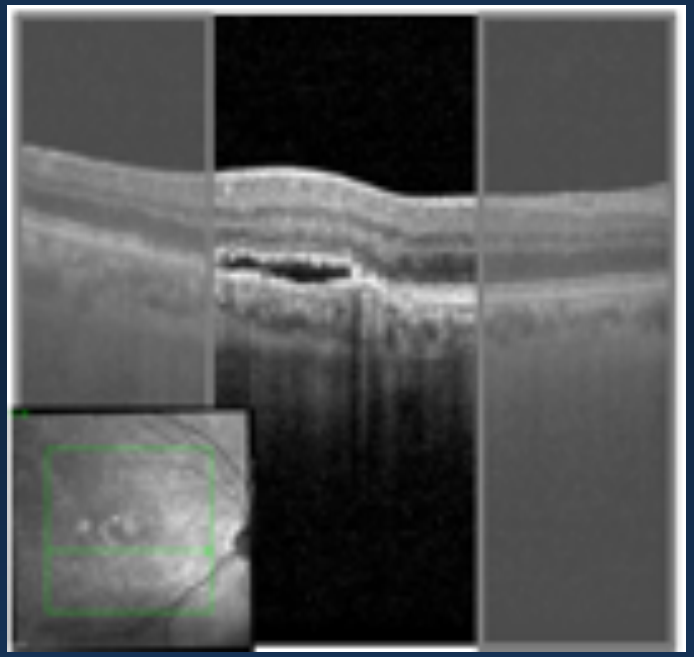
PPA and NPA of V3 Based on Review of 1, 2 or 3 Images

V3	Commercial OCT			PPA and NPA
Notal OCT	+	-	Total	(95% CI)
Fluid status was defined as the identification of fluid in the first self-image				
+	34	1	35	PPA: 34/38 = 89% (75%, 97%)
-	4	37	41	NPA: 37/38 = 97% (86%, 100%)
Total	38	38	76	
Fluid status was defined as the identification of fluid in at least one of the two repeated self-images				
+	36	2	38	PPA: 36/38 = 95% (82%, 99%)
-	2	36	38	NPA: 36/38 = 95% (82%, 99%)
Total	38	38	76	
Fluid status was defined as the identification of fluid in at least one of the three repeated self-images				
+	37	2	39	PPA: 37/38 = 97% (86%, 100%)
-	1	36	37	NPA: 36/38 = 95% (82%, 99%)
Total	38	38	76	

Image Quality Comparison



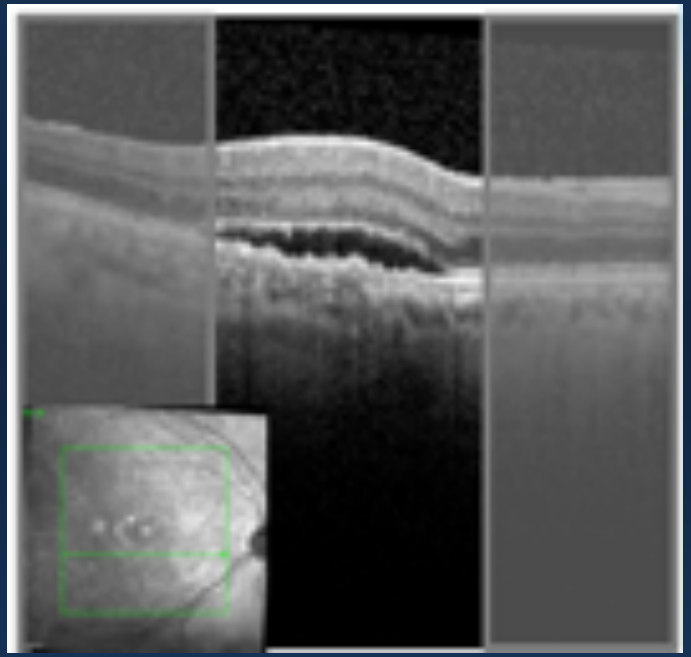
Notal OCT V3, none averaged image



Spectralis, averaged image

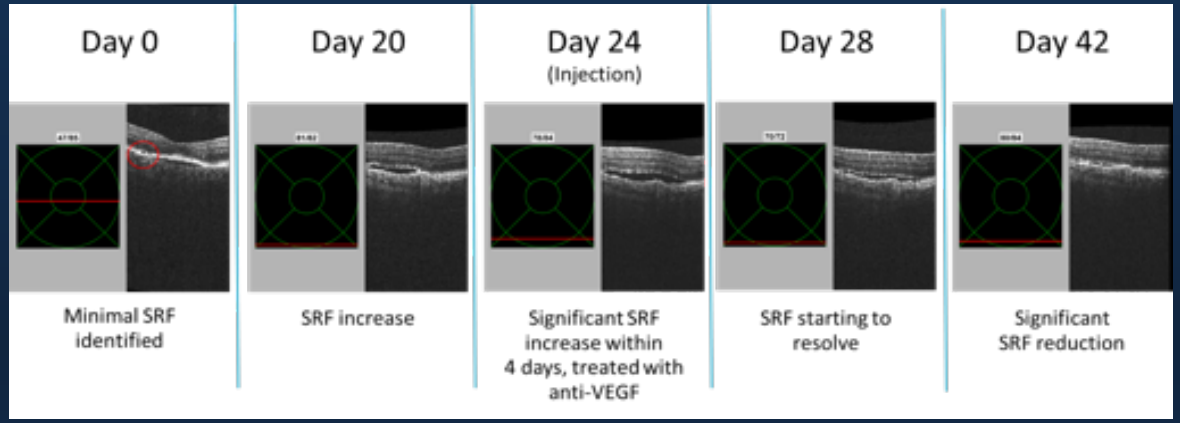
Image Quality Comparison

Notal OCT V3, none averaged image

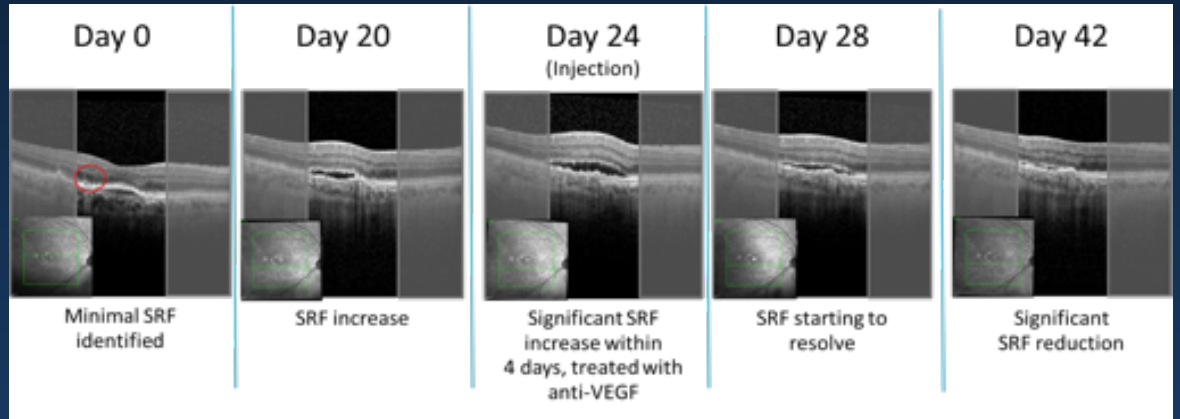


Spectralis, averaged image

Image Quality Comparison – Longitudinal Case



Notal OCT V3



Spectralis

Conclusions – Usability

- A clinical trial was conducted with the patient self-operated Notal OCT on an elderly AMD patient population
- 88% and 93% of eyes were successfully self-imaged by patients on the Notal OCT V2.5 and V3, respectively
- Patient feedback on device usability was consistently positive
- The device meets the requirement of successful patient self-imaging

Conclusions – Image Quality

- Positive and Negative Percent Agreement of fluid identification in at least one of three consecutive Notal OCT V3 self-images compared to commercial in office OCT was 97% and 95%, respectively
- The tight 34 µm spacing between B-scans supports the intended use of Notal OCT as a retinal fluid finder
- The Notal OCT meets the requirement to produce high quality images suitable for reliable identification of retinal fluid by human graders
- The low cost patient self-operated OCT device may assist in monitoring patients with wet-AMD at home

Thank you!

Abstract – to delete later

Purpose

To determine identification rates of retinal fluid of the Notal Vision Home Optical Coherence Tomography (OCT) device (NVHO) when used by people with age-related macular degeneration (AMD).

Methods

Prospective, cross-sectional study where patients underwent commercial OCT imaging followed by self-imaging with the NVHO in clinic setting. Outcomes included patients' ability to self-acquire analyzable OCT images with the NVHO and to compare those with commercial images.

Results

Analyzable images were acquired by the NVHO in 538/605 eyes (88.9%) of 309/335 subjects (92.2%). Higher rates of successful imaging were found in eyes with VA ≥ 20/320. Positive percent agreement/negative percent agreement for detecting the presence of subretinal and/or intraretinal fluid when reviewing for fluid in three repeated volume scans were 97%/95%, respectively for the NVHO.

Conclusions

Self-testing with the NVHO can produce high quality images suitable for fluid identification by human graders.

DISCUSSION

DISCUSSION

Results of these two studies with the NVHO system showed the requirements of acceptable image quality, low-cost supportive hardware with a self-imaging solution to allow retinal fluid identification through patient self-imaging can be met in a high number of eyes: 88% of eyes imaged with the V2.5 and 93% of eyes imaged with the V3 were considered successful images. Patients that could not image with any of the models were older and the ones that failed self-imaging had worse visual acuity. The images were successfully self-captured solely by patients moving their head and gaze in response to directional visual feedback; most clinic-based OCT systems entail the technician moving the imaging head while requiring the patient to hold their head steady.

Both versions of the NVHO were intuitive and easy to operate by an elderly patient population with impaired vision. The device ergonomics assisted the self-imaging process well. The NVHO showed a high PPA/NPA for identifying the presence (within the central 10° of the macula) of any fluid (subretinal and/or intraretinal) when compared to a commercial OCT. The tight 34 µm spacing between B-scans supports the intended use of NVHO as a retinal fluid finder.

The accessibility of the system in a home setting allows multiple volume scans to be obtained quickly, in a daily or close to daily frequency of self-imaging, which in turn may reduce the risk of missing retinal fluid. The study showed that for V3 the review of up to three volume scans increased the PPA of identification of any fluid from 89% to 97% and decreased the NPA of identification of fluid from 97% to 95%. Similar trends were observed for SRF and IRF alone.

The Manufacturer Signal quality Index (MSI) was validated against human graders and was consistent during repeat testing, which validated the system's automated imaging capabilities. The self-reported patients experience with device and tutorial were very positive and should support patient compliance with daily self-imaging.

The device's diagnostic performance generated few false-positives that would prompt unnecessary additional office visits and fewer false-negatives so that true worsening (as indicated by fluid accumulation detected by commercial OCT) was rarely missed by the device with approximately 1% of commercial OCT scans showing fluid exclusively outside the 10° field imaged by the NVHO. Thus, the NVHO device may be useful to monitor between visits for patients with nAMD, and also for patients with intermediate AMD to detect early conversion to nAMD before central VA is affected. The latter indication is particularly relevant for patients receiving intravitreal anti-VEGF injections that have dry AMD in the fellow eye deemed at high risk of conversion.

This study's strengths include comparison to the current clinical standard — commercial OCT — as well as the inclusion of subjects with impaired central acuity in the study eye. The NVHO V3 showed the same outcomes as the V2.5, thereby alleviating the typical concerns about using prototype devices in clinical studies.

Maloca et al. studied the safety and feasibility of a sparse OCT device prototype for patient-delivered retina home monitoring.[8] The device met patient ergonomic requirements but was limited in its imaging capabilities. A small number of B-scans was used to measure the retinal thickness. A quantitative side-by-side comparison of the accuracy to detect retinal fluid was not performed on the nAMD patient population in this study.

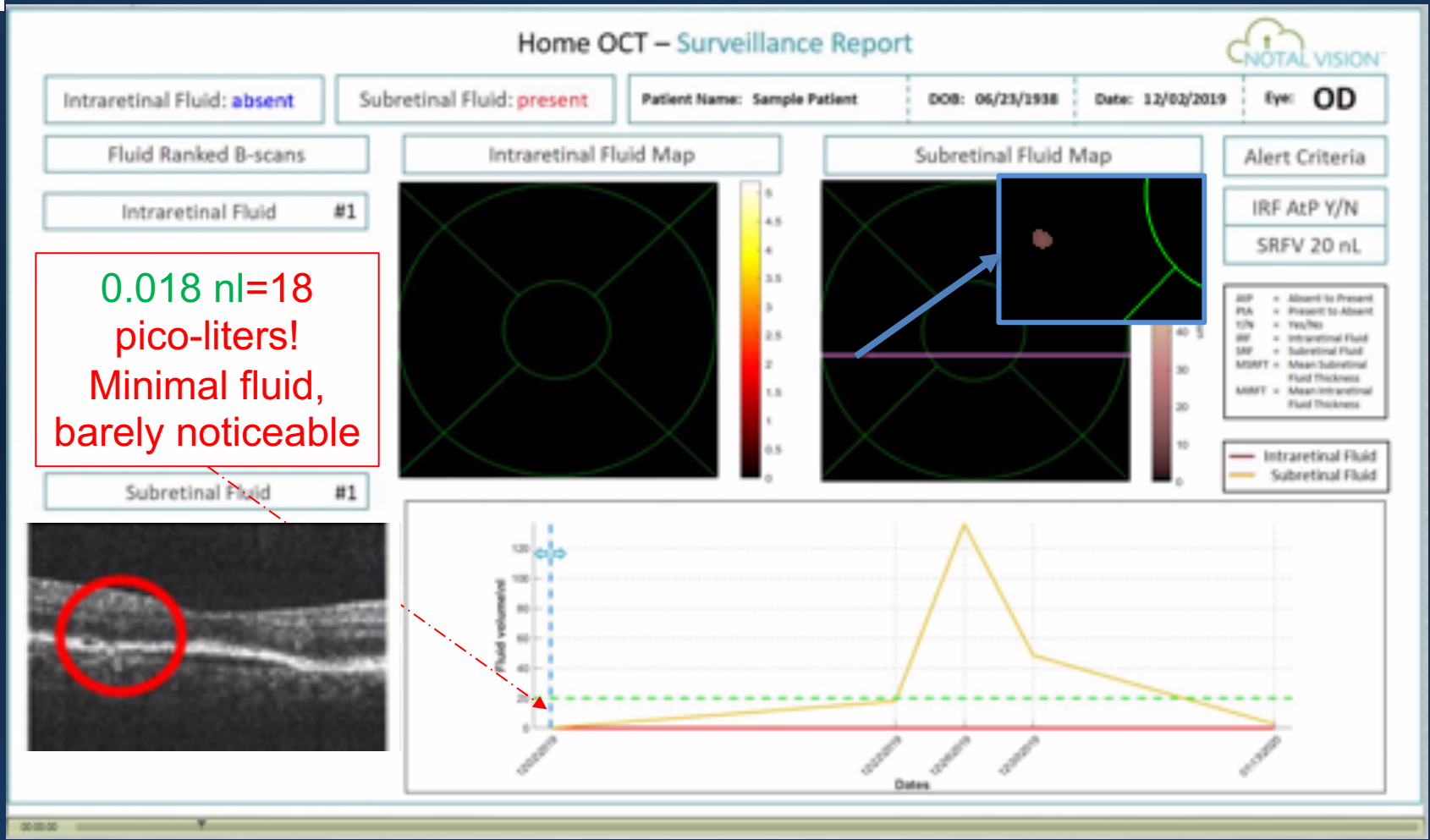
The studies were limited to several aspects of self-imaging enabling home OCT, and further studies will be required to evaluate the performance of a complete home OCT system.

In summary, the investigated patient self-operated SD-OCT systems meet several key design requirements for remote home monitoring of patients with nAMD. More than 90% of the enrolled subjects were able to obtain OCT images of their own disease-affected eyes, suggesting that this planned device may be able to complement standard-of-care clinical assessments and treatments.

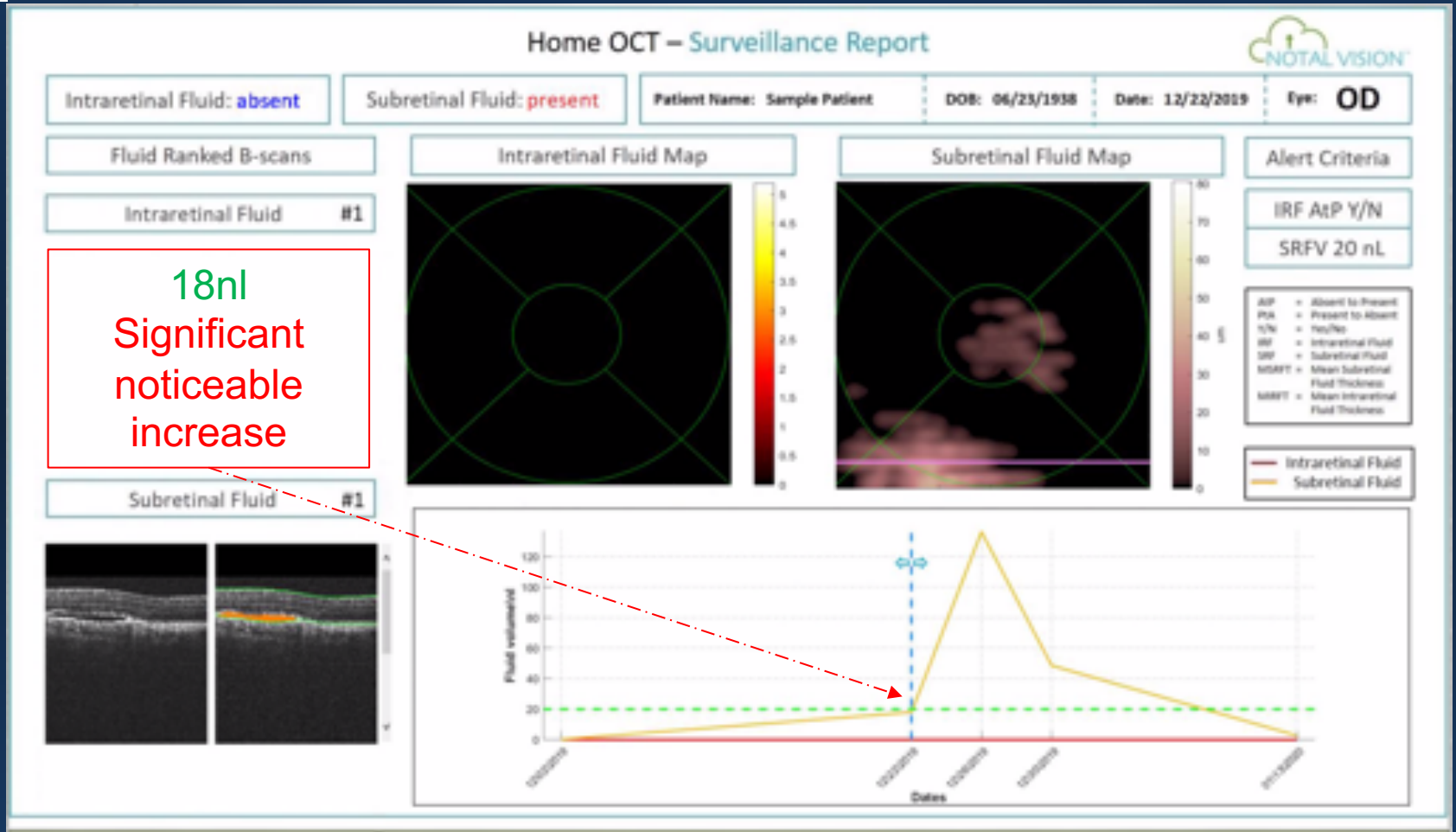
Case #1: Longitudinal monitoring of a patient undergoing anti-VEGF therapy

- 82 year-old male from the TLVMC study cohort
- OD - Neovascular AMD
- OS - Intermediate dry AMD

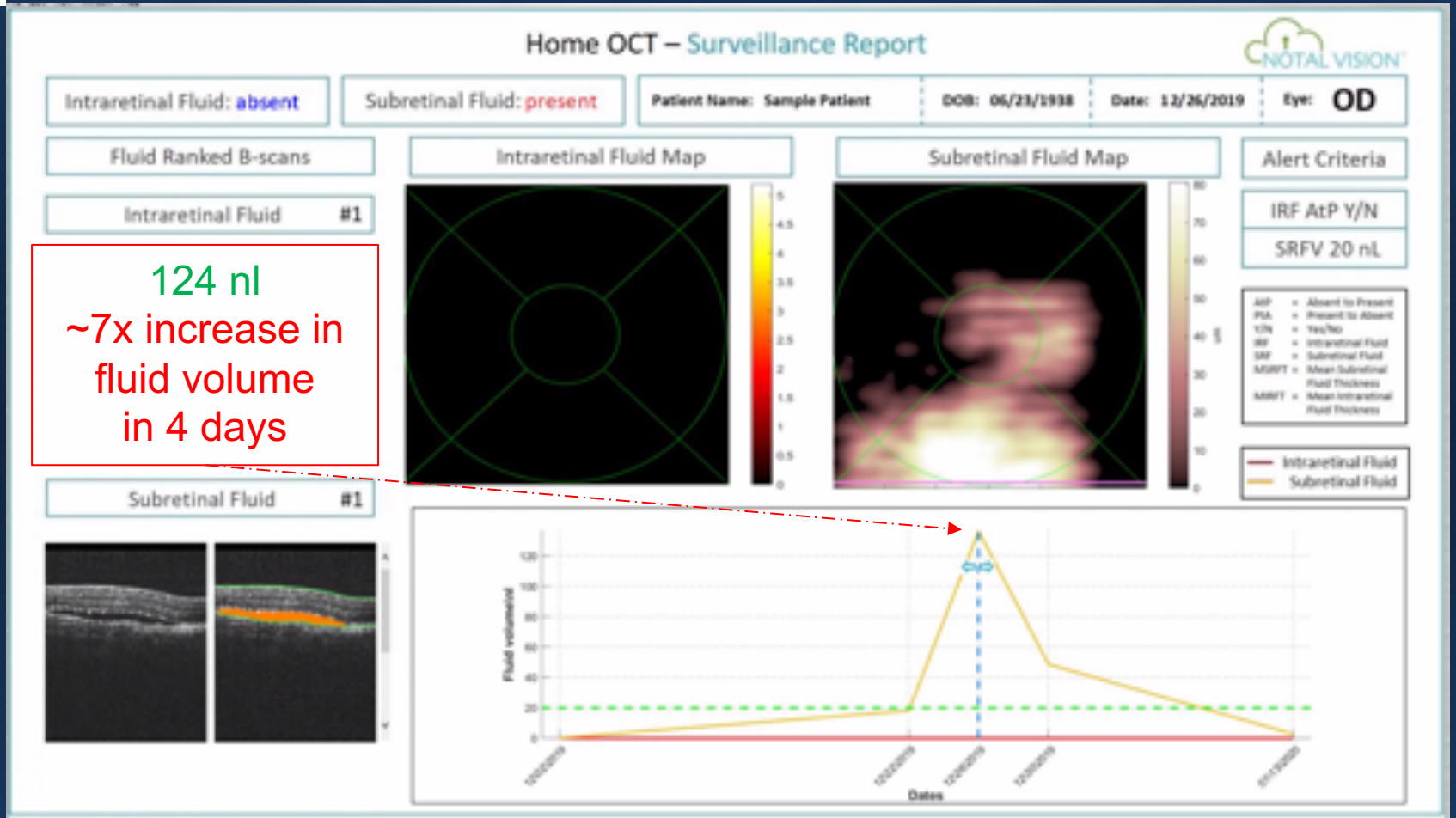
Day 0 - VA 20/25


Home OCT – Surveillance Report
NOTAL VISION
Intraretinal Fluid: absent
Subretinal Fluid: present
Patient Name: Sample Patient
DOB: 06/23/1938
Date: 12/02/2019
Eye: OD
Fluid Ranked B-scans
Intraretinal Fluid #1
Intraretinal Fluid Map
Subretinal Fluid Map
Alert Criteria
IRF AtP Y/N
SRFV 20 nL
0.018 nl=18 pico-liters! Minimal fluid, barely noticeable
Subretinal Fluid #1
Intraretinal Fluid
Subretinal Fluid
Fluid volume(nl)
Dates

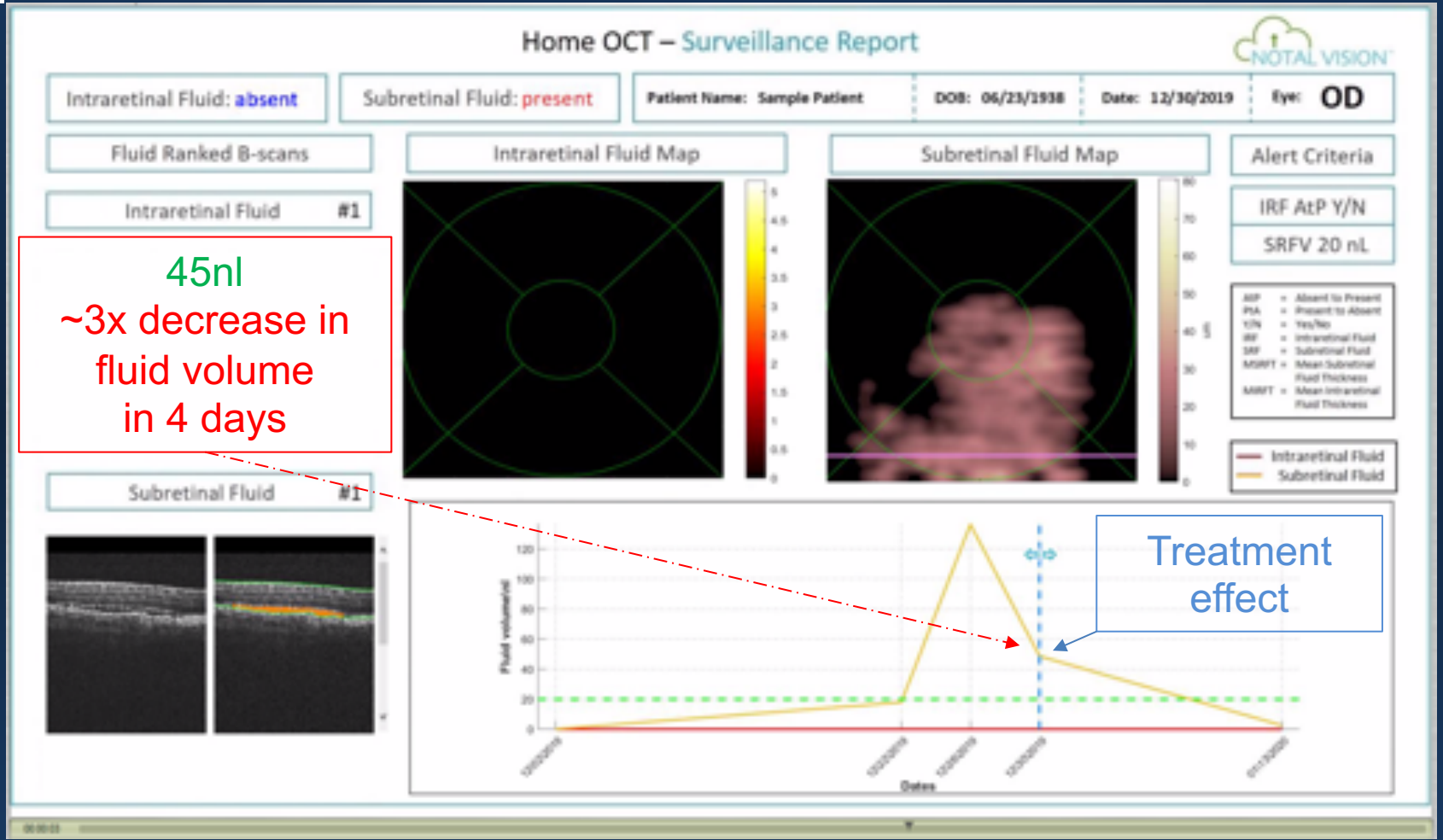
Day 20 – VA 20/21



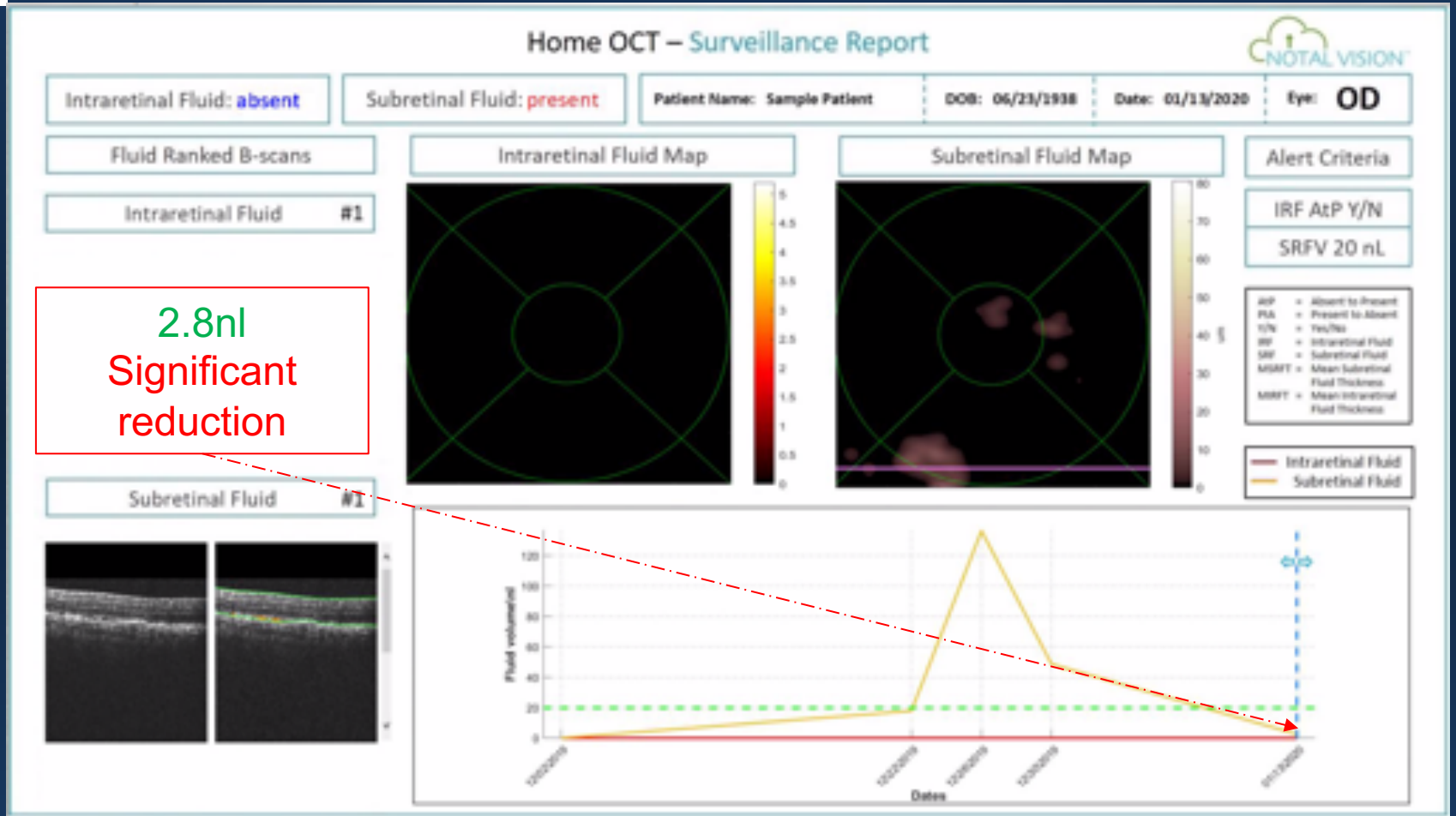
Day 24 (Aflibercept injection) – VA 20/28



Day 28 – VA 20/28



Day 42 – VA 20/25

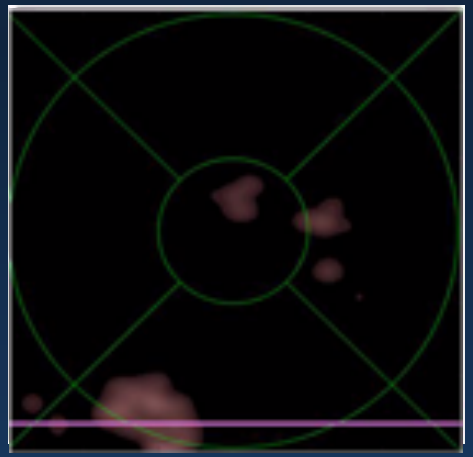


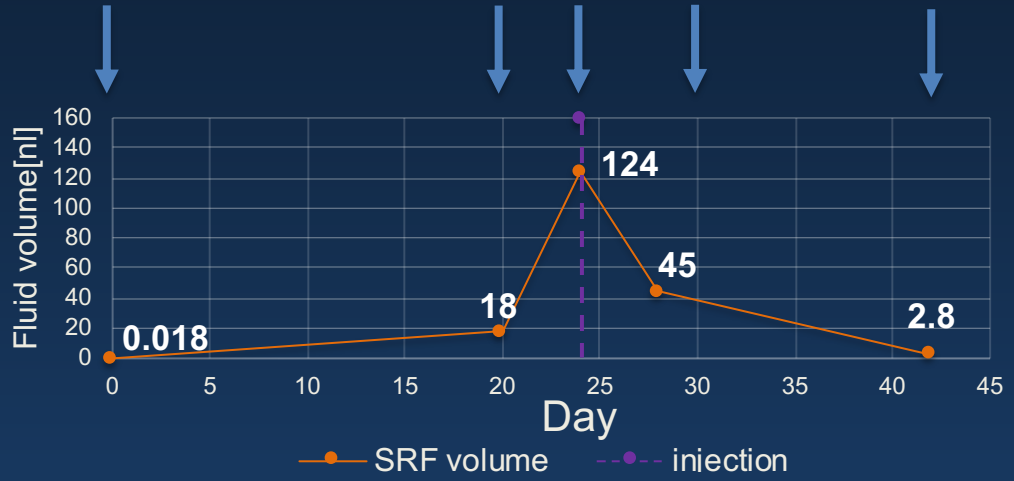
Home OCT testing gives new insights in retinal fluid dynamics

New markers of disease activity

- **Patterns of fluid distribution**
- **Fluid volumes**

SRF Thickness Map





Take home message
Potential impact of Home OCT monitoring

- Information generated by tele-connected OCT in our patients' homes has the potential to support current retinal disease management and any future evolution which may occur in:
  - Monitoring patterns
  - Drug selection and dosing
  - Patient outcomes

Thank you