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HIGHLIGHTS

Published by
MEDIA MICE

Matt Young
CEO & Publisher
Hannah Nguyen
COO & CFO
Robert Anderson
Media Director
Gloria D. Gamat
Chief Editor
Brooke Herron
Editor
Maripet Ledesma Poso
Editor

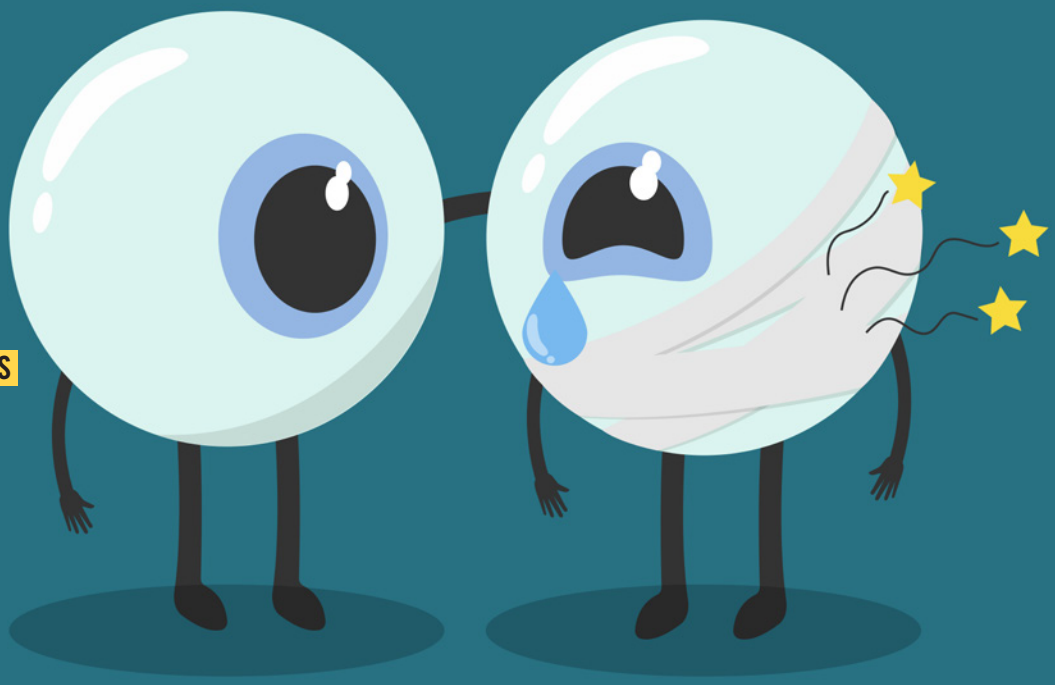
Ruchi Mahajan Ranga
Brandon Winkeler
International Business Development

Writers
Andrew Sweeney
Elisa DeMartino
Hazlin Hassan
Olawale Salami
Nick Eustice
Sam McCommon
Tan Sher Lynn

Maricel Salvador
Graphic Designer

Media MICE Pte. Ltd.
6001 Beach Road, #19-06
Golden Mile Tower, Singapore 199589
Tel. Nos.: +65 8186 7677 | +1 302 261 5379
Email: enquiry@mediamice.com
mediaMICE.com

piemagazine.org
cakemagazine.org
cookiemagazine.org



ASRS 2021 Update

What's new in the specialized world of ocular oncology?

by Brooke Herron

Although ocular tumors are relatively rare compared to conditions like cataract or diabetic retinopathy, these uncommon cancers deserve their share of the spotlight, too. Thus, at the 39th American Society of Retina Specialists (ASRS 2021) Scientific Meeting, experts shared some of the latest developments in this specialized field during the Ocular Oncology Symposium.

A novel, investigational drug

First up was Dr. Prithvi Mruthyunjaya who shared results from "A Phase 2 Safety and Efficacy Trial of AU-011, a Virus-Like Drug Conjugate, with Dose Escalation and Randomized Masked Expansion in Uveal Melanoma".

"AU-011 is a potential first in cancer molecule used to treat tumors and preserve vision," began Dr. Mruthyunjaya. "These viral-like drug conjugates or VDCs are essentially inactivated human papillomaviruses."

VDCs are activated with an ophthalmic laser generating singlet oxygen that disrupts the tumor

Cont. on Page 3 >>

Patient self-operated Notal Home OCT (Notal Vision Inc.)

Something to Smile About

Home OCT takes a step forward with results from first U.S. longitudinal study

by Brooke Herron

We know that regular monitoring of patients with neovascular age-related macular degeneration (nAMD) is critical to preventing disease progression. However, this results in frequent office visits for OCT scans and treatment, which can be burdensome for patients, caregivers, and physicians, alike.

An additional obstacle for these elderly patients is the ongoing COVID-19 pandemic, as many are not overly keen to attend regular in-person office visits for fear of contracting the virus. Therefore, eyes (pun intended) are turning toward home monitoring.

"We know that the majority of patients with nAMD need a caregiver to go to the doctor's office which sometimes limits their ability to see the doctor and receive treatment," shared Dr. Kester Nahen, Ph.D., CEO of Notal Vision, Inc. "By monitoring the patients at home and seeing the doctor when they need treatment, that lessens the burden on the patient — which increases the willingness of patients to stay on therapy longer and thus, maintain vision."

And, fortunately, there is a solution on the way — thanks to Notal Vision (Manassas, VA) and its investigational Home OCT system, which provides patient-initiated retinal OCT scans. This user-friendly device allows for daily disease monitoring to continue from the comfort of patients' homes and complements the existing standard of care in treatments, as well. Although this device is not yet cleared by the FDA, it's well on its way, thanks to continued study and positive results and outcomes.

Indeed, data from the first U.S.-based Home OCT feasibility study, Prospective Longitudinal Study: Fluid Quantification From Daily Self-imaging With Home OCT in Neovascular Age-Related Macular Degeneration, were presented by Jeffrey S. Heier, MD, from Ophthalmic Consultants of Boston, Massachusetts, USA, to an engaged audience at the American Society of Retina Specialists (ASRS 2021) Scientific Meeting.

The study says...

The study was conducted by Dr. Heier, along with co-investigator Nancy Holekamp, MD, from Pepose Vision Institute, St. Louis, Missouri, USA, with the aim of evaluating patients' ability to perform sequential, daily self-imaging of their eyes. The investigators also looked into the patients' ability to set up the device, the telemedicine infrastructure for secure and automated data uploading,

and the deep learning algorithm (the proprietary Notal OCT Analyzer, NOATM) for fluid quantification. Dr. Heier and Dr. Holekamp also observed disease dynamics and treatment responses.

The three-month study took place at the two investigators' practices and included 29 eyes from 15 nAMD patients with a mean visual acuity (VA) of 20/40 (with a range of 20/20 to 20/200). Twenty-three eyes had been diagnosed with nAMD and six with dry AMD, with one eye converting to nAMD during the study. The main outcome measures were the daily self-imaging completion rate, duration of the self-imaging process, image quality, agreement between automated and human grading of retinal fluid, and temporal dynamics of intra- and subretinal fluid volume.

"Over 2,300 images were evaluated: 96% of all images were able to be completed, the mean duration for self-imaging was 40 seconds, and on average patients performed 5.7 scans per week," shared Dr. Heier. During the study, the median self-imaging time decreased from 45.4 to 38.0 seconds, showing progressing patient proficiency in self-operation of the device.

During the study, patients' weekly scan frequency remained consistent over the three-month study, and subjects who did not self-image for two consecutive days received a compliance reminder call from the Notal Vision Monitoring Center, the future provider of the Home OCT monitoring service.

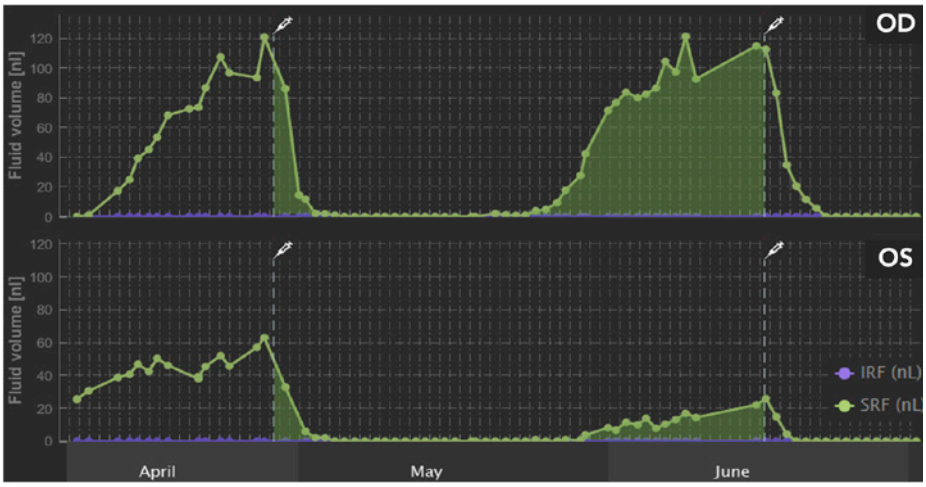
"The overall [subjective] patient experience was excellent, with a grade of strongly agree or agree on all parameters," he continued.

In the image quality assessment, readers determined that an image quality index of 2 or greater was sufficient to be able to grade these images, and 97% of all scans had an index of 2 or greater, said Dr. Heier. Further, 93% of scans (n=2,208) met the criteria for the NOA AI algorithm to perform fluid quantification.

Both Dr. Heier and Dr. Holekamp reviewed the images weekly and compared them against the artificial intelligence (AI) interpretation. There was an 83% agreement between AI-based and investigator grading for presence or absence of fluid; there was a 17% disagreement, but the majority of these were where the investigator determined subtle, trace, or no fluid, said Dr. Heier. Subretinal fluid volume was measured in nano-liters, which allowed for very accurate tracking of disease activity over time.

He continued that using subretinal fluid volume trajectories gives insight into disease dynamics and treatment response — highlighting heterogeneity across the study population. "This gives us the opportunity to look at numerous parameters for fluid volume dynamics," said Dr. Heier. These include fluid volume at the time of treatment, time to 50% reduction in fluid volume after treatment; weekly fluid decrease after treatment; minimum fluid volume between treatments; and area under the fluid volume curve between treatments.

Overall, Dr. Heier shared that successful self set-up and self-imaging with Home OCT was achieved with a high level of adherence and a positive patient experience. "Up to daily self-imaging provided images of satisfactory quality for human grading and AI-based analysis and gave an analysis of trajectories of fluid volume over time," he continued "Parametric description of fluid volume trajectories may support disease and treatment response classification — it will especially do this as we look at the development of sustained drug delivery and other extended durability treatments."



AI-based analysis of daily Home OCT provides insights in temporal subretinal fluid (SRF) volume dynamics between office visits and illustrates fluid exposure to the retina in eyes managed with treat and extend protocol. (Notal Vision Inc.)

Added benefits for patients and physicians

In addition to reducing treatment burden, the Home OCT may also shed light on what exactly happens between office visits. "We know that treatment outcomes in the real world do not match the results of randomized controlled trials … and that's mainly because of undertreatment," explained Dr. Nahen.

The Home OCT could explain why some of this is happening — as well as provide crucial data to doctors. "We're getting great insight into what happens between office visits — we can truly say whether the patient responded to therapy, how quickly they responded, when exactly the fluid reoccurs in the retina, and how fast it recurred. So, we get a much better description of disease activity and treatment response. These new insights will help to better personalize the therapy," said Dr. Nahen.

Another perk for physicians who refer their patients to the monitoring center lies in reimbursement, which they will be able to bill for the review of remote OCT data and images every 30 days.

A final key point raised by Dr. Nahen was on the relationship between AI and physicians.

"The use of new device technology and AI is still a physician-led process — it doesn't take away responsibility or tasks from the physician, it actually enables them to manage the large amounts of data that such a remote OCT technology produces. Thus, AI is the friend to the retinal specialist and it does not replace humans," he concluded.