18 Truths

Optovue, Inc.

About Optovue

The founders and development team of Optovue have been developing devices based on OCT technology since 1993. Five OCT Time-Domain based systems later (and a change in companies), they developed the RTVue® Spectral-Domain OCT system. The first FDA cleared advanced OCT for ophthalmology launched at the Academy of Ophthalmology in October of 2006. The existence of the company was a closely “guarded” secret from the eye care market until one week before the start of the Academy event in 2006.

The first Optovue OCT symposium attracted more than 350 clinicians to hear doctors Yasuo Tano, Jay Duker, Joel Schuman and David Huang speak from the podium about the device they had used in secret for over a year. At that inaugural congress for Optovue, over $1 million worth of RTVue units were sold in four days to attendees who had no prior knowledge of the company’s existence.

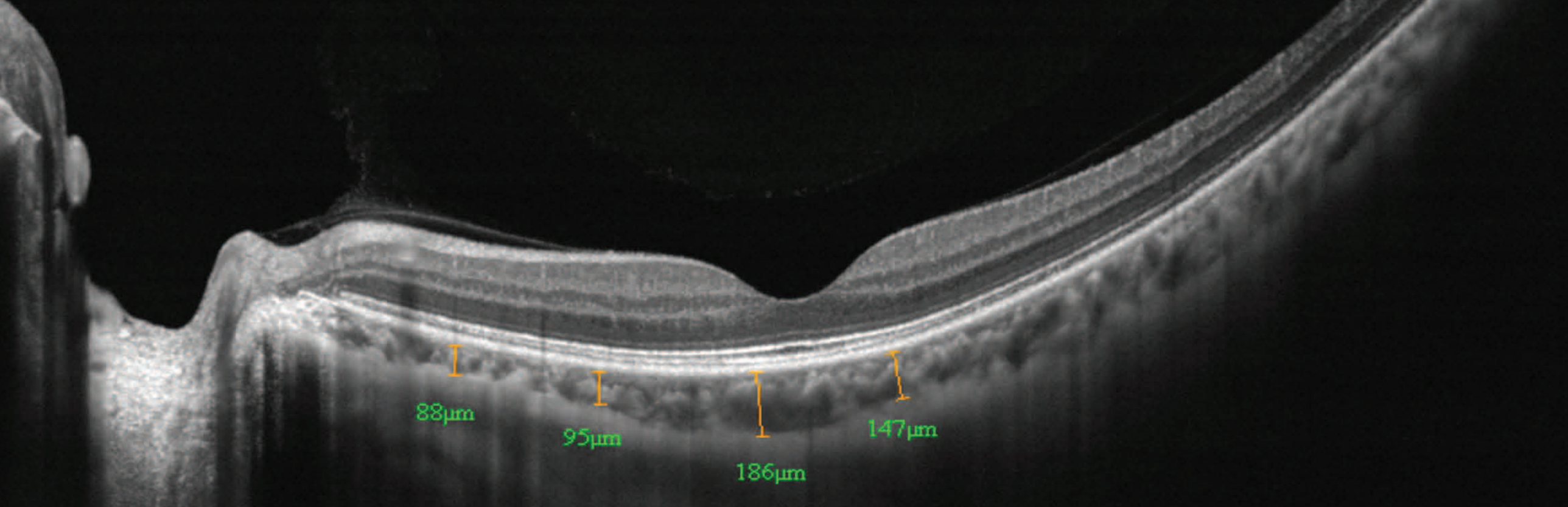
Having an OCT product to sell and understanding OCT technology well enough to know what its capabilities are do not necessarily go hand-in-hand. Optovue is one of the few companies whose principle developers and advanced development team are all multiple patent holders on the technology.

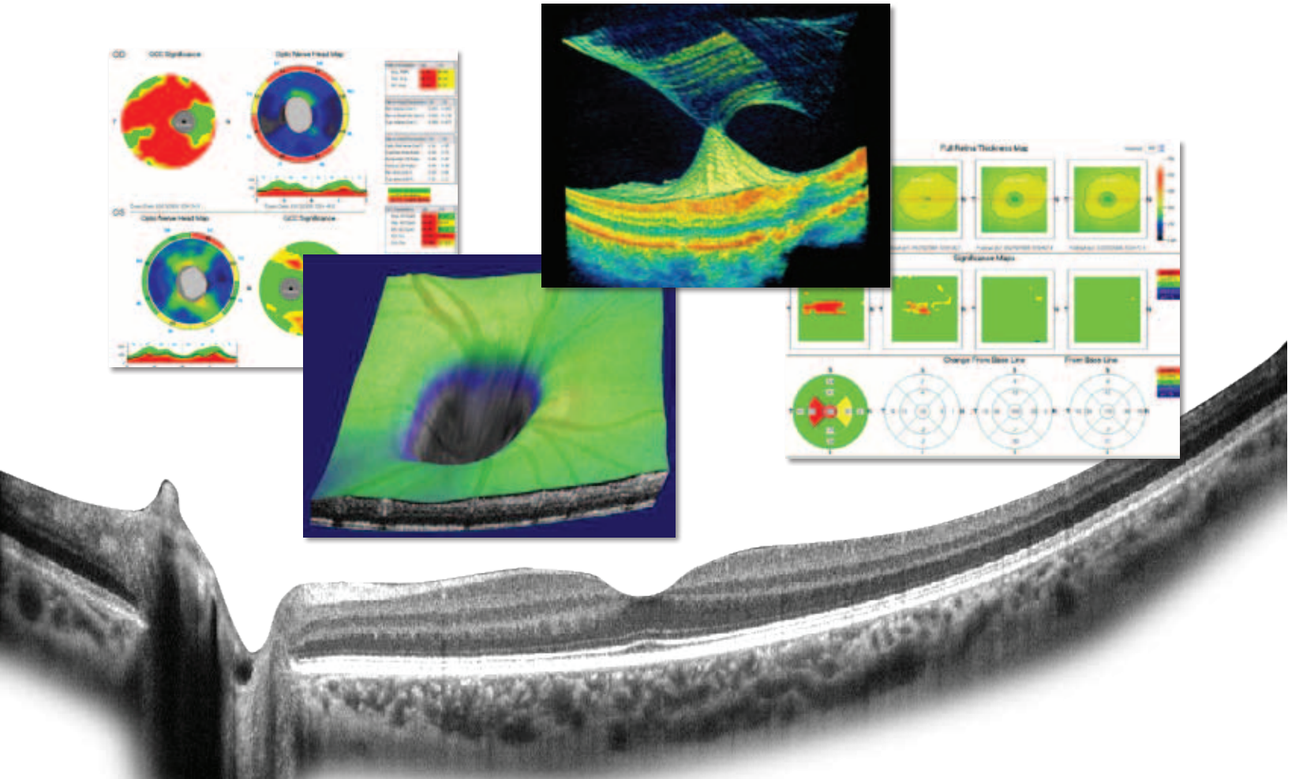
SD-OCT

First FDA Cleared SD-OCT System.

Launched at the 2006 Academy of Ophthalmology in Las Vegas, the RTVue SD-OCT that was developed in secret by the company founders made its debut and caused a sensation for four days. Over 100 distributors from around the world were lobbying to get the distribution rights for their country.

The young company was off to a great start, but the founders knew that to compete in the market over time meant staying ahead of the curve and pushing the technology into places that it had not yet gone – but needed to. The development team members at Optovue are among the most experienced people in OCT product development. This experience and understanding of the technology allows Optovue to be innovative, incorporating new ideas and functionality into its OCT systems more quickly than the competition.

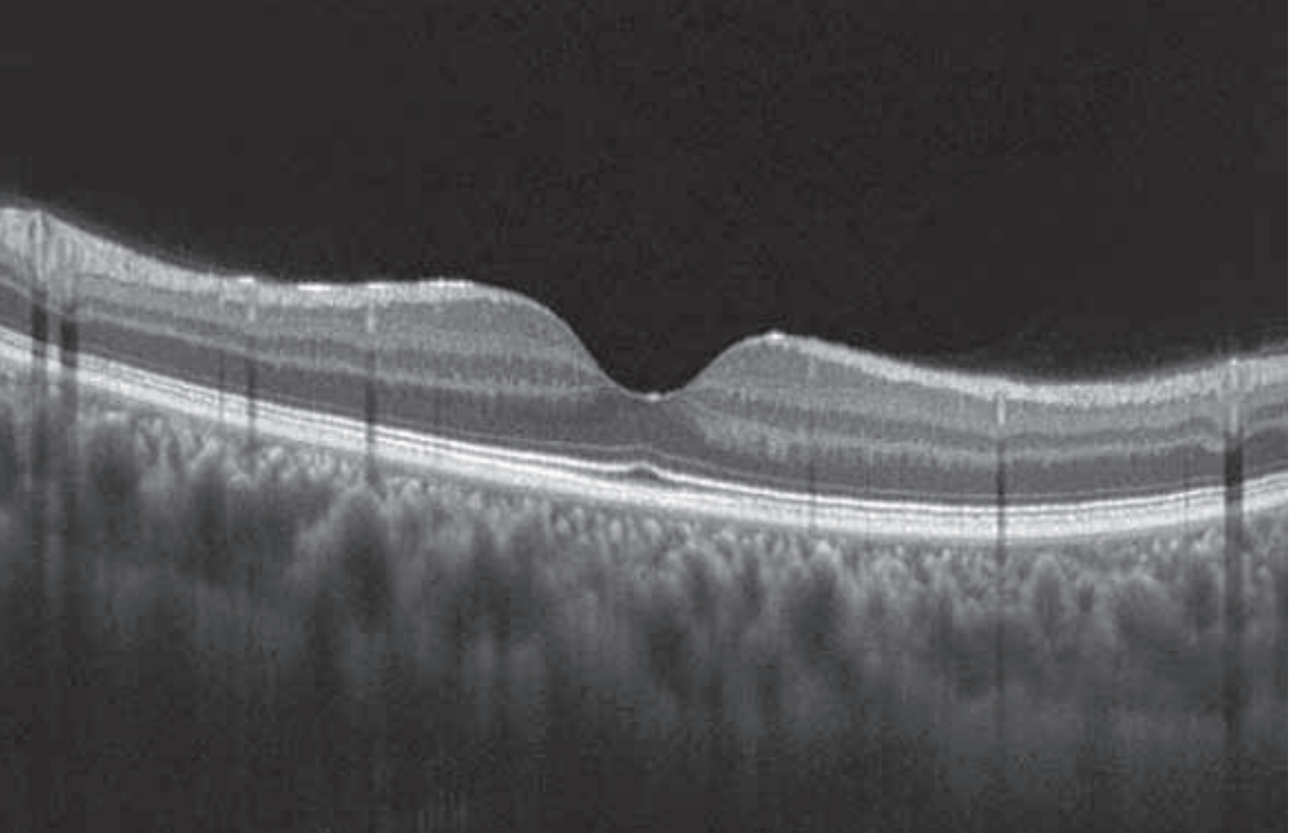

88µm
95µm
186µm
147µm



IMAGING AND ANALYSIS

First SD-OCT system with both retina and glaucoma imaging and analysis.

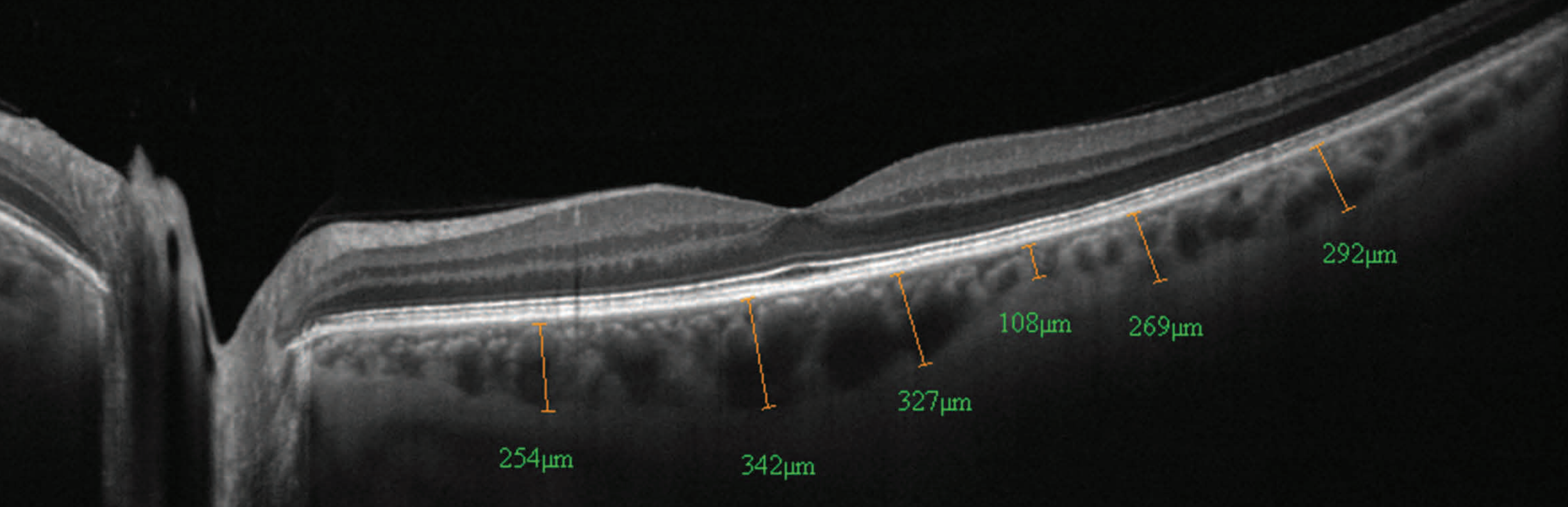
The RTVue SD-OCT system was launched in 2006 with fast retina mapping, 3D retina and optic disc scanning, raster and radial B-scanning patterns, optic nerve head analysis, RNFL mapping with 3.45mm TSNIT results and Ganglion Cell Complex mapping (GCC®).



NOISE CORRECTION

First SD-OCT system to use Noise Correction (also called “speckle reduction” or “averaging”).

Optovue was the first SD-OCT to employ noise reduction, using a unique noise removal technique during the scanning and averaging of B-scans after the acquisition of scans. The RTVue B-scan results presented better retinal detail and scanned deeper in the retina than any system at that time.


254µm
342µm
327µm
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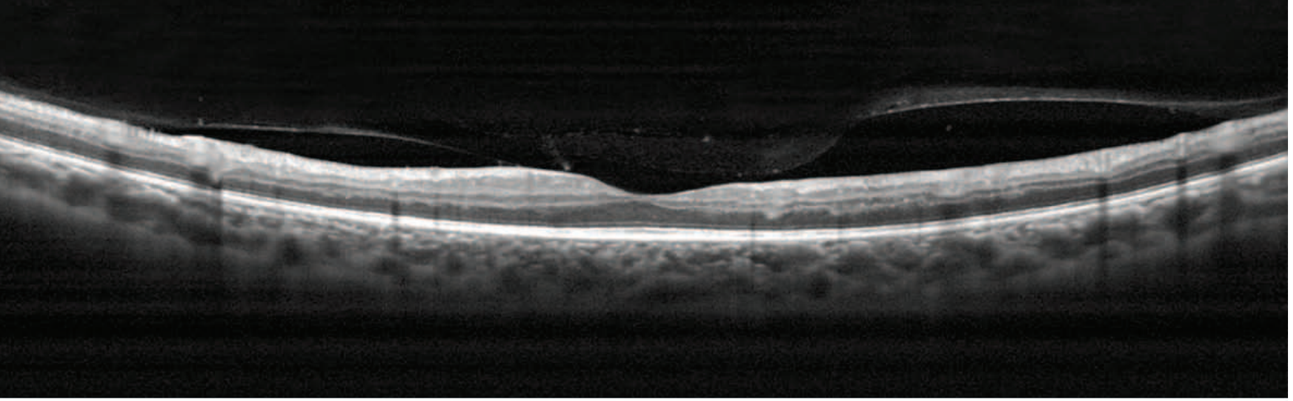
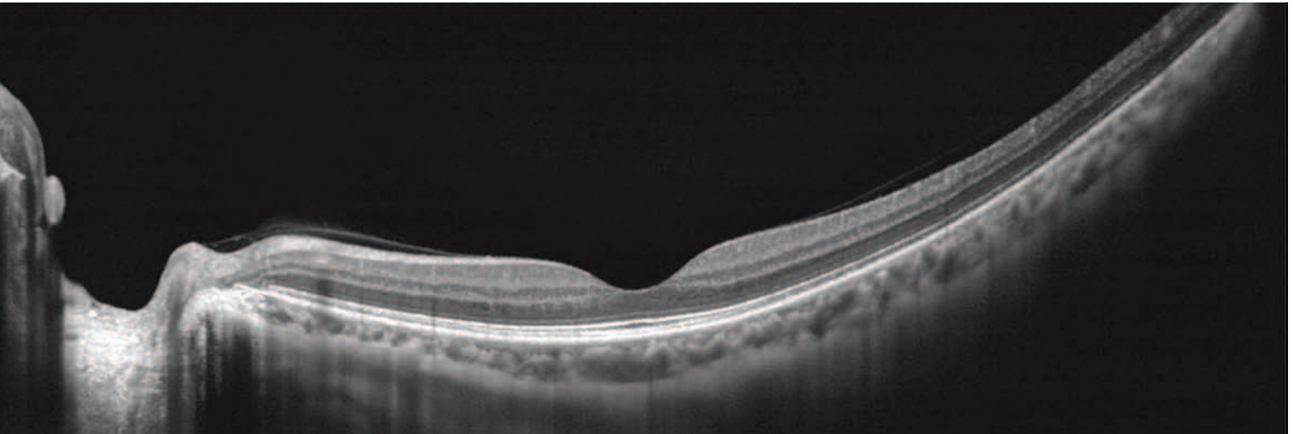
269µm
292µm



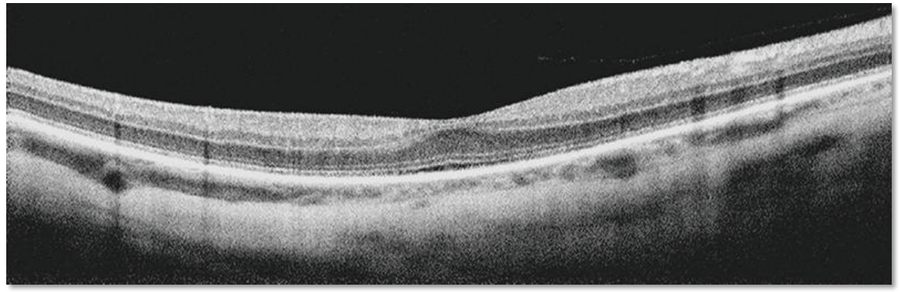


MODE SWITCHING

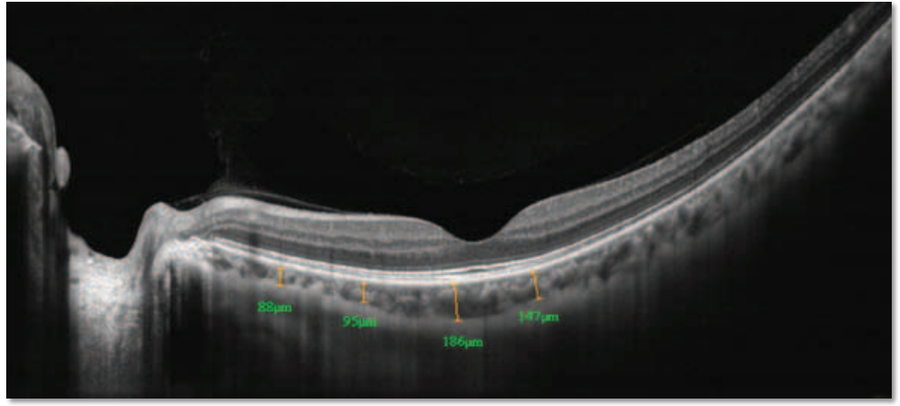
First mode switching SD-OCT to provide user selectable focusing of the scan signal strength in either the vitreoretina or choroid layers of the eye.

When launched in 2006 the RTVue SD-OCT included a mode switching option, allowing the user to move the area of highest signal strength in the scan to either the vitreoretina layers or the deeper choroid layers of the eye. Only later did competitive systems add this type of feature and eliminate the need to scan “upside down” to get better visibility of the choroid layers.

2007



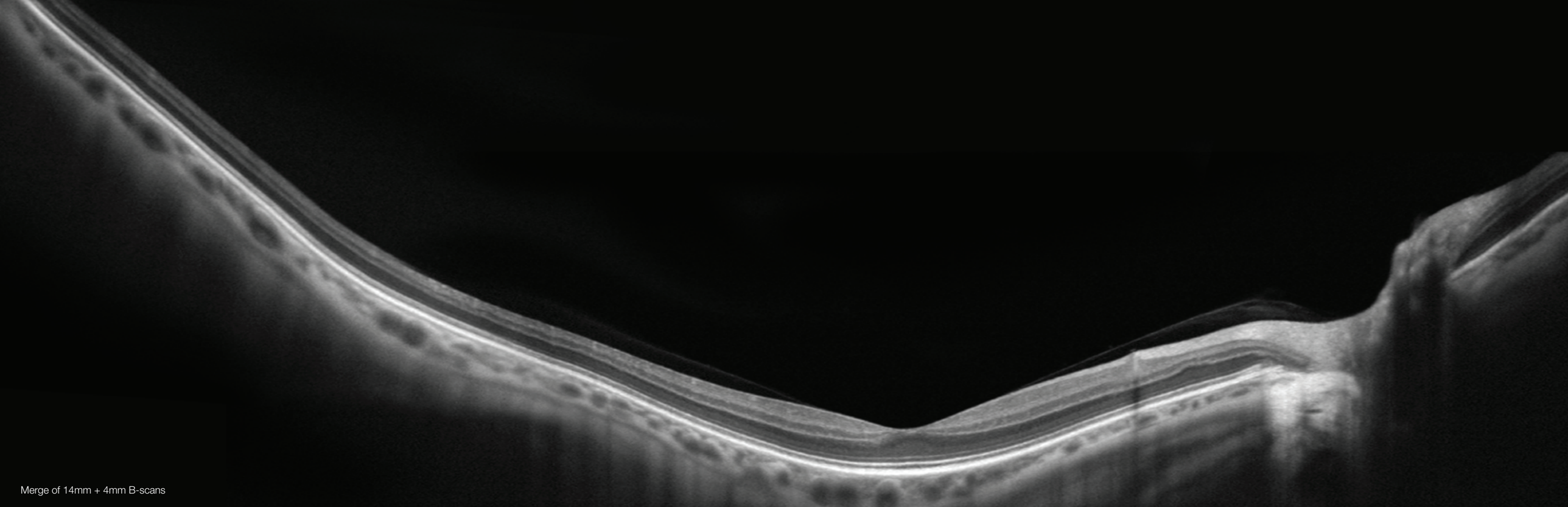
2011



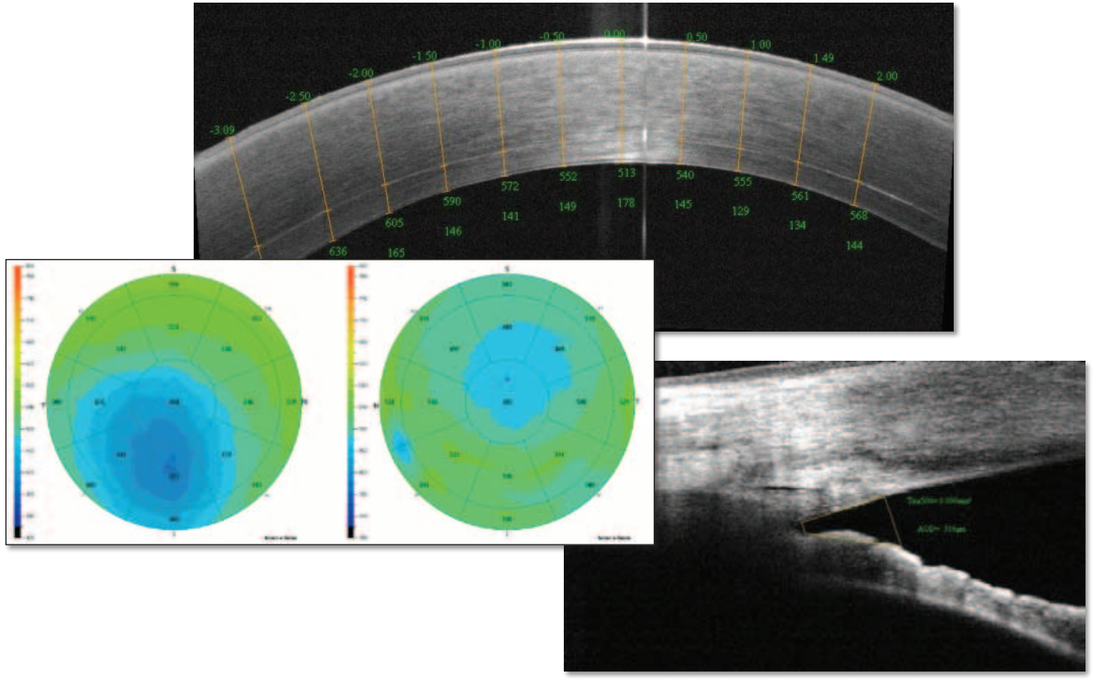
CHOROID IMAGING

First SD-OCT with choroid imaging and measurement.

Since 2006, the RTVue SD-OCT has imaged the choroid and provided clinicians with a method to measure the thickness of the choroid at user selected points. The Optovue Noise Reduction (see TRUTH #3) offered detail in the choroid never seen before at that time.



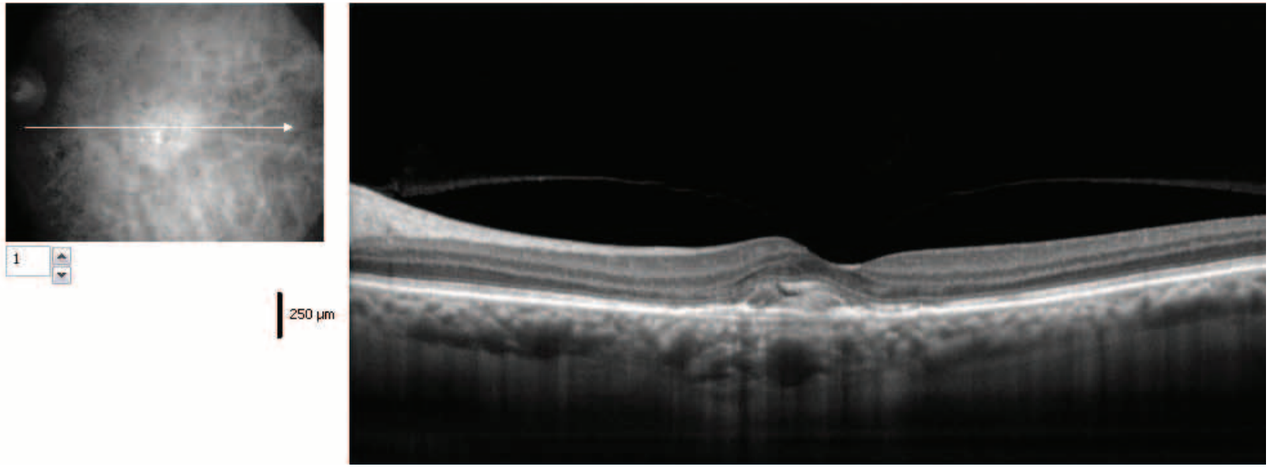
Merge of 14mm + 4mm B-scans

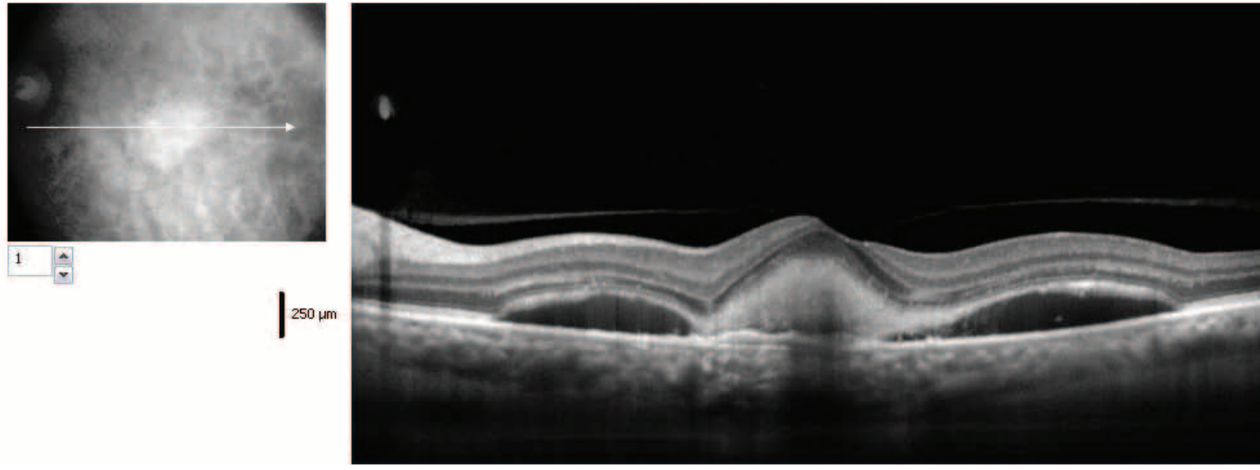


ANTERIOR SEGMENT IMAGING

First SD-OCT system to offer posterior and anterior segment imaging and measurement in one device.

In 2007 Optovue introduced the CAM (Cornea-Anterior Module) option for the RTVue, providing for the first time, true imaging and analysis of the anterior chamber by a posterior OCT device. This option added high resolution and high magnification scanning and measurement of the cornea, angle, anterior lens, ora serrata, 6mm diameter pachymetry map and 3D scanning of anterior structures.


1
250 µm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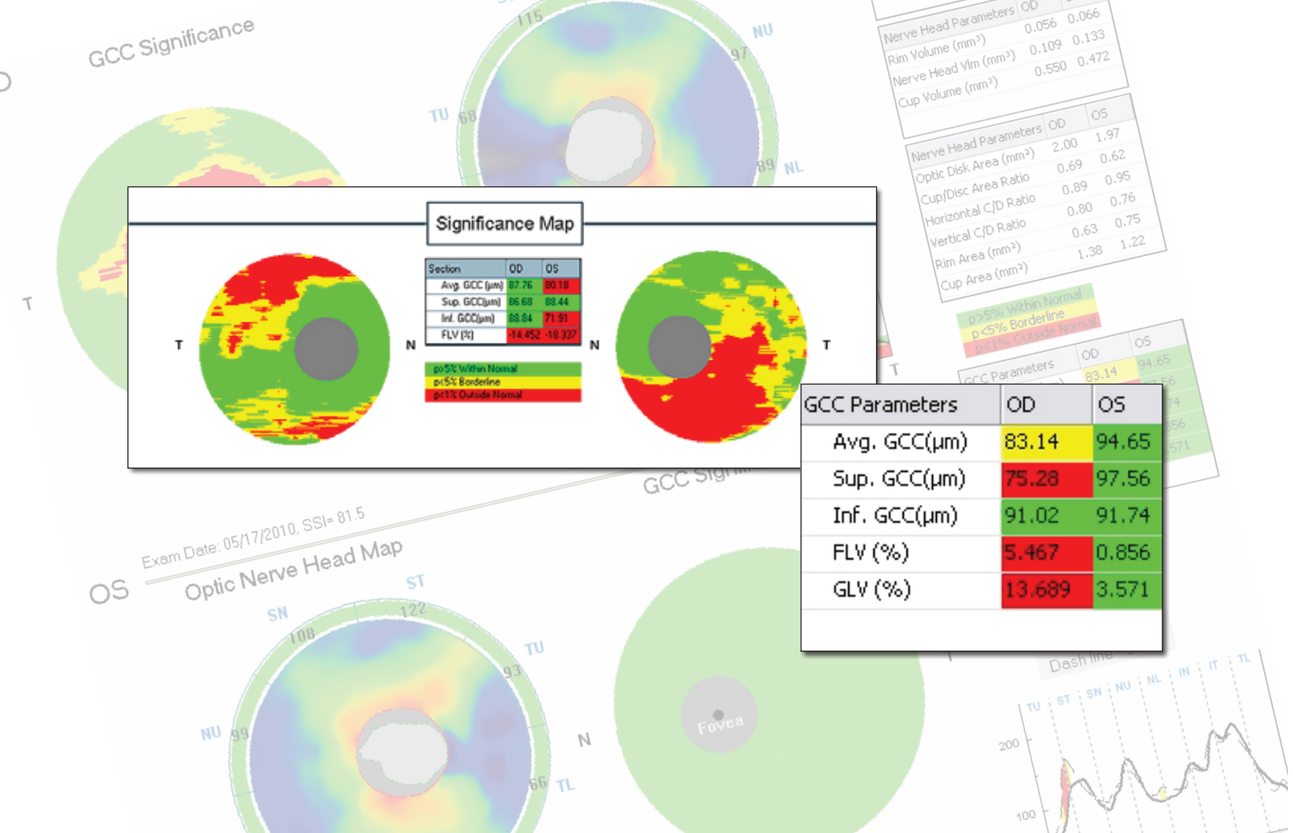
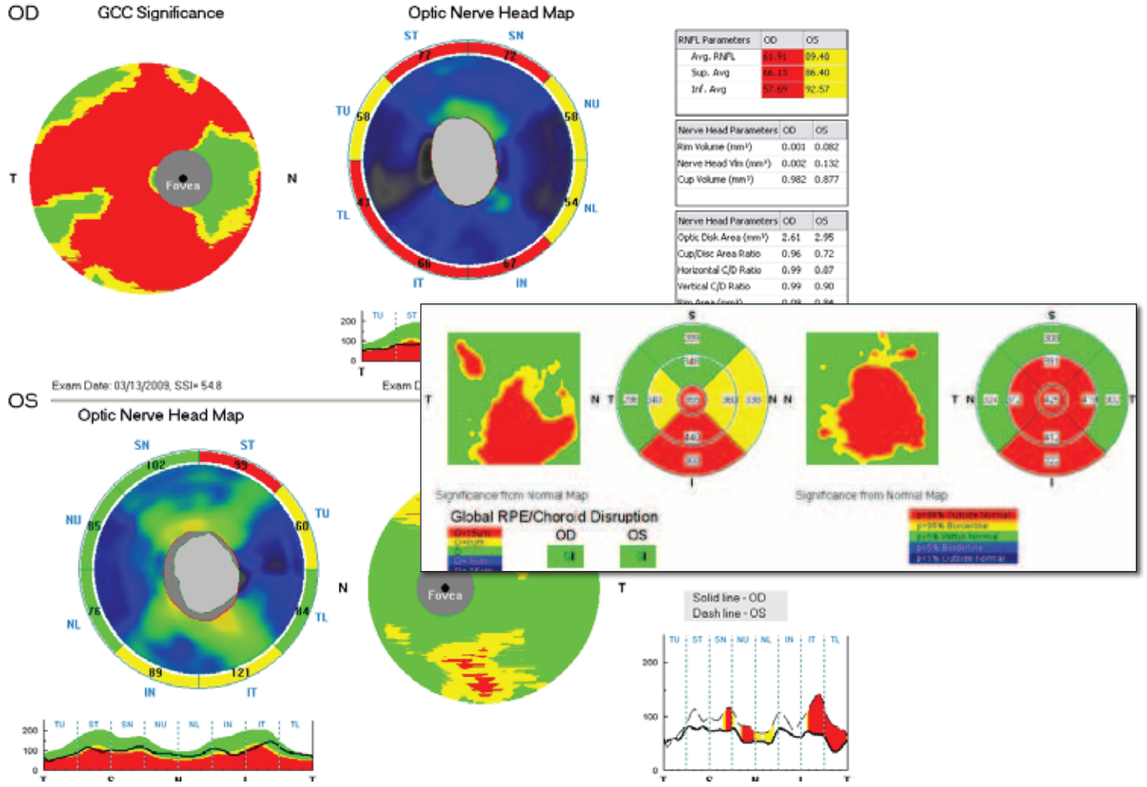


GCC® WITH FLV AND GLV

First SD-OCT system with GCC® (Ganglion Cell Complex) measurement for supporting glaucoma analysis with Focal Loss Volume and Global Loss Volume analysis.

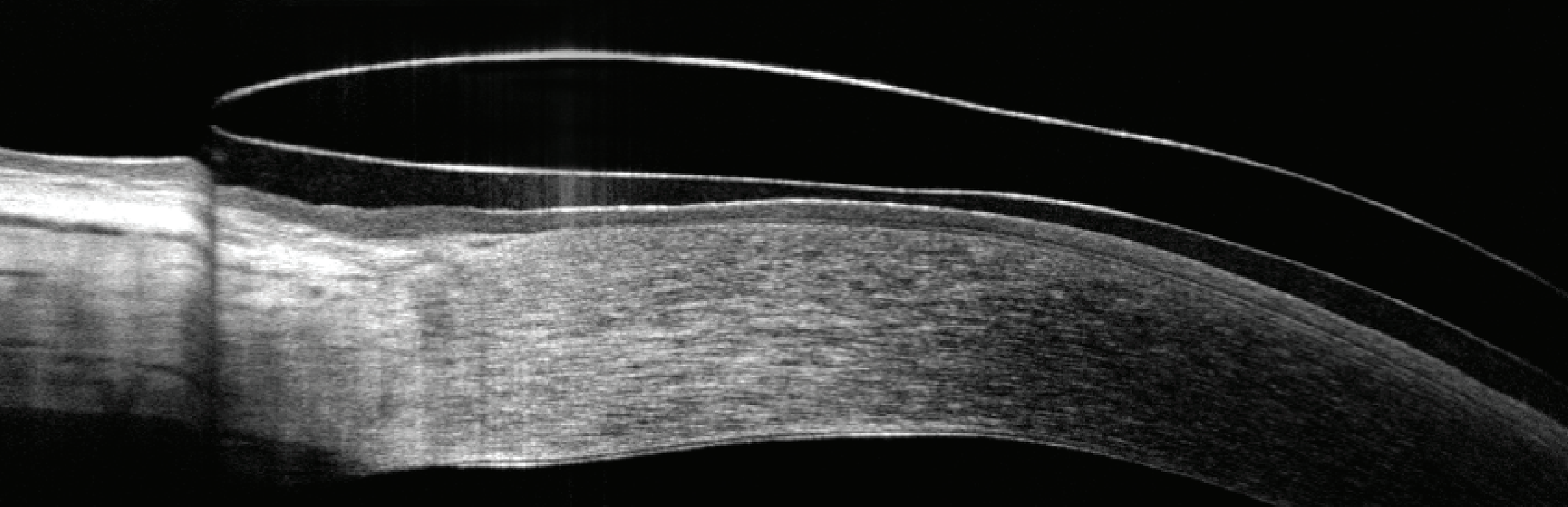
Measuring just the three layers that make up the ganglion cell complex was not a new idea, however until the RTVue was introduced, no device had effectively isolated the three layers, ganglion cells, axons and dendrites and mapped them to follow the changes in the thickness of the anatomy that carries the signals to the visual cortex of the brain. Shown by dozens of ARVO abstracts to often precede measureable changes in the paripapillary RNFL, evaluation of the GCC by the RTVue has moved the potential detection of glaucomatous structural changes earlier in the Glaucoma Continuum.

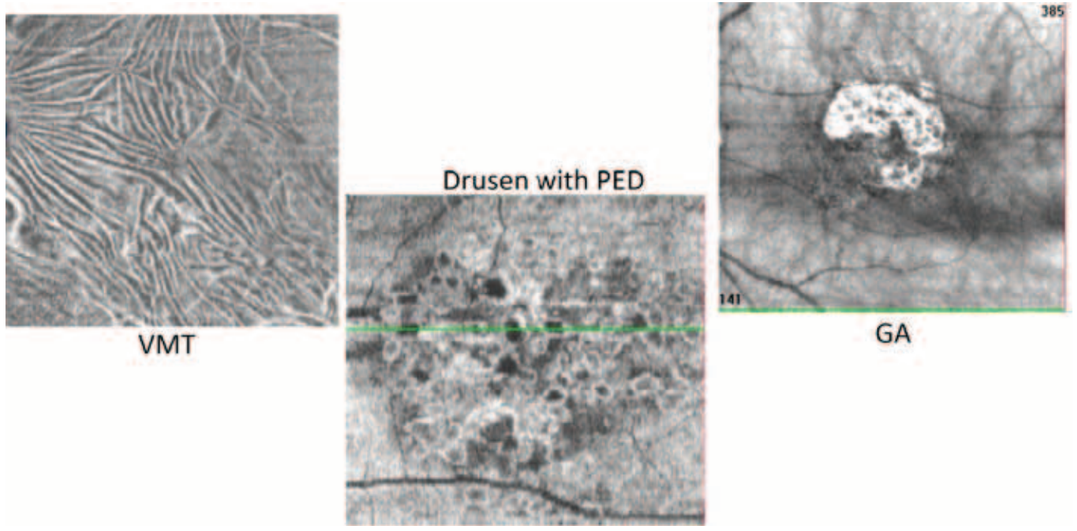


NORMATIVE DATABASE

First SD-OCT with a Normative Database for glaucoma and retina reference.

At the beginning of 2008, Optovue released the first Normative Database (NDB) for a spectral-domain OCT, with normative reference ranges used for both changes in the RNFL, Optic disk and GCC as well as a normative reference for central retina thickness to measure edema and ischemic changes.

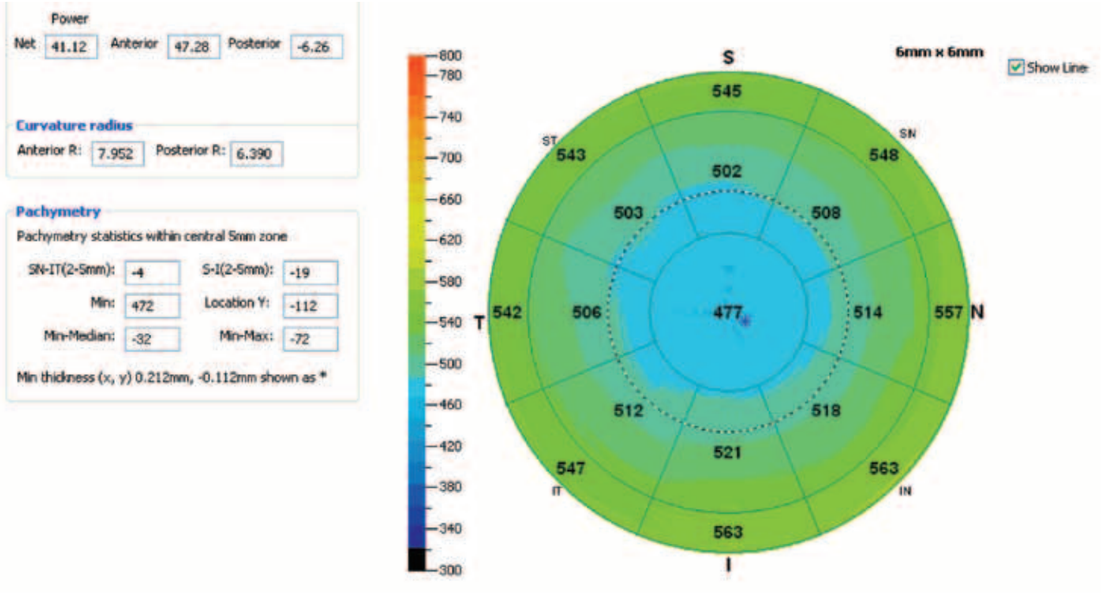




EN FACE ANALYSIS OF 3D DATA SET

First SD-OCT available with en face analysis of 3D data set.

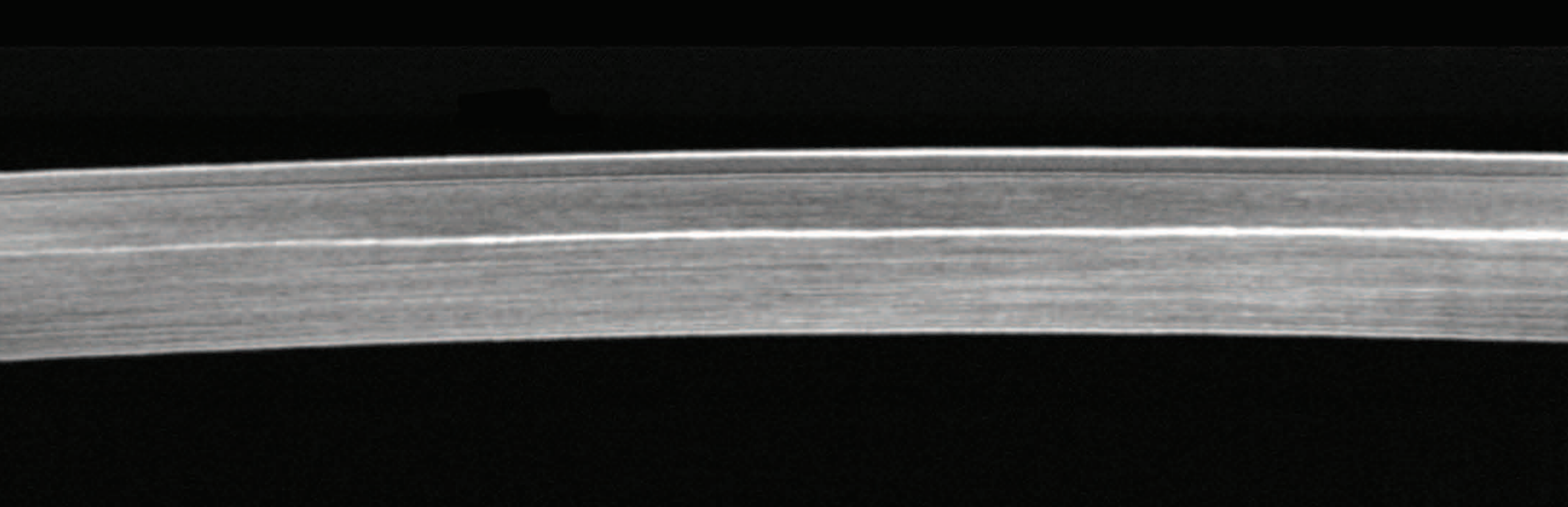
An improvement on the older “C” scan technique, en face presentation utilizes the contour of a selected layer (segmentation) which is used as the shape for the upper and lower boundary using PixelSmart™ technology. The resulting display outlines structural anomalies that are difficult or impossible to see with other imaging methods.



PACHYMETRY MAPPING

First SD-OCT with Pachymetry mapping and assessment.

The CAM option for RTVue SD-OCT provided a 6mm diameter Pachymetry map of the cornea thickness, detecting the anterior and posterior cornea surfaces for direct thickness measurement. An opposing sector assessment provides comparative information that aids in the diagnosis of keratoconus.



CORNEAL POWER

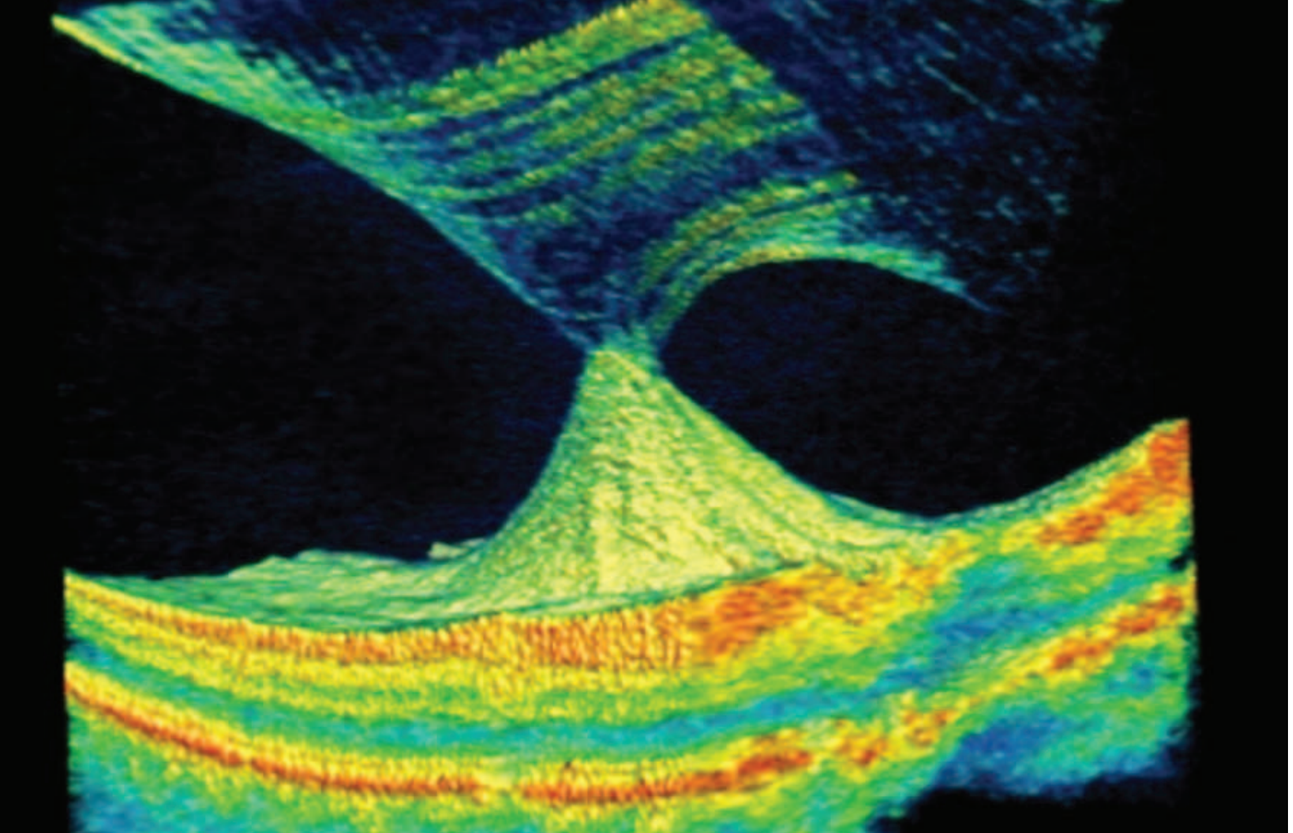
First SD-OCT system with Corneal Power.

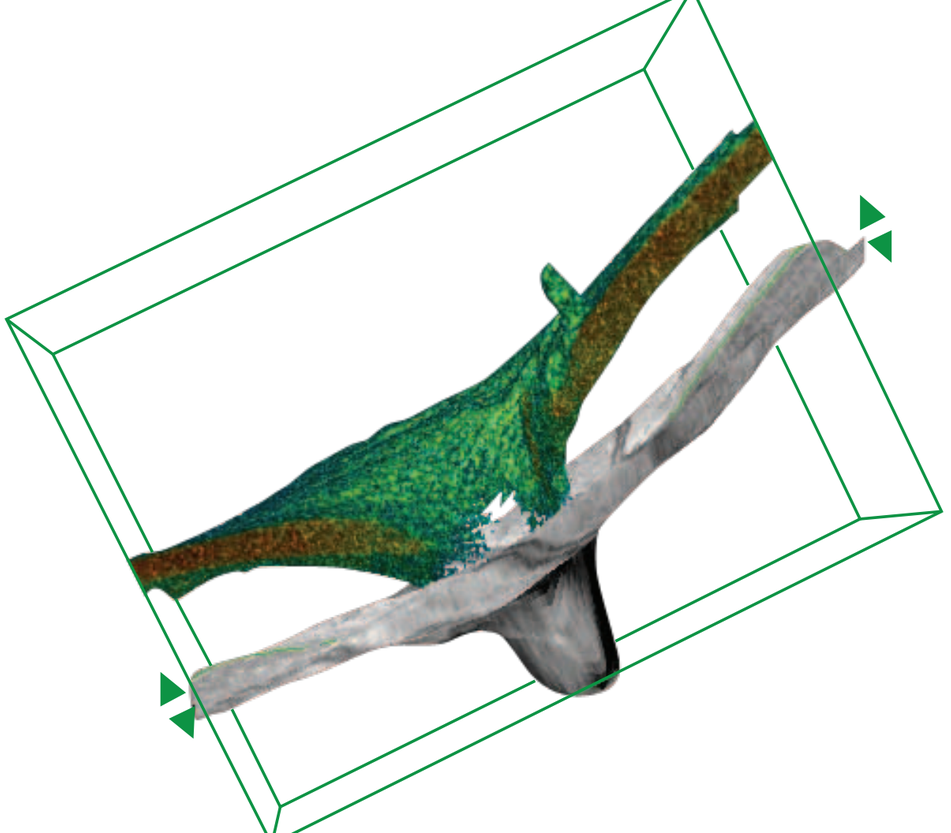
In 2011 Optovue received FDA clearance for the Total Corneal Power (TCP™) option for the RTVue with CAM. It measures both the anterior and posterior corneal surface curvature, the cornea power is calculated in the central 3mm visual zone.

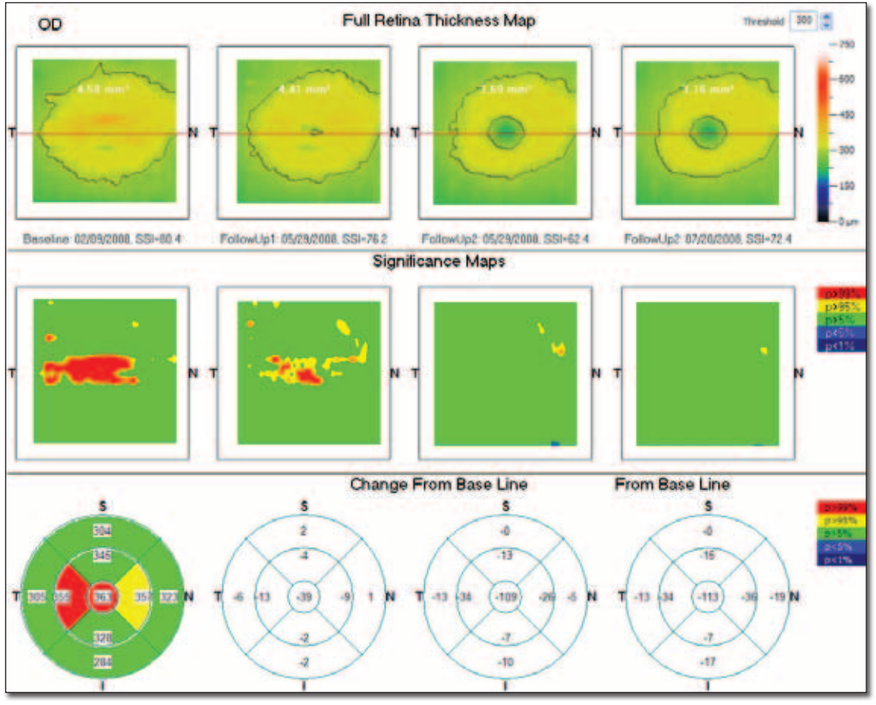
PORTABLE SD-OCT

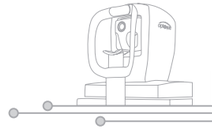
First Portable SD-OCT system: iVue®

The iVue® Compact SD-OCT brought advanced OCT technology to a broader market in 2010, breaking the price barrier of main systems by 35% or more. iVue is designed to provide the specific scans that most private practice eye care providers need for both posterior and anterior assessment. Complete with retina, glaucoma and cornea/anterior segment scanning and analysis, the iVue became the second OCT product introduced by Optovue to shake up the market.





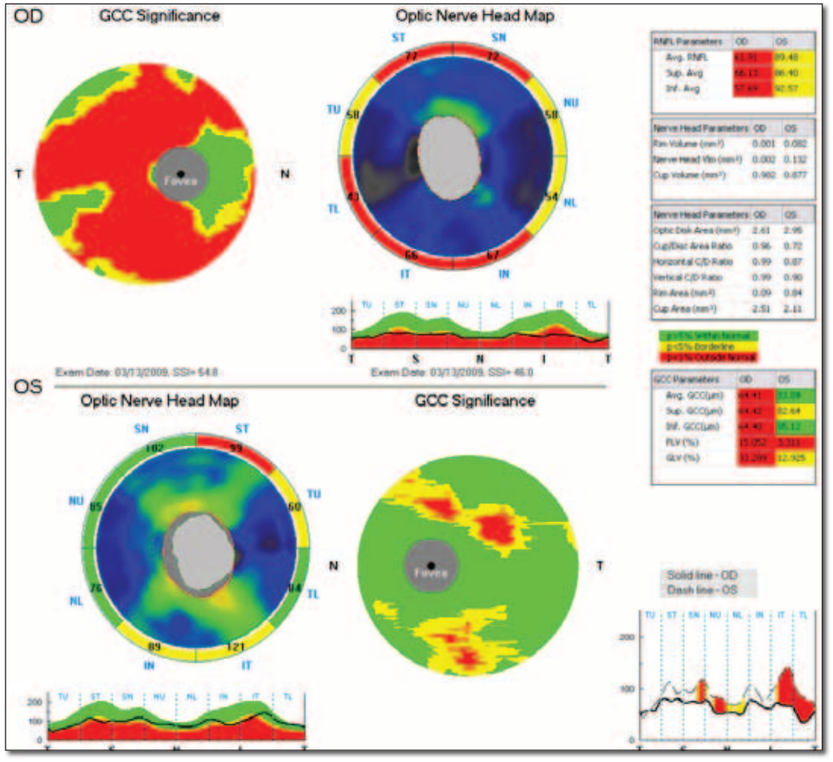




MACULAR VOLUME ANALYSIS

First Macular Volume, change over time analysis with Multi-visit Threshold Volume.

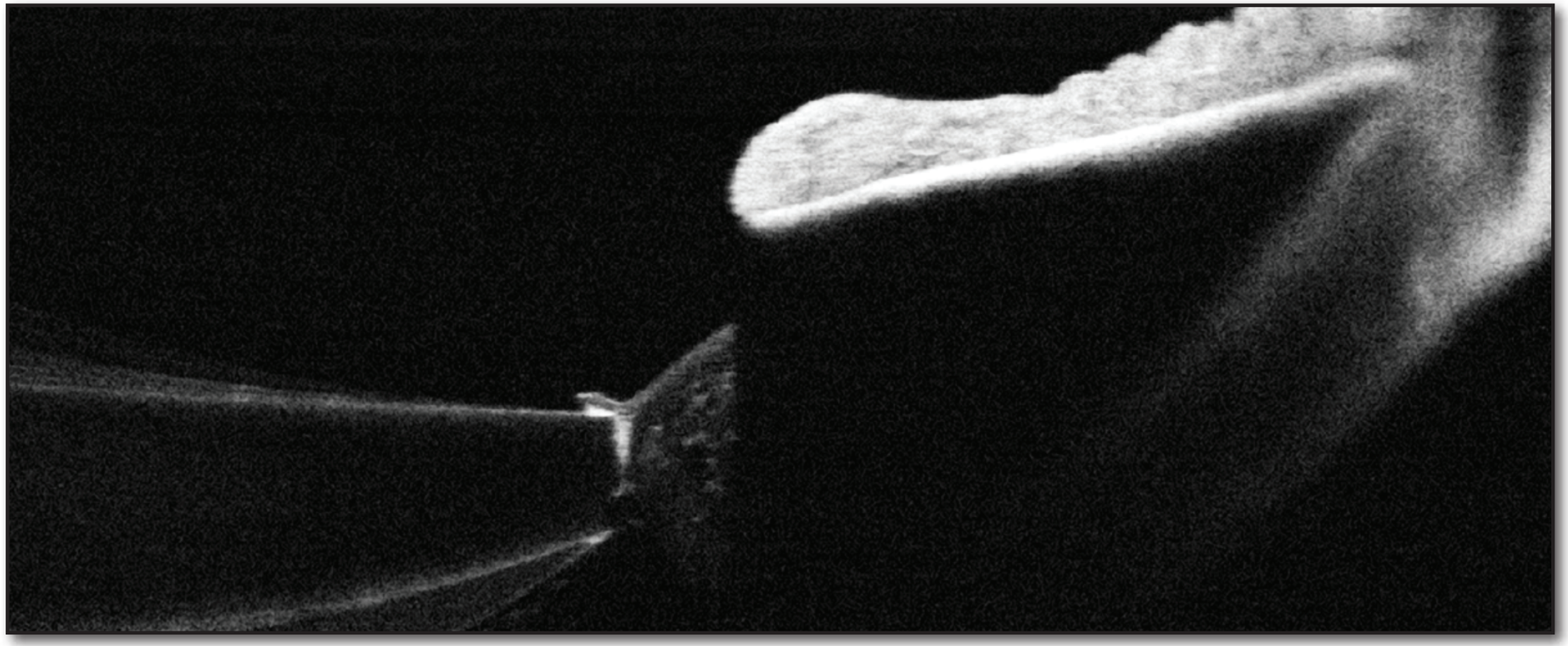
Allowing the user to define the threshold within a volume scan, the volume shown for each visit is the total volume above that threshold. This provides the clinician with a comparison of volume change over time, which is too subtle to see with other methods. Multiple visit comparison/change assessment is another SD-OCT first for Optovue.



NORMATIVE DATABASE

First and only FDA Cleared Normative Database (NDB) that adjusts for Age (every 6 months), Optic Disc size and Signal Strength of the scan.

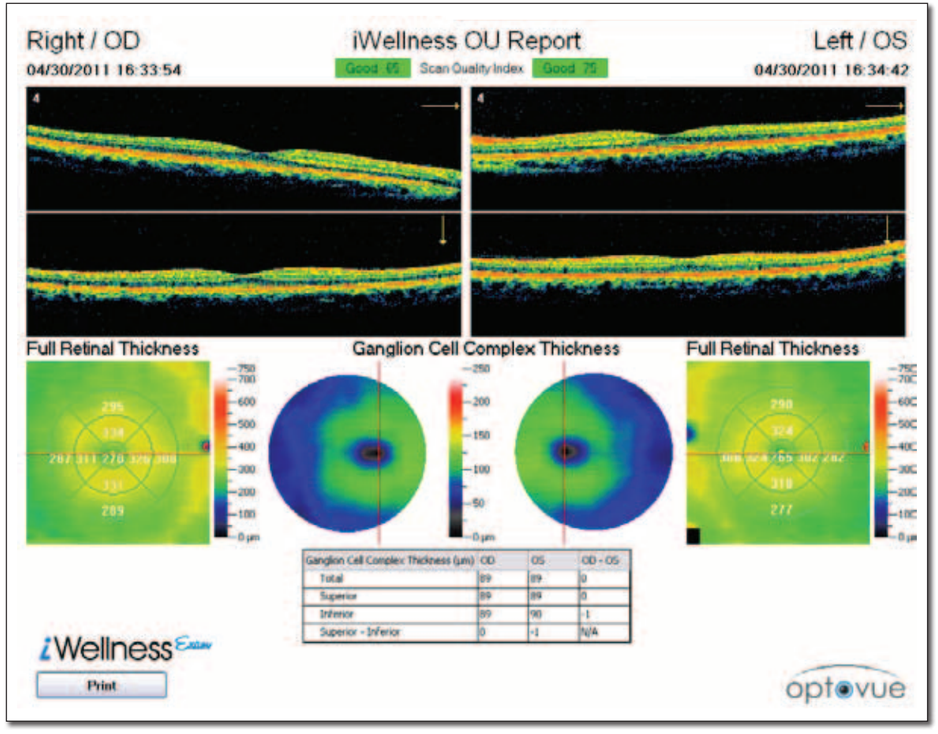
Other normative databases used for reference by OCT systems make an adjustment for the age of the patient using bracket groups of ten years (20 – 29, 30 – 39, etc). The NDB in the RTVue (and submitted for the iVue for US use) makes adjustments for the patient age every six months. It is also the only NDB of any OCT device to also make adjustments for the optic disk size (on disk scans) and signal strength. Studies have shown that variability in the scan signal strength can cause the resulting segmentation measurements to be inconsistent and possibly unreliable. The Optovue NDB makes adjustments for this variability, which has been shown to be measureable against the competition in a published study.



MOBILITY

First mobile option for SD-OCT: iStand™

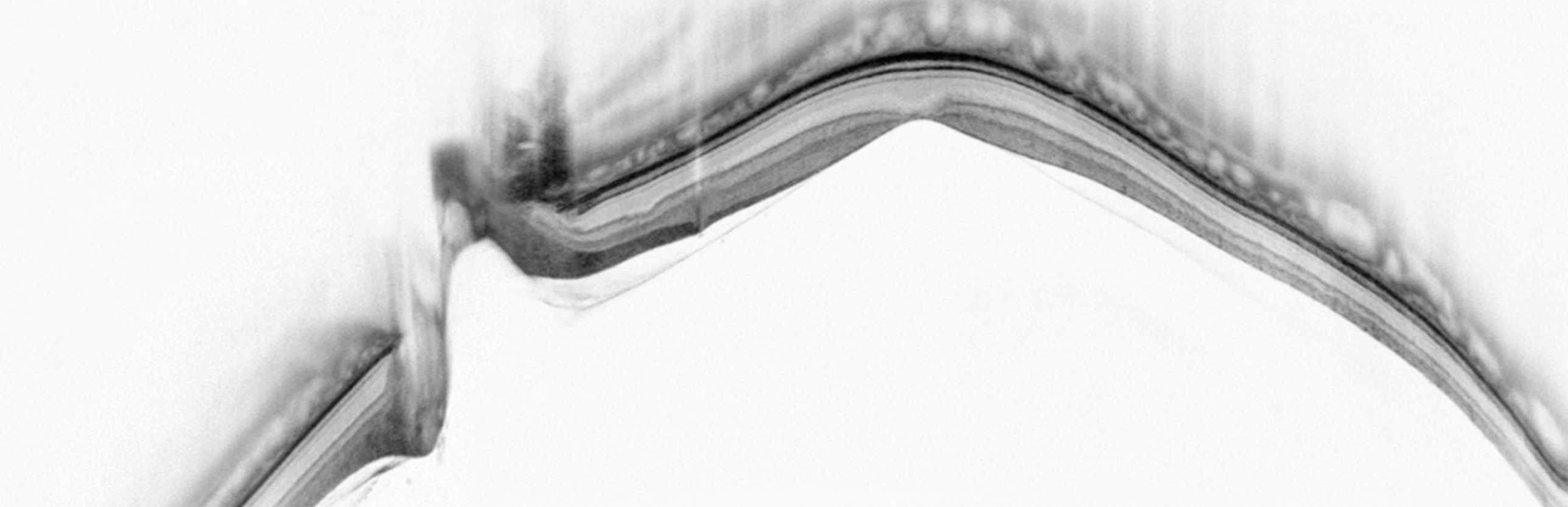
The iStand mobility option for Optovue devices was introduced in early 2011 to allow OCT technology to be used outside the usual office imaging room. iStand offers the user a rolling diagnostic OCT imager for posterior and anterior OCT imaging (when combined with the iVue compact SD-OCT).



SINGLE WELLNESS SCAN

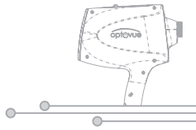
First single scan for retina and glaucoma Wellness assessment.

With the speed of spectral domain OCT and the similarities in the types of scan patterns used to derive the results, it was natural for Optovue to explore a way to provide information relative to both retina based diseases and the changes that may be associated with glaucoma, into one scan. The iWellnessExam® scan pattern covers a larger area than most retina scans, and includes the region that is scanned for the exclusive GCC Significance Analysis. The result is a single scan and display that provides the clinician structural information for edema and ischemic conditions in the retina, detailed information in the FAZ (Foveal Avascular Zone) and an assessment of the Ganglion Cell Complex layers for both eyes in one report.



iWellness Exam®

Powered by optovue



INNOVATIVE PLACEMENT PROGRAM

First with innovative placement program for putting OCT technology in a practice with iWellnessExam® Program.

The iWellnessExam® program was introduced to the market by Optovue in 2011 to provide an optional method for eye clinicians to get OCT technology into their practices for the benefit of their patients. The program bypasses the capital purchase which is the usual method of putting new technology and important clinical diagnostic capability into an eye care practice. The iWellnessExam program offers a Pay-Per-Visit scenario for a term, with options to convert to a purchase at specific intervals.

James Fujimoto, Ph.D.

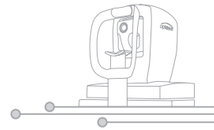
David Huang, M.D., Ph.D.

Michael Hee, M.D., Ph.D.

Tony Ko, Ph.D

Jay Wei

Yonghua Zhao, Ph.D.

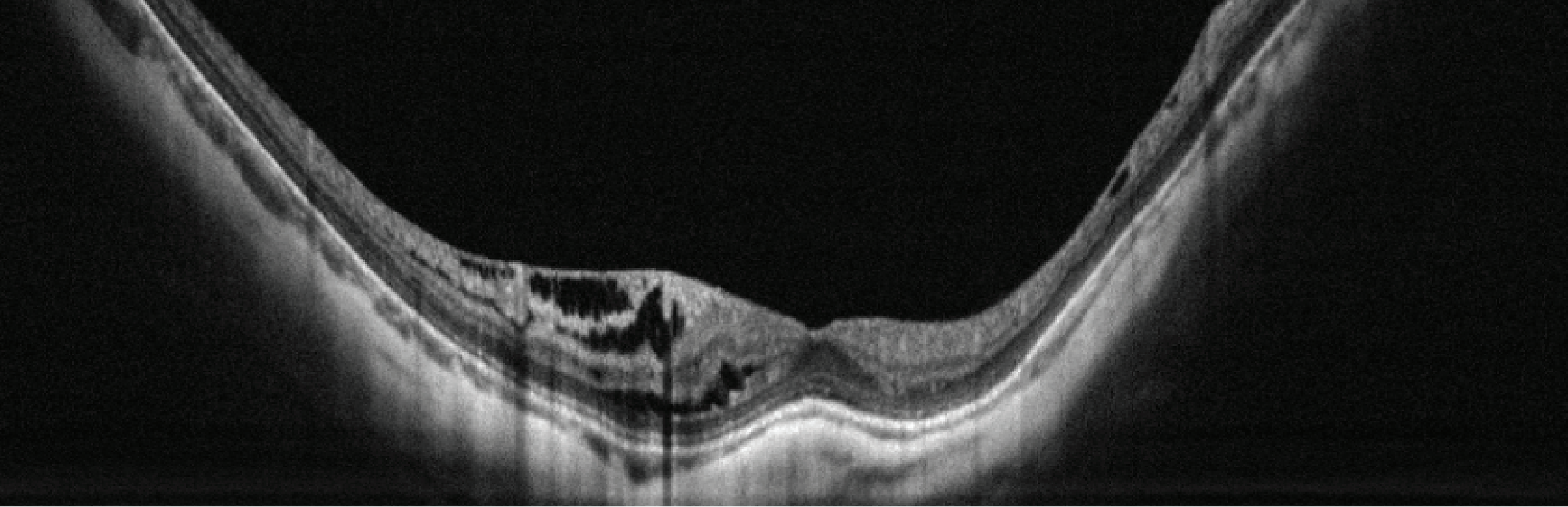


KNOWLEDGE & EXPERIENCE

The knowledge and experience in OCT technology and product development encompassed by the Optovue founders, advisors and consultants are surpassed by no would-be competitor.

Co-inventing - Pioneering - Describing

James Fujimoto, Ph.D. - Co-inventor of OCT, MIT
David Huang, M.D., Ph.D. - Co-inventor of OCT, MIT
Michael Hee, M.D., Ph.D. - Co-author of the first OCT Clinic paper and book, MIT
Tony Ko, Ph.D. - Pioneer of Ultrahigh resolution OCT, MIT
Jay Wei - Pioneer of OCT Ophthalmic Instrument
Yonghua Zhao, Ph.D. - Co-inventor of Doppler OCT



INNOVATION IN

technology

products

distribution

ideas

Optovue… Innovation is our business.