

# Clinical research with the rtx1™ Adaptive Optics retinal camera

## Summary of published results in **age-related macular degeneration**

Dry AMD is the most common type of AMD, accounting for 90% of diagnosed cases. In this form of the disease, the breakdown of macular cells results in growing areas of geographic atrophy (GA). However, the progression is very slow and its detection usually takes months.

Thanks to Adaptive Optics (AO) technology, the rtx1™ enabled visualizing retinal changes in AMD patients at the cellular level. Moreover, since the rtx1 images are distortion-free, follow-up images could be aligned with high precision to study the dynamics of such changes over shorter time scales.

Clinical studies using the rtx1 have resulted in several new findings:

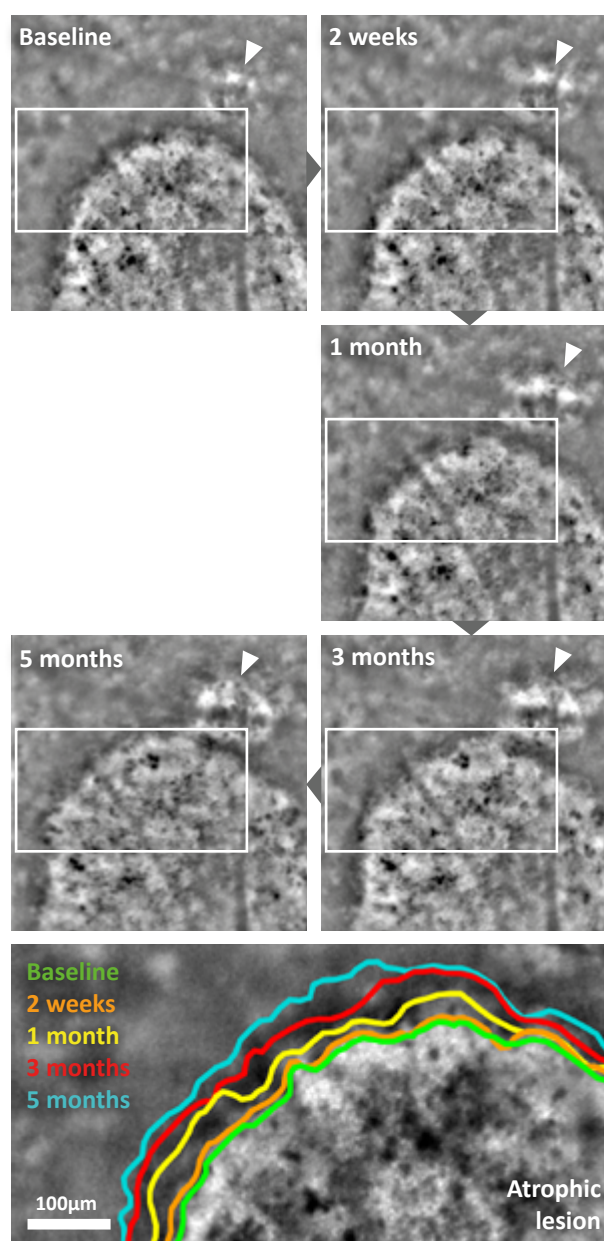
- In the early stages of AMD, rtx1 images showed that drusen cause changes in the contrast of the cone mosaic. Conventional drusen and reticular pseudodrusen were characterized by different reflectivity profiles<sup>1-3</sup>.
- On eyes with dry AMD, GA borders and spared foveal areas appeared more detailed on rtx1 images than on SLO and autofluorescence (AF) images<sup>4,5</sup>. Time-lapse rtx1 imaging enabled tracking displacements of GA borders with micrometer precision, and progression could be detected in less than 1 month<sup>4</sup>.
- The rtx1 also revealed a new candidate biomarker for dry AMD: the hyporeflective clumps (HRCs) which accumulate and migrate during disease progression. Although HRCs are invisible with other imaging techniques, the rtx1 enabled to observe their motion within a few days<sup>1,4</sup>.
- In addition to dry AMD, the rtx1 is also being used in two clinical investigations of stem-cell therapies for the wet form of late-AMD. rtx1 images helped assessing the survival of the implanted RPE cells<sup>6</sup> in one investigation, and of cone cells<sup>7</sup> in the other.

” *The current technological level of robustness and the possibility to obtain quantitative biomarkers already permits the integration of AO in large scale trials in AMD*

Paques et al., *Progress in Retina and Eye Research*, 2018

” *Using AO NIR imaging, we could measure the progression of emerging atrophic areas at a relatively small temporal and spatial scale.*

Gocho et al., *Investigative Ophthalmology & Visual Science*, 2013



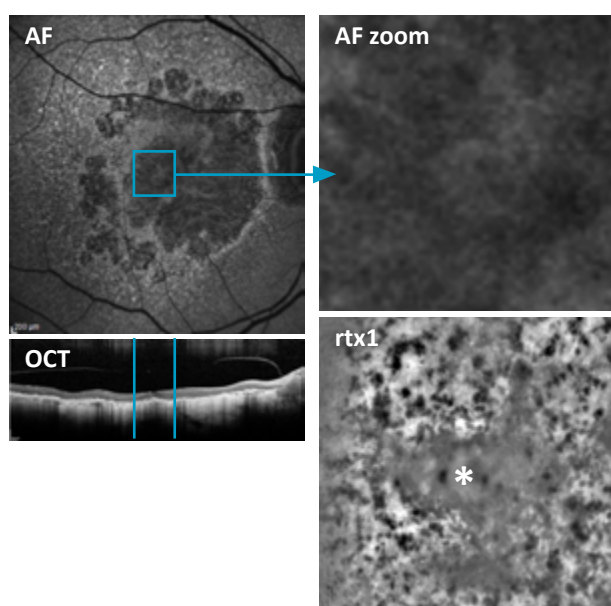
Geographic atrophy progression monitored with the rtx1. Top: a nascent GA (arrowhead) is visibly growing. Bottom: enlarged part of the baseline image with the positions of the main GA border overlaid. Credit: Quinze-Vingts National Eye Hospital, Paris

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” Preservation of functional cone photoreceptors could be demonstrated on en face AO images in areas of foveal sparing that highlights the utility of this imaging modality in the evaluation of emerging treatments for GA.

Querques et al., *Retina*, 2016



Multimodal imaging of foveal sparing in a dry AMD case. Compared with the AF image, the rtx1 image shows the spared area (\*) more sharply and reveals HRCs in the atrophic area (dark dots). Credit: Quinze-Vingts National Eye Hospital, Paris

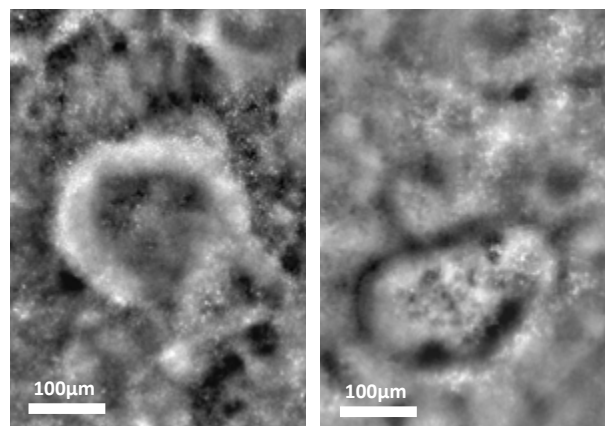
” Migration of HRCs is a highly dynamic process in AMD; it can indeed be detected over a timescale of days while atrophy progression is only detectable over a timescale of weeks.

Paques et al., *Progress in Retina and Eye Research*, 2018



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rtx1 images of conventional drusen (left) with hyperreflective rings, and of pseudodrusen (right) with hyporeflexive rings. Credit: Quinze-Vingts National Eye Hospital, Paris

” The rtx1 allowed us to directly observe stem cell-derived RPE cells after their transplantation in a patient's retina. Thanks to the rtx1's microscopic resolution, we could verify that the mosaic arrangement of these cells was similar to that of natural RPE cells, and stable over time.

Dr. Seiji Takagi, Kobe City Eye Hospital, Japan, 2019

### References

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rtx1 is a certified medical device of class IIa in the European Union. rtx1 is an approved medical device in Japan and China. In the USA, rtx1 has not received FDA clearance; it is an investigational device that requires Institutional Review Board (IRB) oversight. For use by trained eyecare professionals only. AOdetect is an option of the certified rtx1 device in the European Union. In other territories, AOdetect is a separate product for research use only.