

Clinical research with the rtx1™ Adaptive Optics retinal camera

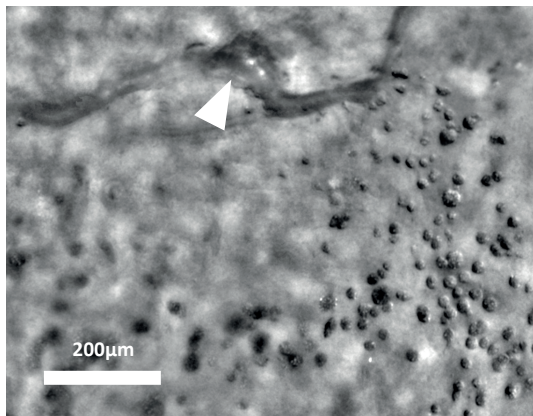
Summary of published results in **diabetic retinopathy**

The detection of early damage to organs is of key importance in the management of diabetes.

The rtx1™, thanks to adaptive optics (AO) technology, has enabled visualizing multiple early alterations caused by diabetes to the retina, often before any damage is visible using other retinal imaging techniques.

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

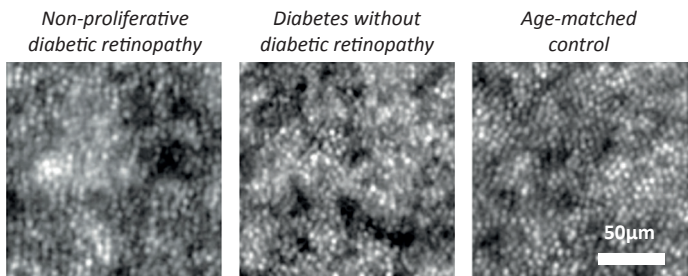
- rtx1 images revealed microscopic hemorrhages^{1,2,3}, non-flowing blood cells¹, edematous cyst walls¹, and modified arteriolar structure⁴⁻⁶.
- Microaneurysms could also be visualized without injecting any contrast agent³.
- rtx1 images allowed the use of morphological metrics* for assessing retinal changes in diabetic patients, including modifications in capillary diameter⁵ and in the density of visible photoreceptors^{2,7,8}.
- Such microscopic signs of pathology were observed not only in diabetic retinopathy (DR)^{1-3,5,7}, but also at earlier stages, including diabetes without DR^{2,4,7,8} and pre-diabetic conditions⁶.



Aneurism (arrowhead) and hard exudate (spots) on rtx1 image. Credit: Quinze-Vingts National Eye Hospital, Paris

” AO imaging may potentially assist in detecting diabetic retinopathy at an earlier stage, may help elucidating the pathophysiology of the diseases and may be used for evaluating the effects of clinical interventions on diabetic retinopathy

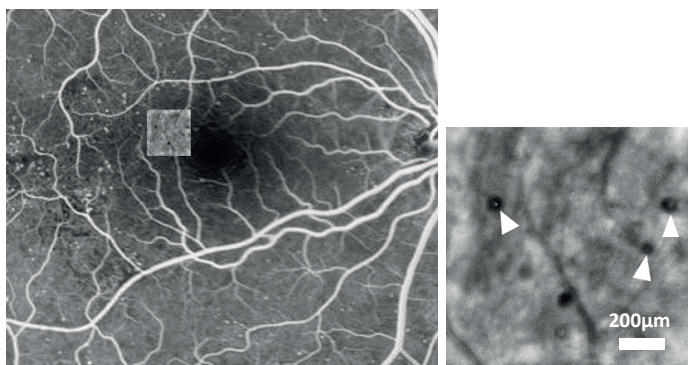
Bek et al. *Acta Ophthalmologica*, 2014



Changes in photoreceptor visibility revealed by the rtx1 in diabetic patients compared to age-matched control. Credit: Lombardo et al. 2016

” Detection of photoreceptor loss at early stages of diabetic retinopathy may contribute to changing the current standard regimen of treatment via earlier intervention to stop further damage

Soliman et al. *PLOS ONE*, 2016



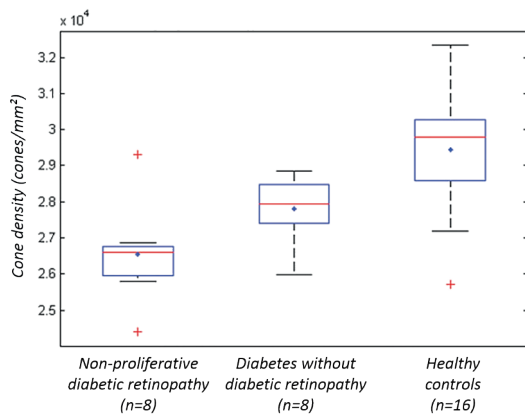
Left: Fluorescein angiography image in a case of diabetic retinopathy. Overlay: Microaneurysms (arrows) imaged without contrast agent with the rtx1. Credit: Quinze-Vingts National Eye Hospital, Paris

” [...] an exquisitely fine documentation of microscopic features such as microaneurysms, microhemorrhages, and hard exudates can also be obtained with adaptive optics ophthalmoscopy

Paques et al. *Prog in Retina and Eye Res*, 2018

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Box plot showing the distribution of values for cone density measured on rtx1 images, at 1.5 degrees eccentric from the fovea, in diabetic patients and age-matched controls. Credit: Lombardo et al. 2016

” Our findings indicate that parafoveal cone density decreased by a mean of 1672 cones/mm² per step of diabetic retinopathy progression

Soliman et al. *PLOS ONE*, 2016

” In all patients, AO images showed dark elements that were smaller than what could be resolved by fundus imaging and OCT. The smallest of these lesions were circular with a size corresponding to both leucocytes (diameter approximately 20 microns) and erythrocytes (diameter approximately 7 microns)

Bek et al. *Acta Ophthalmologica*, 2014

” The average capillary lumen in eyes with non-proliferative diabetic retinopathy was 15% narrower than in healthy eyes of age-matched subjects

Lombardo et al. *Retina*, 2014

” The retinal image analysis with rtx1 offers a novel noninvasive measurement of early changes in the vasculature that are not detectable on routine clinical examination. This measurement may allow the identification of individuals at risk of diabetes

Zaleska-Zmijewska et al. *Journal of Diabetes Research*, 2017



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(*) Quantifications based on adaptive optics retinal images have not been approved for clinical use.

The rtx1 is an approved medical device in the European Union (device class 2a) and in Japan. In the USA, the rtx1 has not received FDA clearance. It is an investigational device and requires Institutional Review Board (IRB) oversight for use in any research application. Further information is provided in the user's documentation.