

Clinical research with the rtx1™ Adaptive Optics retinal camera

Summary of published results in **arterial hypertension**

As cardiovascular events (CVE) are the leading cause of death worldwide, their prevention is of key importance to global health. The most important known risk factor for CVE is arterial hypertension (AHT)¹.

Previous studies demonstrated that analyzing the wall morphology of small arteries could enhance the prediction of CVE²⁻⁶. Unfortunately, the assessment method required biopsies of subcutaneous arterioles. The invasive nature of this technique has prevented further application in clinical routine⁷.

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

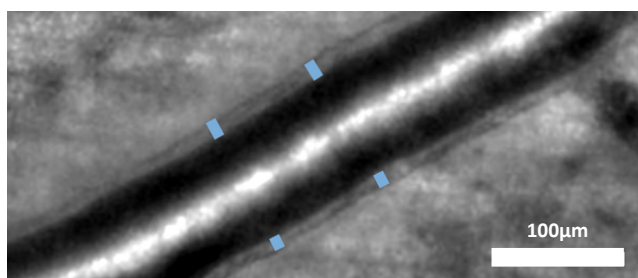
- The rtx1 has enabled direct non-invasive visualization of retinal arteriolar walls^{6,8,9}
- It has allowed assessing retinal microvascular biomarkers* with micrometer reproducibility, including lumen diameter (LD) and wall-to-lumen ratio (WLR)¹⁰
- AHT patients were found to have significantly lower retinal LD and higher WLR when compared with normotensive subjects⁸⁻¹². Such abnormalities were also detected in patients with masked AHT¹¹
- Clinical retinal findings with the rtx1 were found to be strongly correlated with ex-vivo measurements in subcutaneous arterioles¹⁰, which are known to provide highly predictive prognostic biomarkers for CVEs²⁻⁶
- The rtx1 has revealed morphological changes in small arteries during the course of anti-hypertensive therapies, including drug treatments¹² and baroreceptor stimulation¹³

” *The evaluation of microvascular structure is progressively moving from bench to bedside, and it could represent, in the near future, an evaluation to be performed in all hypertensive patients*

Agabiti-Rosei, *Journal of Hypertension*, 2017

” *There is undoubtedly a need for noninvasive approaches in the evaluation of microvascular morphology that may provide us with a better risk stratification of patients, as well as with further important information about the effects of antihypertensive drugs*

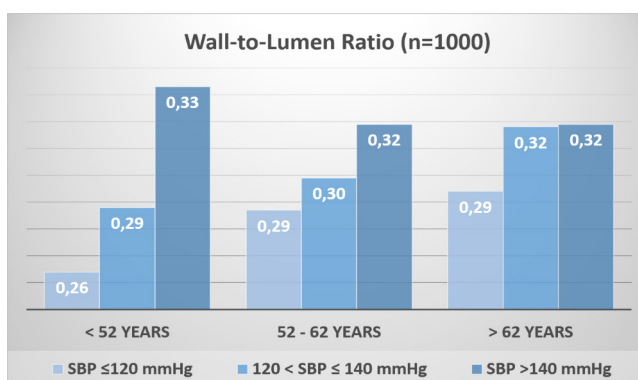
Rizzoni & Docchio, *Journal of Hypertension*, 2016



Walls of the retinal arteriole (blue marks) imaged with the rtx1.

” *High resolution imaging of retinal vessels by adaptive optics allows quantitative microvascular phenotyping*

Koch et al. *Journal of Hypertension*, 2014



Wall-to-lumen ratio (WLR) of retinal arterioles vs. blood pressure.

Credit: Rosenbaum et al. 2016

” *Subjects with reported arterial hypertension showed a significantly increased age-adjusted wall-to-lumen ratio*

Meixner et al. *Graefe's Arch. for Clin. and Exp. Ophthalmology* 2015

Clinical research with the rtx1™ AO camera

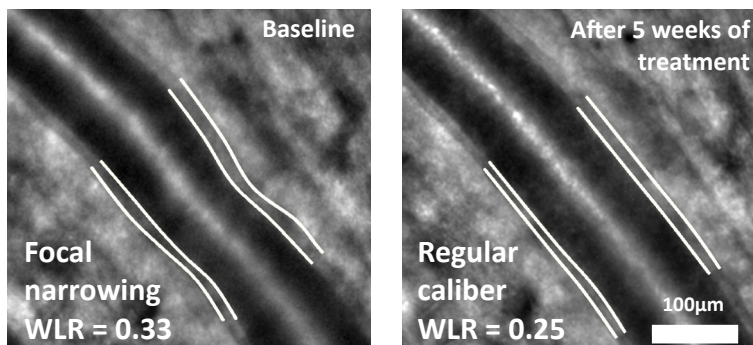
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“Noninvasive and easily repeatable procedure such as the evaluation of the arterioles in the fundus oculi by adaptive optics may provide similar information regarding microvascular morphology compared with an invasive, accurate and prognostically relevant micromyographic measurement of the MLR of subcutaneous small arteries

De Ciuceis et al. *Journal of Hypertension*, 2018

“In arterial hypertension, WLR is a robust, dimensionless parameter that can be measured on large cohorts of nondilated patients

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



Arteriolar remodeling during anti-hypertensive therapy. Credit: Pitié-Salpêtrière Hospital, Paris, France

“We were able to observe a decrease in WLR in case of a significant blood pressure drop [...] shortly after antihypertensive treatment introduction or reinforcement

Rosenbaum et al. *Journal of Hypertension*, 2016

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www.imagine-eyes.com

18 rue Charles de Gaulle
91400 Orsay, FRANCE
+33 (0) 1 64 86 15 66
contact@imagine-eyes.com

(*) Biomarkers 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.