Ophthalmic Artery Angioplasty Improves Choroidal Thickness in Subjects With Geographic Atrophy

Jimena Rojas[1,2], Ivan Lylyk[3], Nicolas Monteros[1,2], Pedro Nicolas Lylyk[3], Pablo Bazterrechea[1,2], Carlos Bleise[3], Fernanda Forgues[1,2], Juan Manuel Cortalezzi[4], Ignacio Zeolite[5], Jeff Franco[6], Michael W Calhoun[6], Luana R Wilbur[6], Philip J. Rosenfeld[7], Pedro Lylyk[3], Mario J Saravia[1,2]

[1] Buenos Aires Macula Clinical Research, Buenos Aires, Argentina, [2] Foundation Retina Research & Development Network, Buenos Aires, Argentina, [3] Department of Interventional Neuroradiology, Instituto Médico ENERI, Buenos Aires, Argentina, [4] Cortalezzi Vision, CABA, Argentina, [5] Fundación Oftalmológica Argentina Jorge Malbran, Buenos Aires, Argentina, [6] OcuDyne, Inc. Brooklyn Park, Minnesota USA, [7] Bascom Palmer Eye Institute, University of Miami Miller School of Medicine, Miami, USA

Posterboard #: A0113

Abstract Number: 4049873

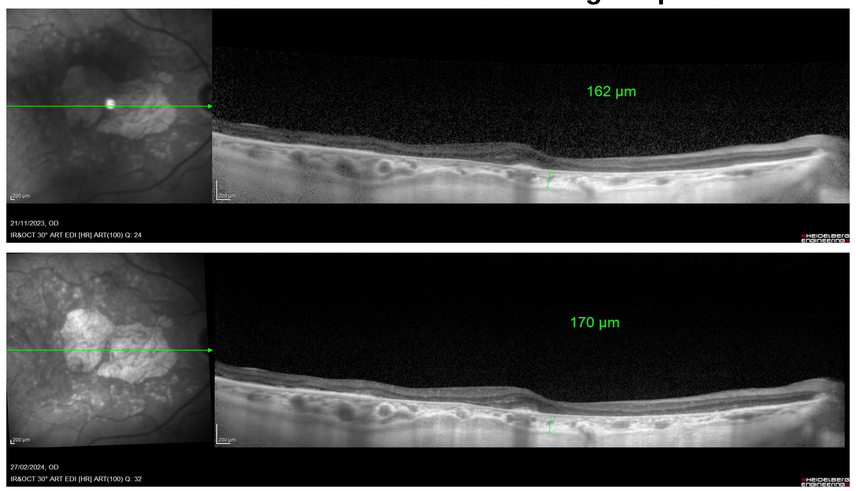
PURPOSE

The causal relationship between choroidal perfusion and the onset and progression of AMD remains unproven. However, the retinal pigment epithelium and outer retina are dependent on choroidal perfusion and involved in AMD, so it's reasonable to assume that choroidal perfusion plays an important role. In this open-label study (NCT05091476), ophthalmic artery (OA) angioplasty performed using an investigational microcatheter system in the treatment of patients with geographic atrophy (GA) secondary to AMD, we investigated the relationship between ocular perfusion and choroidal thickness.

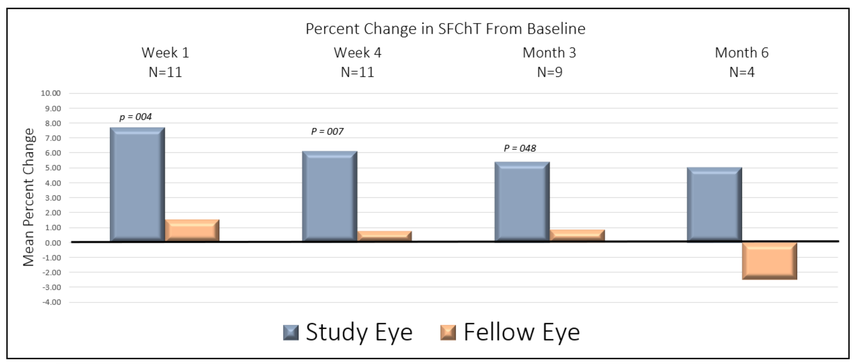
METHODS

Patients ≥60 years old with ETDRS best-corrected visual acuity <56 letters (<20/80) due to GA were identified with OA stenoses and underwent the study procedure per protocol. Spectral-domain optical coherent tomography imaging (SD-OCT, Spectralis; Heidelberg, Germany) was used to capture subfoveal choroidal thickness (SFChT). The vertical SFChT measurements were taken from the hyperreflective line of Bruch's membrane to that of the choroid-scleral interface (top) using the Heidelberg software caliper tool in horizontal 9-mm line enhanced depth imaging (EDI) scans (ART=100). All measurements were performed by the same masked investigator and were collected at each visit. Normal distribution of both data sets were confirmed via a Shapiro-Wilk test (*p>0.05*) and a two-tailed, paired analysis was used to derive statistical significance over baseline at the 1-week, 4-week, and 3-month visits. At the time of this analysis, there was an insufficient sample size at the 6-month visit to calculate *p-value*.

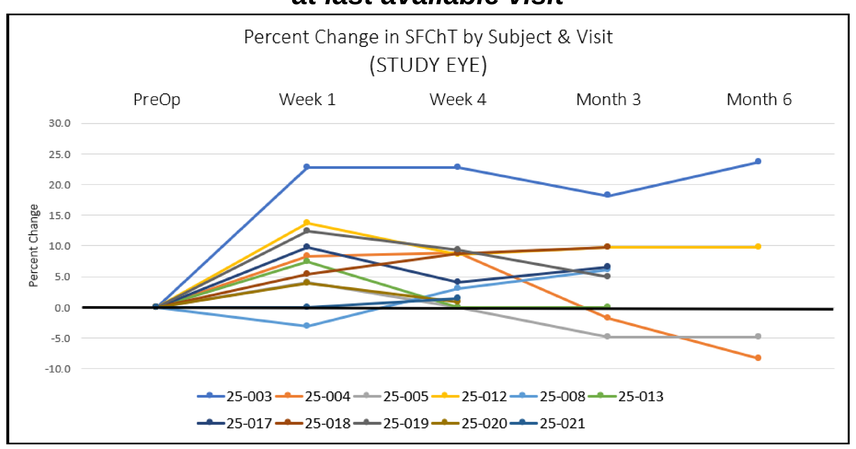
SFChT measurements with Heidelberg caliper tool



Mean percent change in SFChT demonstrating a statistically significant increase over baseline in the Study Eye Cohort



81.8% of Study Eye SFChT remains at or above baseline at last available visit



RESULTS

Eleven consecutively treated subjects have completed postoperative visits ranging from 4 weeks to 6 months. The SFChT measurements increased from the mean (SD) baseline SFChT (µm) of 143.4 (66.07), to 155.0 (72.04), 151.8 (67.64), 151.4 (73.42), and 179.5 (44.31), at weeks 1 and 4, and months 3 and 6, respectively. These changes represent a statistically significant increase through the 3-month visit. Individual thickness changes varied up to 23.64% and 9 (81.8%) of study eye SFChT measurements remain at or above baseline at last available visit. In contrast, the Fellow Eye cohort demonstrated mean SFChT within 1% of baseline out to month 3, with the smaller cohort demonstrating a decline at month 6.

CONCLUSIONS

In this case series, preliminary evidence suggests that balloon angioplasty of ophthalmic arteries with stenotic lesions improved SFChT in subjects with GA secondary to AMD. Longer follow-up and additional patients are needed to confirm that balloon angioplasty is a viable strategy to increase OA blood flow and choroidal perfusion.

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Disclosures: J Rojas, (N); **I Lylyk**, (N); **N Monteros**, (N); **PN Lylyk**, (N); **P Bazterrechea**, (N); **C Bleise**, (N); **F Forgues**, (N); **JM Cortalezzi**, (N); **I Zeolite**, (N); **J Franco**, OcuDyne (I,O,P); **MW Calhoun**, OcuDyne (C,O,P), **L Wilbur**, OcuDyne (C), STAAR Surgical (C); **P.J. Rosenfeld**, Alexion (R), Annexon (C), Apellis (C,F), Bayer (C), Boehringer-Ingelheim (C), Carl Zeiss Meditec (C,R), Chengdu Kanghong Biotech (C), Gyroscope Therapeutics (R), InflammX Therapeutics (C), OcuDyne (C,I), Regeneron (C), Stealth Bio Therapeutics (R), Unity Biotechnology (C), Valitor (F), Verana Health (F); **P Lylyk**, OcuDyne (F); **MJ Saravia**, Apellis (C,F), OcuDyne (F).