The Evaluation of Ophthalmic Artery Lesions in the Treatment of Geographic Atrophy

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PURPOSE

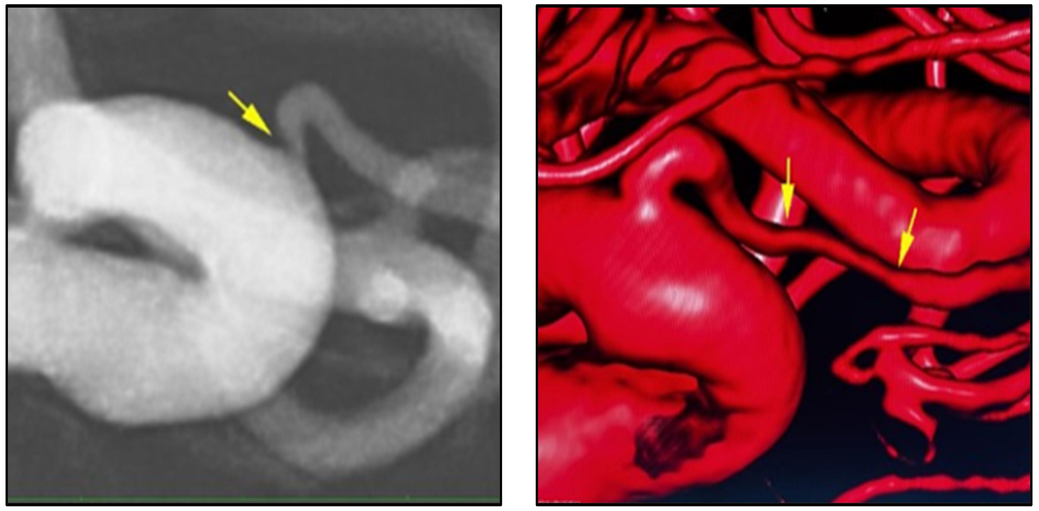
Stenoses of the ophthalmic artery (OA) in patients with geographic atrophy (GA) secondary to age-related macular degeneration (AMD) may contribute to disease progression in AMD. Validation of this mechanism of disease progression requires the ability to accurately and reproducibly evaluate lesions in the OA that effect ocular perfusion. In this ongoing open-label safety and feasibility study (NCT05091476), we developed imaging and grading methodologies to assess the extent of OA stenoses both before and after artery balloon angioplasty utilizing an investigational microcatheter system designed specifically for this purpose.

METHODS

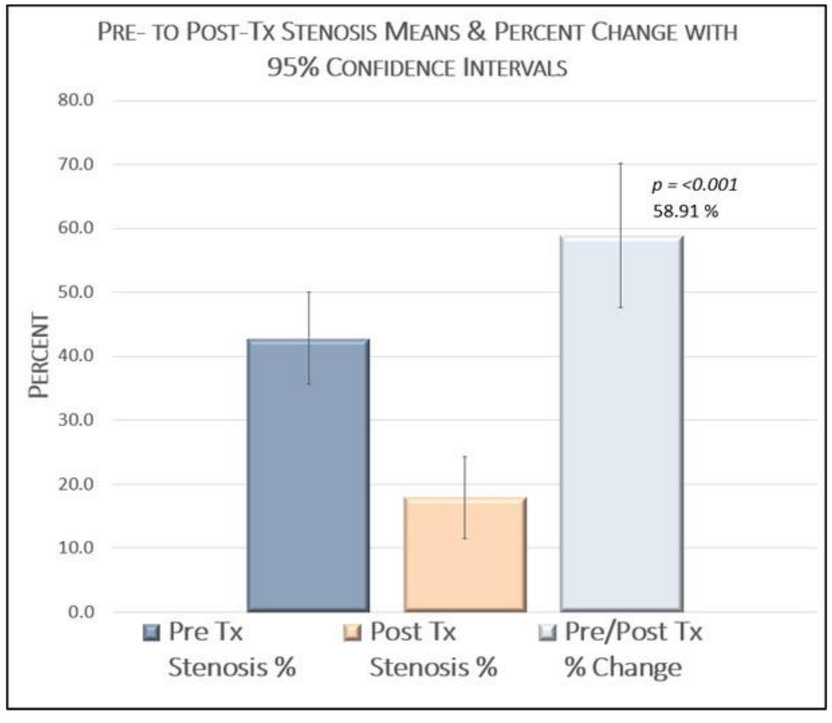
This study enrolled subjects ≥60 years old with best-corrected visual acuity of <56 letters (20/80 or worse) due to GA secondary to AMD, and with evidence of OA stenosis. Procedural feasibility, defined as successful OA canulation and balloon angioplasty with demonstrative change to the artery lumen, is a primary focus of this study. Eligibility screenings were performed preoperatively using magnetic resonance angiography (MRA) and computed tomography (CT). Intraoperatively, pre- and post-procedural 2D and 3D digital subtraction angiography (DSA) were performed, as well as exploratory collection of perfusion mapping, mean aneurysm flow amplitude, and choroidal blush. Based on the location and morphology of vascular disease presented in the OA, a variety of imaging modalities were used to facilitate accurate characterization of lesion status pre- and post-procedurally. Final stenoses evaluations and measurements were conducted by experienced radiology specialists using recorded intraoperative imaging and consensus on all measurements were obtained. P-values were calculated using a two-tailed, paired analysis.

Ophthalmic Artery Stenotic Lesions

Focal (2D-DSA) vs. Diffuse (3D-DSA)



The ability to effect a statistically significant change to the diseased artery was demonstrated in this population



RESULTS

Thirteen lesions in 11 consecutively treated subjects are reported. Nine subjects (81.8%) presented with a single lesion and 2 (18.2%) presented with two lesions that were either focal (61.5%) or diffuse (38.5%). There were 8 (61.5%) located in the ostium / short limb region, 2 (15.4%) in the long limb, and 3 (23.1%) in the distal part. Of the 13 lesions, 8 (61.5%) measured 29.0 to <40.0% stenoses, one (7.7%) measured 40.0 to <50.0%, two (15.4%) measured 50.0% to < 60.0%, and the final two measured 60.0% to <70.0% stenoses. Mean (SD) pre-procedural stenoses of 42.78 (13.22) percent was decreased to a mean (SD) of 17.95 (11.72) percent, representing a 58.91% ($p = <0.001$) decrease in mean stenosis.

CONCLUSIONS

From the ostium to the central retinal artery branch bifurcation, the OA is a challenging segment to image due to the small vascular caliber, its anatomical complexity, and the tortuosity along its path. With the imaging modalities presented here, we demonstrate the potential to identify clinically relevant OA stenoses and the ability to effect change in the target anatomy.

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Disclosures: F Forgues, (N); **I Lylyk**, (N); **N Monteros**, (N); **PN Lylyk**, (N); **J Rojas**, (N); **C Bleise**, (N); **P Bazterrechea**, (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); **MJ Saravia**, Apellis (C,F), OcuDyne (F);); **P Lylyk**, OcuDyne (F).