



Oraya IRay™ system: Prospective case series of radiation therapy for naïve patients with choroidal neovascularization secondary to Age-related Macular Degeneration as a primary therapeutic approach.

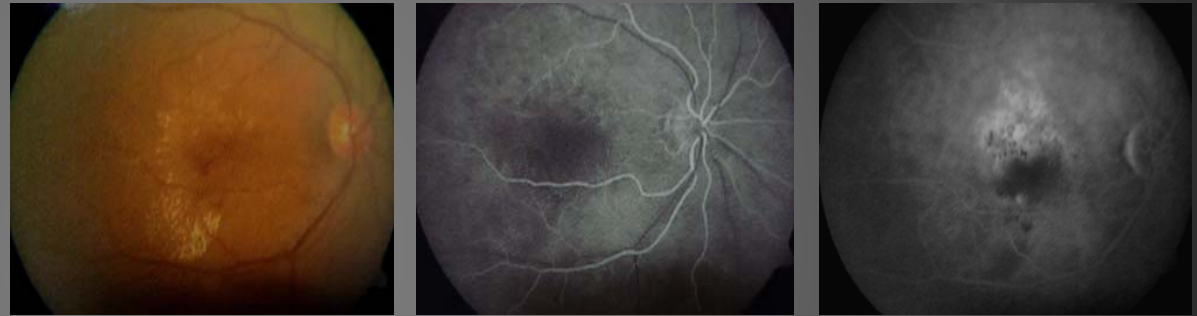
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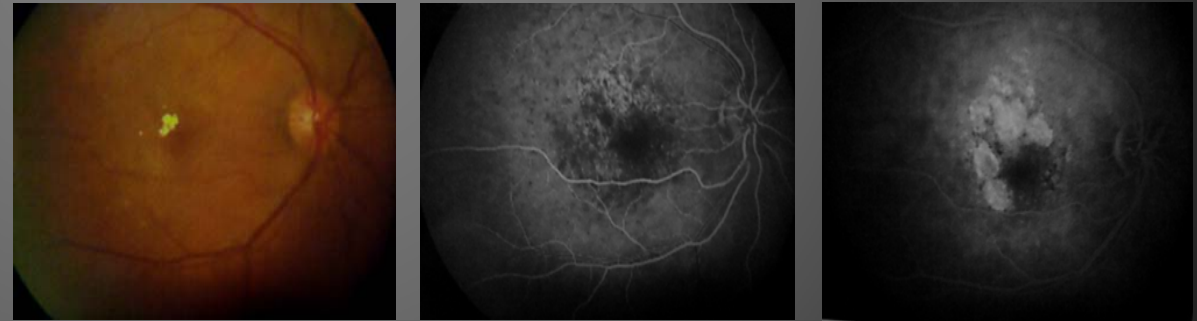
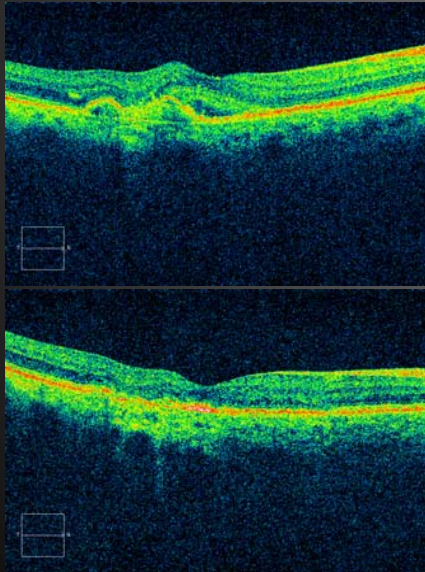
Purpose: To report clinical, anatomical and angiographic outcomes in a consecutive series of patients treated with external x-ray irradiation using Oraya's IRay non-invasive system as primary therapy followed by intravitreal ranibizumab as adjunctive treatment as necessary for choroidal neovascularization (CNV) secondary to age-related macular degeneration (AMD)

Results: Twelve patients were included in this protocol. The mean follow-up time was: 5.7 months (Range: 2 to 11 months). The average letter change from baseline was: 0 letters (Range: -17 to +16 letters). All but two patients required additional intravitreal ranibizumab injections. The mean injection rate was: 1.00 ± 0.6 (Range: 1 to 2 injections) over the follow-up period. Leakage in FA improved in 6 cases, was stable in 5 cases and worse in 1 case.

Methods: Patients with clinical diagnosis of treatment-naïve neovascular AMD were included. At baseline, all patients underwent a complete eye examination: best corrected visual acuity (BCVA) assessment using protocol ETDRS refraction, fluorescein angiography (FA), and a spectral domain optical coherence tomography (SD-OCT). Patients received a radiation dose of 16 Gy delivered in three sequential external beams through the pars plana and converging on the macula, using Oraya's IRay system. Prospective adjunctive intravitreal ranibizumab injection was performed for the following indications: loss of 10 or more ETDRS letters, new subretinal blood, or fluid recurrence by SD-OCT of greater than 100 microns. SD-OCT was repeated monthly during the follow-up.



Baseline SD-OCT, Color Fundus image and fluorescein angiography showing drusen, exudation and leakage in one patient



Follow up at 6 months, SD-OCT Color Fundus image, and fluorescein angiography, the same patient, showing improvement in findings

Conclusion: The administration of external x-ray irradiation delivered with Oraya's IRay system produced a clinical stabilization of the CNV that is not consistent with either the natural history or an as-needed intravitreal ranibizumab injection protocol requiring 1 treatment every 5 months, with improvement in angiographic leakage pattern and decreased retinal thickness by OCT. The changes in BCVA were not significant. The average intravitreal injection was 1 in over 5.6 months.