

Oraya's IRay™ System for Delivery of Microcollimated Pars Plana External Beam Radiation to the Eye: Local Safety and Patient Tolerability.

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Introduction:

Oraya's IRay is an investigational office-based device, which delivers low energy X-rays to the macula for treatment of choroidal neovascularization due to age-related macular degeneration. It combines a robotically positioned 100 keV X-ray tube, eye alignment and tracking via the I-Guide™ scleral cup, treatment planning, and automated safety features. The beams are highly collimated, with a diameter of 3.5 mm on the sclera and 4 mm on the retina. Clinically, IRay delivers up to 22 Gy to the 90% isodose, using 3 sequential beams which pass through the sclera and overlap at the macula. The aim of this study was to describe the safety and patient tolerability of the radiotherapy procedure.

Methods:

We included 32 patients treated with the IRay system. Every patient had a complete ophthalmologic examination at baseline, 10 minutes, and one week after treatment. We intentionally searched for local adverse effects (AEs) during examination and by interviewing the patients. We recorded type, duration and treatments if needed for every AE.

Results:

All patients presented with mild superficial punctate keratitis (SPK) secondary to the I-Guide. This was noted at ophthalmic examination but no symptoms were reported by any

patient. All cases lasted less than a week and needed no treatment. There were no other local AEs or reports of discomfort.

Conclusion:

Treatment with Oraya's IRay system is safe and well tolerated in the short term. The only AE reported (SPK) is a common reaction with the use of all devices which include a contact lens.