RayOne® Hydrophobic Pre-Launch Clinical Information

As part of Rayner's pre-launch clinical evaluation of the brand new RayOne® Hydrophobic fully preloaded IOL, an *in-vivo* surgeon evaluation was organised to evaluate the lens' optical performance as well as its usability within a real-world operating room.

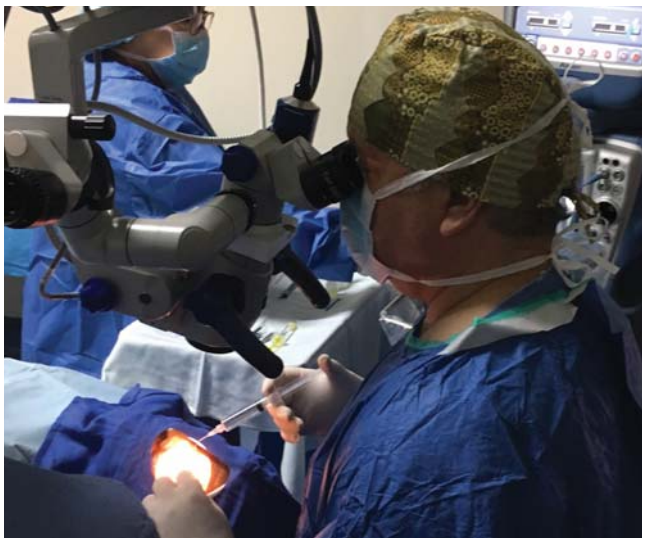
Based on Rayner's high performance RayOne® platform which features a fully preloaded injector system with 1.65 mm nozzle, RayOne® Hydrophobic introduces a proprietary hydrophobic material and unique lens design. This combination of a proven injector system along with brand new lens is designed to provide high levels of user friendliness and surgical efficiency, whilst delivering the optical outcomes that patients demand.

During August 2017, fifty RayOne® Hydrophobic IOLs were implanted at the Clínica Quesada in Central America. The evaluation was led by Dr. Kevin Waltz (United States), a surgeon who pioneers first-in-eye studies supported by local surgeons Dr. Gabriel Quesada, Dr. Rodrigo Quesada and Dr. Marco Robles.

"The cataracts, in general, were quite dense (20/200 or worse pre-operation) and some patients had small pupils. The surgeries were challenging, thus challenging the RayOne® Hydrophobic injector system. However, all IOLs centred well in the capsular bag with no significant lens issues identified. The RayOne® injector system performs very similarly, if not identically, between the hydrophilic and hydrophobic variants", noted Dr. Gabriel Quesada.

All patients had follow up appointments at one week, one month and three months post-surgery. Target refraction was +/-0.50 D, with average spherical equivalence results across all implantations of -0.04 D after three months. No IOL-related adverse events were reported.

Follow up period	1 week	1 month	3 months
SE ± SD (D)	0.00 ± 0.64	0.15 ± 0.68	0.04 ± 0.67



The full surgeon evaluation dataset and report is to be published in 2018.

Lens material safety – clinical study at the S.Fyodorov Eye Microsurgery Federal State Institution, Moscow

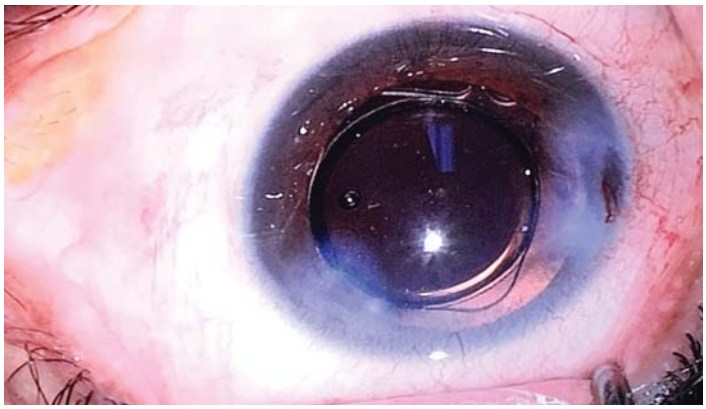
A study was conducted to evaluate the efficacy and safety of the new RayOne® Hydrophobic flexible acrylic IOL material.

125 patients with age-related cataracts were selected:

- 125 were examined 1-2 days post-operatively
- 109 were examined 7-14 days post-operatively
- 103 were examined 30-60 days post-operatively
- 100 were examined 120-180 days post-operatively

During the study, the new Rayner hydrophobic material showed good results for visual acuity recovery in patients following cataract treatment. No IOL-related adverse events were reported during the study.

Investigators at the S.Fyodorov Eye Microsurgery Federal State Institution concluded that, "it was demonstrated that the lens could be safely implanted into the eye, and no negative differences were found compared to the historical control group in accordance with international standard ISO 11979-7:2014, thus ensuring predictable data for post-operative eye refraction."



To find out more about how we're setting new standards for both surgeons and patients, visit **rayone.com/hydrophobic**

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