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Alcon Announces Findings from IRIS Registry Analyses on Real-World Cataract Patients at the American Academy of Ophthalmology Annual Meeting

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Alcon, the global leader in eye care, today announced findings from the American Academy of Ophthalmology (AAO) IRIS® Registry (Intelligent Research in Sight) that support the clinical value of the AcrySof® platform. The IRIS Registry was used to assess characteristics and complications of intraocular lens (IOL) implantation after cataract surgery.

AAO launched the IRIS Registry, the specialty's first comprehensive national database, in 2014. As the largest clinical specialty database in the world, the IRIS Registry currently includes clinical information from more than 15,000 participating eye care physicians and 252 million patient visits, representing more than 60 million unique patients. AAO developed this registry with the goal of striving for continual improvement in the delivery of eye care. In addition, the real-world data is useful for clinical care, analytics and regulatory compliance.

The study findings presented at AAO followed a cohort-based protocol and were completed in collaboration with Verana Health, the Academy's data curation and analytics partner. Results from an analysis of the 6,482 eyes implanted with a TECNIS* or an AcrySof monofocal toric IOL, presented in poster and paper presentations by Dr. Brent Kramer, demonstrated that the incidence of post-operative repositioning was significantly lower at a rate of 0.6% in the AcrySof group compared to 3.1% in the TECNIS group ($P<0.0001$). Additionally, the rate of undergoing IOL repositioning surgery was over five times higher among patients who received TECNIS lenses compared with those who received AcrySof lenses.

"Toric IOL misalignment can lead to poor visual outcomes and patient dissatisfaction," said John Berdahl, MD, of Vance Thompson Vision in Sioux Falls, SD, who was a co-author on these presentations. "This analysis corroborates other studies which demonstrate the excellent rotational stability of AcrySof IOLs. This large dataset can help surgeons make informed choices regarding toric IOL selection."

In a separate analysis of the IRIS Registry, the incidence of YAG laser capsulotomy due to posterior capsular opacification (PCO) and time to PCO after lens implantation was compared between types and brands of IOLs in over 78,000 eyes. In a poster authored by Dr. Jeffrey Horn, YAG rates with monofocal lenses were lower than multi-focal/extended depth of focus lenses (4.5% vs 22.4%, $P<0.0001$). For monofocal YAG rates, AcrySof lenses were significantly lower than TECNIS lenses (3.7% vs 7.8%, $P < 0.0001$). In another poster

authored by Dr. Bret Fisher, the mean time to PCO diagnosis was significantly longer in the AcrySof monofocal group (171.1 ±99.3 days) versus the TECNIS monofocal group (155.2 ±96.0 days), P<0.0001.

“The IRIS Registry is the most robust resource for real-world data and clinical outcomes in the U.S.,” said Dr. Stephen Lane, Chief Medical Officer, Alcon. “By evaluating parameters such as repositioning rates and YAG incidence due to posterior capsular opacification between different types of IOLs, we can provide surgeons with valuable information to enhance their clinical knowledge and patient outcomes. Being able to analyze such immense amounts of information has the ability to revolutionize clinical practice and demonstrates the value of the data in this registry along with Alcon’s commitment to providing the highest integrity data in the industry.”

Alcon will continue its commitment to evaluating its products with additional studies using the IRIS Registry in the future. For more information on the study findings presented at AAO, please visit AAO.org.

About the Studies

The studies relied on electronic health records (EHR) and physicians’ documentation in the EHR. There may be potential errors in documentation or variations among the different EHR systems. The follow-up of toric IOL repositioning or YAG due to PCO may not be captured in patients who changed their physician to one not participating in the IRIS Registry.

About AcrySof IOLs

The family of AcrySof® single-piece intraocular lenses (IOLs) includes AcrySof® UV-absorbing IOLs (“AcrySof® UV”), AcrySof® IQ, AcrySof® IQ Toric, AcrySof® IQ ReSTOR®**,** AcrySof® IQ ReSTOR® Toric, AcrySof® IQ PanOptix® and AcrySof® IQ PanOptix® Toric IOLs. Each of these IOLs is indicated for visual correction of aphakia in adult patients following cataract surgery. In addition, the AcrySof Toric IOLs are indicated to correct pre-existing corneal astigmatism at the time of cataract surgery. The AcrySof IQ ReSTOR IOLs are for cataract patients with or without presbyopia, who desire increased spectacle independence with multifocal vision. The AcrySof® IQ PanOptix® lens mitigates the effects of presbyopia by providing improved intermediate and near visual acuity, while maintaining comparable distance visual acuity with a reduced need for eyeglasses, compared to a monofocal IOL. All of these IOLs are intended for placement in the capsular bag.

Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting any IOL in a patient with any of the conditions described in the Directions for Use that accompany each IOL. Caution should be used prior to lens encapsulation to avoid lens decentration or dislocation. Physicians should target emmetropia, and ensure that IOL centration is achieved.

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