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ORIGINAL RESEARCH

IRIS® Registry (Intelligent Research In Sight) Analysis of the Incidence of Monovision in Cataract Patients with Bilateral Monofocal Intraocular Lens Implantation

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Purpose: To determine the incidence of pseudophakic monovision among patients bilaterally implanted with monofocal intraocular lenses (IOLs) and to characterize the distribution of myopic offsets achieved.

Patients and Methods: This retrospective database study included data on patients receiving care from ophthalmologists who contributed to the Academy IRIS® (Intelligent Research In Sight) Registry. Anonymized data were collected, including patient age, ethnicity, procedure data (CPT code, date, laterality), and postoperative manifest refractive spherical equivalent (MRSE) in both eyes implanted with monofocal or monofocal toric IOLs. No data regarding IOL manufacturer, model, or power were collected. One primary outcome measure was the percentage of patients achieving monovision (defined as emmetropia within ±0.25 diopters [D] in one eye and a myopic offset of ≥0.50 D in the fellow eye) among all patients receiving bilateral monofocal IOLs at the time of cataract surgery between January 1, 2016, and September 1, 2019, with at least 90 days of follow-up. Other primary outcomes included the distribution and frequency of myopic offsets (anisometropia) between eyes.

Results: Of the 16,765 people receiving bilateral monofocal IOLs within the study period, 4796 (28.6%) achieved emmetropia in at least one eye, as defined by an MRSE within ± 0.25 D. The incidence of monovision among these patients was 34.2% (1638/4796). One-quarter (24.7%; 405/1638) of patients who achieved monovision had a myopic offset between 0.50 and 0.74 D, with more than one-third (35.2%; 576/1638) falling within 0.75–1.24 D and 18.0% within 1.25–1.74 D. A myopic offset ≥1.75 D was observed in 22.1% (362/1638) of patients who achieved monovision.

Conclusion: Pseudophakic monovision for presbyopia correction was achieved in ~34% of patients in the IRIS Registry bilaterally implanted with monofocal IOLs, with myopic offsets typically ranging from 0.5 to 1.24 D.

Keywords: presbyopia, monovision, monofocal IOLs, myopic offset, diopter correction

Introduction

Presbyopia, an age-related loss of accommodation resulting in reduction of near vision, is estimated to affect about 1.8 billion people worldwide,[1] with up to 50% having little to no correction.[1,2] Uncorrected presbyopia diminishes both productivity[3,4] and quality of life,[5] both of which are improved with presbyopia correction.[4,5] Uncorrected presbyopia in people aged <65 years has been estimated to reduce annual global productivity by more than US $25 billion, whereas this amount could be reduced to US $1.4 billion by correction of presbyopia.[3]

Options for presbyopia correction include spectacles, contact lenses, surgical procedures and pharmaceutical agents. One approach to presbyopia correction is monovision, in which one eye is corrected for distance vision and the contralateral eye is corrected for near vision using a myopic offset. Examples include monofocal contact lenses,[6] corneal refractive surgeries,[7] and pseudophakic monofocal intraocular lenses (IOLs).[6,8,9] An alternative approach is to restore multifocal vision to each eye, using, for example, bi-, tri-, and multifocal spectacles[6] and bi- and multi-focal contact

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lenses.[10] Alternatively, presbyopia can be corrected using multifocal refractive procedures that create a corneal multifocality to increase depth of focus with or without a corneal inlay;[7,11–13] multifocal, accommodating, and extended depth of focus (EDOF) IOLs;[14,15] and scleral expansion procedures.[12,16] Presbyopia can also be corrected by treatment with drugs, most of which are miotics that rely on the pupillary pinhole effect or are intended to restore crystalline lens flexibility.[17]

While advances in IOL technology have provided innovative means of correcting presbyopia with multifocal techniques, pseudophakic monovision remains a common solution to this high-prevalence problem. Since first reported in 1984,[18] studies have examined outcomes associated with pseudophakic monovision, in which one eye is targeted for emmetropia and the contralateral eye is targeted for modest myopia, thereby providing intermediate and/or near visual acuity (VA). Traditional monovision uses a myopic offset in the range of 1.75 to 3 D to produce equivalent distance and near VA outcomes compared with multifocal IOLs to increase spectacle independence,[9,19,20] but significantly reduces stereopsis.[9] Modified and mini-monovision have smaller myopic offsets and have worse near VA outcomes but better stereoacuity and binocular intermediate VA than traditional monovision.[9] Spectacle independence with monovision has been found to decrease over time, with one study reporting that 44% of patients were spectacle independent at 1 year, whereas only 22% were spectacle independent at 5 years.[21]

Despite the large number of options for presbyopia correction at the time of cataract surgery, surprisingly little is known regarding the frequency of pseudophakic monovision in large-scale, real-world settings. The present study describes the incidence of monovision achieved among patients included in the IRIS® Registry (Intelligent Research In Sight) database of the American Academy of Ophthalmology (Academy) who underwent cataract surgery and received bilateral monofocal or monofocal toric IOLs. The distribution and frequency of myopic offsets (anisometropia) among these monovision patients were evaluated.

Methods

This was an analysis of existing, anonymized data drawn from the IRIS Registry. The IRIS Registry is an ongoing database of real-world data extracted from the electronic health records (EHRs) of 440 million encounters between 74 million unique patients and over 15,000 ophthalmologists and the clinicians working in their practices between January 1, 2013, and April 1, 2022.[22] The database search and resulting data set were provided by Verana Health (San Francisco, CA, USA), the vendor designated by the American Academy of Ophthalmology. The study was conducted in accordance with the Declaration of Helsinki. An Institutional Review Board waiver is not applicable to the study because (i) the research and analysis was conducted on anonymized data in accordance with the deidentification standard promulgated under 45 CFR § 164.514 and (ii) no research was conducted on human subjects.

Data were drawn from the EHRs of adults aged ≥45 years with bilateral age-related cataract, as defined by International Classification of Diseases, Tenth Revision (ICD-10) diagnosis codes developed by the World Health Organization (Supplementary Table 1). Patients with other ICD-10 diagnosis codes were excluded (Supplementary Table 2). All included patients underwent bilateral cataract extraction with implantation of bilateral monofocal (including monofocal toric) IOLs, as defined by Current Procedural Terminology (CPT) codes maintained by the American Medical Association (Supplementary Table 3) between January 1, 2016, and September 1, 2019, with the maximum interval between fellow-eye surgery of ≤365 days. Other eligibility criteria included specification of laterality of both procedure codes, a minimum of two pre-operative visits before first-eye surgery and 90 days of follow-up after second-eye surgery with postoperative refractive data available for both eyes; one eye with postoperative spherical equivalent (SE) between +0.25 D and −0.25D inclusive; the fellow eye with a postoperative SE of ≤0.5 D; a difference in SE between the two eyes of ≥0.5 D; and the absence of disallowed CPT codes (Supplementary Table 4).

Data collected included age, gender, race/ethnicity, procedure data (CPT code, date, laterality), and postoperative manifest refractive SE (MRSE) in both eyes. No data regarding IOL manufacturer, model, or power were collected.

The primary outcome of this analysis was the incidence of monovision (defined as final refractive emmetropia (SE ± 0.25 D) in one eye and myopic offset or inter-eye difference in SE, of ≥0.5 D) among patients with bilateral monofocal IOL implantation. Secondary outcomes included the distribution and frequency of inter-eye myopic offsets among monovision patients. All outcomes were analyzed using descriptive statistics only. No formal power/sample size analysis was conducted a priori. The

final sample size consisted of all patients in the IRIS Registry database meeting the eligibility criteria of this study. All descriptive statistical analyses were performed using RStudio 1.2.5033 statistical software.

Results

This analysis identified 16,765 patients who underwent bilateral cataract surgery with bilateral monofocal IOL implantation within the study timeframe, with all required data available for both eyes (Figure 1). The demographic characteristics of these patients are shown in Table 1.

Of the 16,765 individuals receiving bilateral monofocal IOLs during the study period, 4796 (28.6%) achieved emmetropia in at least one eye, as defined by a refractive SE within ± 0.25 D. Moreover, 1638 patients achieved monovision with myopic offset ≥0.50 D in the second eye; the demographic characteristics of this latter subset are also presented in Table 1 and are similar to those in the larger group. The incidence of monovision (one eye within ± 0.25 D of emmetropia and the fellow eye with myopic offset of ≥0.5 D) among these patients was 34.2% (1638/4796).

Figure 2 shows the distribution of myopic offsets among the 1638 patients with monovision. There was a myopic offset between 0.50–0.75 D for 24.7% (405/1638) of patients, 0.75–1.24 D for 35.2% (576/1638), and 1.25–1.74 D for 18.0% (295/1638). A myopic offset ≥1.75 D was observed in 22.1% (362/1638) of monovision patients.

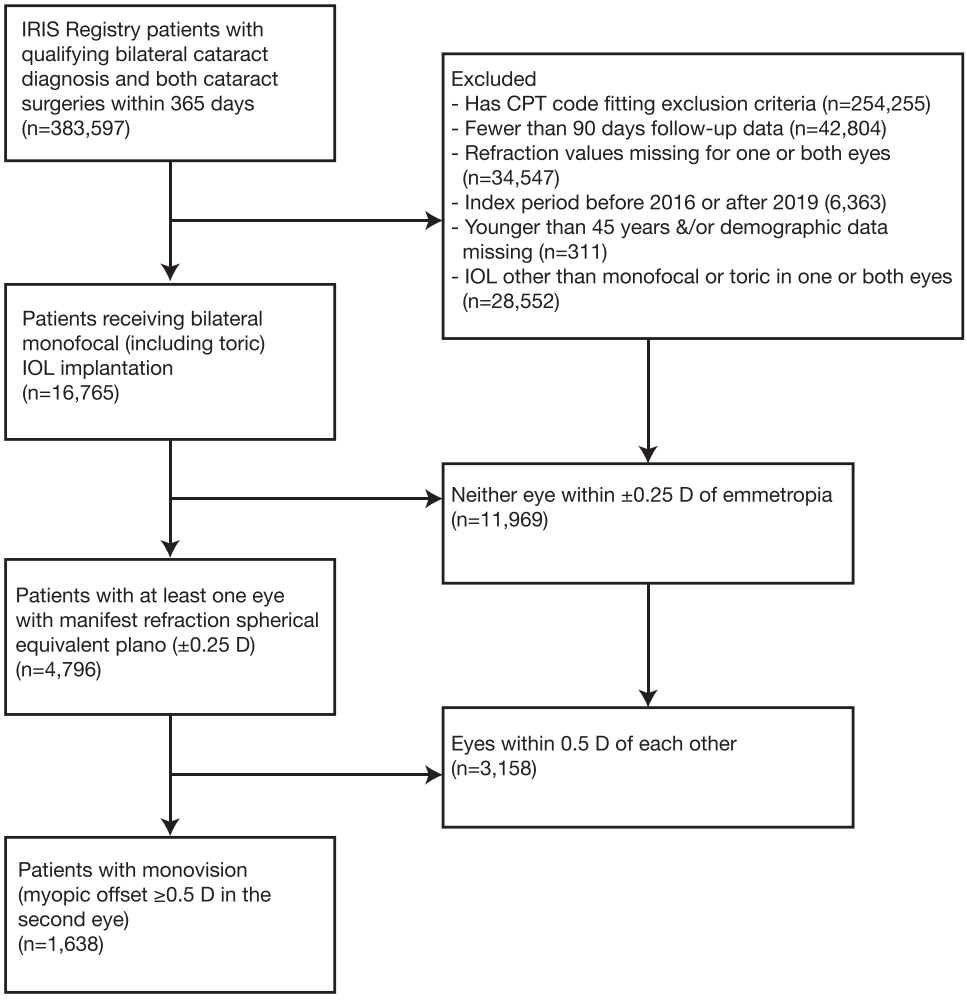

Figure 1 Study design: retrospective descriptive analysis of the IRIS clinical registry database.

Table 1 Demographic Characteristics of All Patients Receiving Bilateral Monofocal Intraocular Lens Implantation and the Subgroup Achieving Pseudophakic Monovision

	Patients with Bilateral Monofocal IOL Implantation (N=16,765)	Patients with Pseudophakic Monovision (N=1638)
Age, mean (SD)	70.3 (8.0)	70.1 (7.7)
Gender, n (%)		
Male	6364 (38.0)	599 (36.6)
Female	10,401 (62.0)	1039 (63.4)
Ethnicity		
White	13,600 (81.1)	1356 (82.8)
Black	660 (3.9)	45 (2.8)
Unknown	2505 (14.9)	237 (14.5)

Discussion

This analysis describes the achievement of pseudophakic monovision for presbyopia correction after bilateral cataract surgery using data from the IRIS Registry. Monovision (one eye with SE within ± 0.25 D of emmetropia and the fellow eye with a ≥ 0.5 D myopic offset) was achieved in ~34% of patients received bilateral monofocal IOL implantation.

These real-world findings from US cataract surgeons participating in the IRIS Registry are similar to other reports of pseudophakic monovision utilization, showing that monovision is still a common approach to manage presbyopia at the time of cataract surgery. Prior to the development of modern presbyopia-correcting IOLs, pseudophakic monovision was common, with 86% of surgeons in a 2003 survey of the American Society of Cataract and Refractive Surgery utilizing this technique.[23] A more recent 2017 survey of more than 1900 delegates of the European Society of Cataract and Refractive Surgery found that surgeons utilized monovision or mini-monovision for presbyopia correction in 43% of

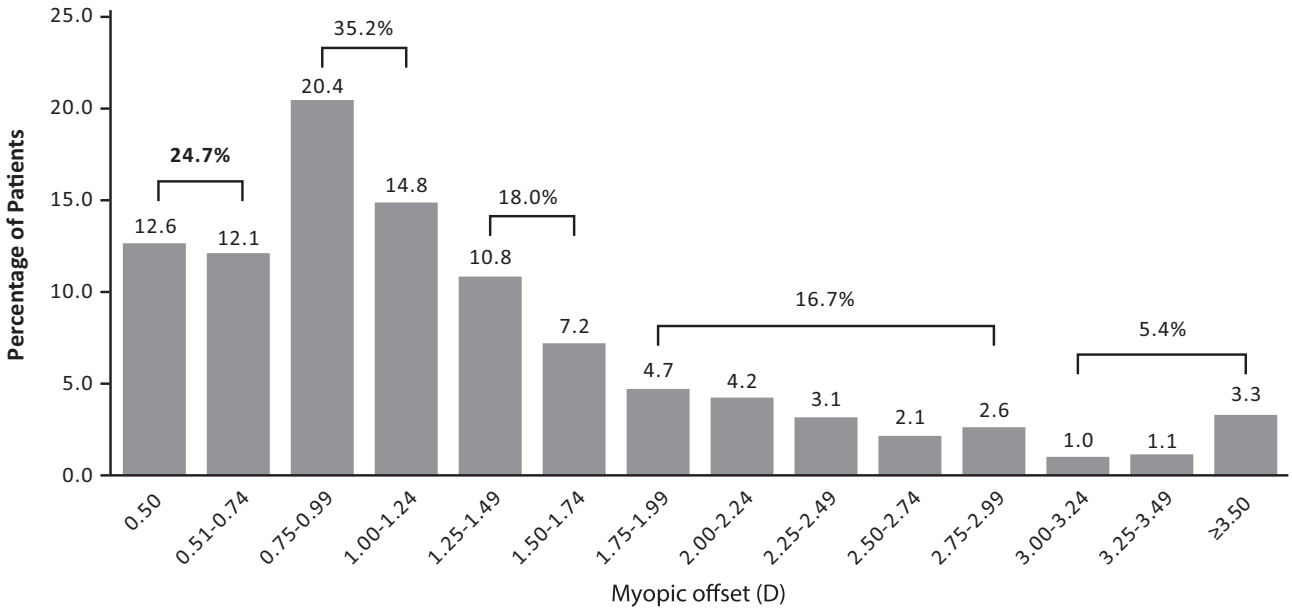

Figure 2 Frequency and distribution of myopic offsets among 1638 patients with pseudophakic monovision.

cataract procedures, whereas presbyopia-correcting IOLs were used in only 6% of procedures.[24] These findings were consistent with a 2019 survey of the ASCRS, in which 27% of cataract procedures involved use of pseudophakic monovision and only 10% utilized presbyopia-correcting IOLs.[25] The use of presbyopia-correcting IOLs has increased in recent years, as shown in a 2022 survey of the ASCRS, which reported that 17% of cataract procedures involved use of presbyopia-correcting IOLs, whereas 22% utilized pseudophakic monovision IOLs.[26]

Presbyopia-correcting IOL technology has advanced markedly over the past ten years. Compared with former generations of presbyopia-correcting IOLs, modern diffractive bifocal, trifocal, and EDOF IOLs have shown beneficial effects on spectacle independence and patient satisfaction.[15,27–29] Monovision with monofocal IOLs, which can provide some level of presbyopia correction, has limitations, however, with some patients showing low tolerance due to reduced binocularity and stereopsis, especially with traditional monovision, and relatively low and unsustainable spectacle independence.[30–34] The relatively high usage of monovision with monofocal IOLs in the present study and the relatively low adoption rate of presbyopia-correcting IOLs throughout the study period were somewhat surprising. The possible reasons include cost, as most patients must bear the added cost of premium IOLs over standard monofocal IOLs and the visual phenomena associated with diffractive IOLs, which can include glare, halos, and starbursts, as well as decreased contrast sensitivity.[15,20,35] Novel non-diffractive EDOF IOLs, which have been found to provide an extended range of vision, accompanied by a lower incidence of visual phenomena, as compared with diffractive EDOFs, may help increase the adoption of presbyopia-correcting IOLs.[36–38]

The target postoperative refraction and the preoperative intent to achieve monovision were not analyzed in the current EHR dataset due to lack of data availability. The present study defined monovision in refractive terms, rather than functionally, as an emmetropic eye and a myopic offset in the contralateral eye. The myopic offsets in near eyes ranged from 0.5 D to 10.125 D, with the majority (59.9%) falling between 0.50 D and 1.24 D, but only about one-fifth (22.1%) being ≥1.75 D. Offsets >3.0 D may, however, be associated with inaccurate IOL power calculations, because surgeons rarely target anisometropia >2.5D.[9] The myopic offsets observed in the present study were consistent with those reported in other studies, with a trend for smaller degrees of anisometropia to preserve stereopsis and minimize aniseikonia in recent years. Early studies evaluated myopic offsets of ≥2.0 D,[21,23,39–41] later studies explored the range of 1.5–2.0 D,[42,43] and more recent studies have evaluated offsets of 0.75–1.75 D.[44–49] These latter offsets were initially referred to as mini-monovision to distinguish them from the higher offsets used earlier. At present, however, offsets <1.0 D are considered mini-monovision.

Although this study was unable to analyze preoperative monovision intent and target postoperative refraction, this study found that 34% of the patients achieved monovision, as defined by at least one eye achieving emmetropia (postoperative MRSE within ± 0.25D) and a myopic offset ≥0.50 D in the contralateral eye. Of these patients, 35.2% and 24.7% had myopic offsets of 0.75 D–1.24 D and.0.5 D–0.74 D, respectively, a distribution consistent with current trends of modified or mini-monovision with monofocal IOLs.

The strengths of this study include its use of data from the IRIS Registry, reflecting the real-world practice of over 12,000 US ophthalmologists. The limitations include the incomplete participation of United States ophthalmology practices and hospital systems in the IRIS Registry. This observational dataset is subject to errors in EHR documentation, missing data, and miscoded diagnoses or procedures. Additionally, there is limited availability of data on preoperative planning including target postoperative refractions as well as binocular VAs at distance, intermediate, and near, which are not routinely tested in most patients.

Conclusions

In summary, this analysis of real-world data from the IRIS Registry database demonstrates that pseudophakic monovision was achieved for presbyopia correction in ~34% of eyes bilaterally implanted with monofocal IOLs, with 59.9% of myopic offsets in the range of 0.5–1.24 D.

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Disclosure

Dr Shamik Bafna is a key opinion leader for Alcon, Zeiss, and BVI, outside the submitted work. Mrs Helene Fevrier is an employee of Verana Health which was contracted to perform these analyses. Dr Xiaolin Gu and Dr Mohinder Merchea are employees of Alcon Vision, LLC. The authors report no other conflicts of interest in this work.

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