ORIGINAL RESEARCH Immediate Sequential Bilateral Cataract Surgery in Patients with Bilateral Visually Significant Cataracts

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Purpose: To report our experience of performing immediate sequential bilateral cataract surgery (ISBCS) in patients with visually significant cataracts and reduced preoperative corrected distance visual acuity (CDVA).

Methods: Data of patients who underwent ISBCS for visually significant cataracts and had preoperative CDVA <20/32 (<0.2 logMAR) in each eye were retrospectively reviewed. Refractive and visual outcomes were evaluated for the last available postoperative visit. Intraoperative and serious postoperative adverse events occurring within the first three months of surgery were reviewed.

Results: A total of 1335 patients (2670 eyes) were included in the analysis, with a mean age of 71.9 ± 9.5 years. On the last visit, 50.2% and 89.1% of eyes achieved uncorrected distance visual acuity (UDVA) $\geq 20/20$ (0.0 logMAR) and $\geq 20/32$ (0.2 logMAR), respectively. Of all eyes, 83.8% were within ±0.50D, and 96.4% were within ±1.00 D of emmetropia. Ten patients had postoperative bilateral ametropia of more than 1.00D in each eye, but eight of them still achieved binocular UDVA $\geq 20/40$. Intraoperative events occurred in 14 eyes of 13 patients (per-eye incidence: 0.524% or 1 in 191 eyes). A total of 86 postoperative adverse events occurred in 80 eyes of 53 patients (per-eye incidence 2.996% or 1 in 33 eyes), of which cystoid macular edema was the most common. Only three eyes had CDVA reduced by more than two Snellen lines compared to preoperative CDVA, two of which were not related to cataract surgery. There was no patient with bilateral CDVA loss.

Conclusion: In our cohort of patients with visually significant cataracts, ISBCS resulted in good refractive predictability and a low incidence of serious adverse events.

Keywords: immediate sequential bilateral cataract surgery, visual outcomes, refractive outcomes, adverse events

Introduction

Delayed sequential bilateral cataract surgery (DSBCS) has traditionally been considered to be the standard of care in the treatment of bilateral cataracts, with the primary reasons contributing to this decision being the potential risk of infection, blindness, and refractive surprise.^{1,2} However, there is growing evidence that same-day immediate sequential bilateral cataract surgery (ISBCS) is a safe alternative to DSBCS.³ ISBCS affords the patient a more rapid and comfortable visual recovery, reduced symptoms caused by DSBCS of induced anisometropia, and a reduction in costs and wait times for surgery.^{1,2,4} There is also a suggestion that same-day cataract surgery for both eyes has the potential to use financial, environmental, and human resources more effectively and also afford patients the opportunity to experience a faster return to binocular visual function.^{5–7}

The aim of this study is to report our experience of performing ISBCS in a large population of patients with visually significant cataracts with a reduced corrected distance visual acuity (CDVA) of 20/32 or less, focusing on the refractive predictability, visual outcomes, and adverse events rates.

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Patients and Methods

This study was deemed exempt from review by the University of California, San Francisco Institutional Review Board because it used only retrospective, de-identified patient data. All patients provided full informed consent to undergo cataract surgery as well as to have their de-identified information used for statistical analysis and research purposes. The study adhered to the tenets of the Declaration of Helsinki.

The electronic medical record of Optical Express (Glasgow, United Kingdom) was searched to identify patients who underwent bilateral same-day surgery for visually significant cataracts (corrected distance visual acuity 20/32 or worse in each eye) between January 2019 and November 2022. Patients' demographics, preoperative and postoperative clinical data, as well as intraoperative and serious postoperative adverse events occurring within the first three months of surgery were extracted from the electronic medical record. The main focus was on adverse events that manifest in the early postoperative period, have the potential to become sight-threatening and could potentially lead to bilateral reduction in visual acuity. Thus, the aim was to identify early adverse events that could have been diagnosed and managed had there been a delay between the first and the second eye. Late-onset postoperative events have not been evaluated because these have the same potential to affect patients bilaterally whether the patient has ISBCS or DSBCS.

The pros and cons of bilateral same-day vs delayed sequential surgery were discussed with the patients and they were given the opportunity to choose between the two approaches. Patients with hypermature cataracts or those with significant ocular co-morbidities that were more likely to lead to intraoperative or serious postoperative complications were not offered bilateral same-day surgery.

All patients underwent a full ophthalmic examination including but not limited to manifest refraction, visual acuity testing, anterior eye slit lamp examination, and dilated fundus examination. Diagnostic scans included autorefraction and tonometry (Tonoref II, Nidek Co. Ltd., Gamagory, Japan), corneal tomography (Pentacam, Oculus Optikgeräte GmbH, Wetzlar, Germany), endothelial cell count (SP 2000P specular microscope, Topcon Corp, Tokyo, Japan), biometry (IOLMaster 700, Carl Zeiss Meditec AG, Jena, Germany) and retinal optical coherence tomography (Cirrus 4000/5000 OCT, Carl Zeiss Meditec AG, Jena, Germany). Preoperative and postoperative visual acuity measurements included monocular corrected distance visual acuity (CDVA) and monocular and binocular uncorrected distance (UDVA) visual acuity.

Surgeries were performed with standard phacoemulsification, and the surgical procedure followed the recommendations of the "General Principles for Excellence in ISBCS".⁸ The surgeries were performed by 18 surgeons in 17 surgical centers across the United Kingdom. When deciding on the treatment sequence of the two eyes, the first treated eye was typically the worse eye according to the surgeon's clinical judgment (eg, the eye with poorer corrected visual acuity or more advanced cataract). If the two eyes were similar, the non-dominant eye was treated first. Intracameral cefuroxime was used at the end of surgery as a prophylaxis for endophthalmitis (with the exception of patients with proven penicillin allergy, where moxifloxacin was used).

The standard postoperative regimen included 250mg acetazolamide tablet per oral taken 4–6 hours after discharge, topical broad-spectrum antibiotic drops (levofloxacin 5mg/mL) for 2 weeks (every two hours for the first 24 hours and then four times a day for the remaining 13 days), and topical steroid drops (dexamethasone 0.1%) for four weeks (every two hours for the first 24 hours, four times a day for 13 days and three times a day for further 14 days).

Statistical Analysis

The analysis of refractive and visual outcomes was based on the last available follow-up visit of each patient and included only patients that reached a minimum of one-month follow-up. The incidence of adverse events was calculated for all patients in the cohort (regardless of the follow-up length) and included intraoperative events and serious postoperative events that occurred within the first three months of surgery. The standards for reporting outcomes of lens-based surgery were used to present the clinical outcomes of the study group.⁹ All calculations were performed in Microsoft Excel (Microsoft Corp.).

Results

The study included 1335 patients (2670 eyes), of whom 1192 patients (89.3%) reached a minimum of one-month postoperative visit. The mean age of the study group was 71.9 ± 9.5 years (median 73 years, range 34 to 96 years). Of all patients, 758 (56.8%) were male and 577 (43.2%) were female.

The mean axial length of the study group was 23.82 ± 1.34 mm (median 23.68 mm, range 19.85 to 29.75 mm). Of all eyes, 182 (6.8%) had an axial length shorter than 22.00 mm, 2308 eyes (86.4%) had an axial length between 22.00 and 26.00 mm and the remaining 180 eyes (6.7%) had an axial length longer than 26.00 mm. Most of the eyes (99.7% or 2662 eyes) had a monofocal lens implant, while only 8 eyes (4 patients, 0.3%) had an extended depth of focus or a low near addition multifocal IOL. A non-toric IOL was used in 2162 eyes (81.0%), and a toric IOL was used in 508 eyes (19.0%). Demographics of the study group, preoperative and postoperative clinical outcomes are summarized in Table 1.

Visual and Refractive Outcomes

Visual and refractive outcomes were calculated for a group of patients who reached at least one-month follow-up visit. The mean follow-up of this group of patients was 3.3 ± 3.4 months (range 1 to 15 months). Figure 1 depicts standard graphs for reporting outcomes of lens-based surgery in the cataract population. Of all eyes, 50.2% (1196/2384) and 89.1% (2123/2384) achieved postoperative monocular UDVA 20/20 and 20/32 or better, respectively (Figure 1A). Binocularly, UDVA of 20/20 and 20/32 or better was achieved in 72.7% (866/1192) and 96.6% (1152/1192) of patients, respectively.

Of all eyes, 83.6% (1992/2384) had their postoperative monocular UDVA within one Snellen line of their postoperative CDVA (Figure 1B). The mean CDVA changed from a preoperative value of $0.48 \pm 0.41 \log MAR$ ($\approx 20/60$) to $0.02 \pm 0.15 \log MAR$ ($\approx 20/20^{-2}$).

Figure 1C depicts the distribution of postoperative manifest spherical equivalent. Of all eyes, 83.8% (1998/2384) were within $\pm 0.50D$, while 96.4% (2299/2384) were within ± 1.00 D of emmetropia. The mean postoperative manifest spherical equivalent of the study group was $\pm 0.02 \pm 0.47$ D. Of the eyes that reached one month follow-up, eyes with a toric IOL had a slightly lower percentage of eyes within ± 0.50 D of emmetropia: 84.5% (1624/1922) of eyes with a non-toric IOL and 81.0% (374/462) of eyes with a toric IOL were within ± 0.50 D of emmetropia, but the difference did not reach statistical significance (p = 0.06). However, eyes with toric and non-toric IOLs had a very comparable

	Preoperative	Last Follow-Up* (3.3±3.4 Months)	P value*
No of eyes (patients)	2670 (1335)	2384 (1192)	n/a
Age [years] Mean ± SD (Median) Range	71.9 ± 9.5 (73) 34, 96	n/a	n/a
Male/Female (%)	56.8%/43.2%	n/a	n/a
Sphere [D]	-0.27 ± 3.20 (0.0)	+0.33 ± 0.51 (0.25)	<0.01
Mean ± SD (Median) Range	-19.00, +10.00	-3.50, +3.25	
Cylinder [D]	-0.99 ± 0.87 (-0.75)	-0.61 ± 0.50 (-0.50)	<0.01
Mean ± SD (Median) Range	-8.00, 0.00	-4.75, 0.00	
MSE [D]	-0.77 ± 3.23 (-0.50)	+0.02 ± 0.47 (0.00)	<0.01
Mean ± SD (Median) Range	-20.88, +9.00	-3.88, +2.38	
Monocular UDVA [logMAR]	0.98 ± 0.59 (0.80)	0.09 ± 0.18 (0.10)	<0.01
Mean ± SD (Median) Range	0.18, 3.00	-0.18, 1.30	
Binocular UDVA [logMAR] Mean ± SD (Median) Range	n/a	0.01 ± 0.12 (0.00) -0.18, 1.00	n/a
Monocular CDVA [logMAR]	0.48 ± 0.41 (0.40)	0.02 ± 0.15 (0.00)	<0.01
Mean ± SD (Median) Range	0.20, 2.70	-0.18, 1.30	

Table I Preoperative and Postoperative Clinical Data of the Study Group

Note: *Calculated for eyes that reached a minimum of one-month postoperative visit.

Abbreviations: SD, standard deviation; D- diopter; MSE, manifest spherical equivalent; UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; logMAR, logarithm of the minimum angle of resolution.

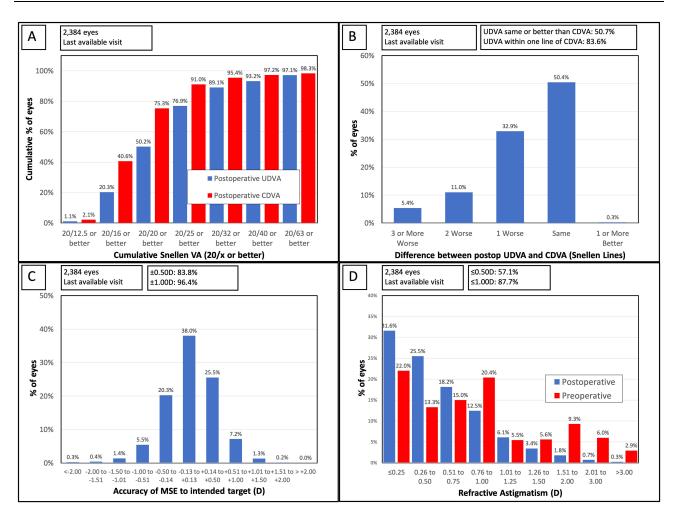


Figure I Refractive and visual outcomes of patients with a minimum of one-month postoperative visit. Outcomes are based on the last available follow-up visit (mean follow-up 3.3 ± 3.4 months). (A) Cumulative postoperative monocular uncorrected (UDVA) and corrected (CDVA) distance visual acuity; (B) A histogram of the difference between postoperative UDVA and postoperative CDVA; (C) The distribution of postoperative manifest spherical equivalent (MSE). (D) The distribution of preoperative and postoperative refractive astigmatism.

percentage of eyes within ± 1.00 D of emmetropia: 96.4% (1853/1922) of non-toric IOL eyes and 96.5% (446/462) of toric IOL eyes were within ± 1.00 D of emmetropia; p = 0.90.

Figure 1D shows the distribution of preoperative and postoperative refractive cylinder. Postoperatively, 57.1% (1361/ 2384) of eyes had refractive cylinder $\leq 0.50D$, while 87.7% (2091/2384) of eyes had refractive cylinder $\leq 1.00D$.

Postoperative Bilateral Ametropia

Ten patients (0.84% or 10/1192) had postoperative bilateral ametropia of more than 1.00 D in each eye. No patients had postoperative bilateral ametropia of more than 1.50 D in each eye. Eight out of 10 patients with postoperative bilateral ametropia still achieved postoperative binocular UDVA of 20/40 or better. Of the ten patients with bilateral refractive surprise, two subsequently elected to undergo laser vision correction for treatment of the ametropia.

Adverse Events

Table 2 shows the summary of all intraoperative and postoperative adverse events recorded within the first 3 months.

Intraoperative Adverse Events

Intraoperative events occurred in 14 eyes of 13 patients (per-eye incidence: 0.524% or 1 in 191 eyes, per-patient incidence 0.974% or 1 in 103 patients). Posterior capsule (PC) tear occurred in 5 eyes (per eye incidence; 0.187% or 1 in

Table 2 Intraoperative and Postoperative Adverse Events

	Per-Eye Incidence Number of Eyes (%) Incidence (I in Eyes)	Per-Patient Incidence ^a Number of Patients (%) Incidence (I in <u>Patients</u>)	Bilateral Incidence ^b Number of Patients (%) Incidence (I in <u>Patients</u>)
Intraoperative Events			
Posterior capsule tear	5 (0.187%) 1:534	5 (0.375%) 1:267	0%
Torn iris	5 (0.187%) 1:534	4 (0.300%) 1:334	I (0.075%) I:I335
Dropped nucleus	I (0.037%) I:2670	I (0.075%) I:I335	0%
Zonule dialysis	I (0.037%) I:2670	I (0.075%) I:I335	0%
Zonule rupture - Vitreous loss	I (0.037%) I:2670	I (0.075%) I:I335	0%
Surgical equipment failure	I (0.037%) I:2670	I (0.075%) I:I335	0%
Postoperative Events			
Cystoid macular edema CME diagnosed with optical coherence tomography within the three postoperative months and persisting for longer than 1 month	32 (1.199%) 1:83	21 (1.573%) 1:64	(0.824%) : 2
Corneal edema Surgery-related corneal edema persisting for longer than 1 month postoperatively.	21 (0.787%) 1:127	13 (0.974%) 1:103	8 (0.599%) 1:167
Elevated IOP Intraocular pressure raised by > 10mmHg compared to preoperative level on more than one occasion during the three postoperative months.	(0.412%) 1:243	9 (0.674%) 1:148	2 (0.15%) 1:668
Persistent anterior uveitis Anterior uveitis with the onset within the first postoperative month, persisting for longer than 4 weeks	12 (0.449%) 1:223	7 (0.524%) 1:191	5 (0.375%) 1:267
Decentred intraocular lens Clinically significant decentration of IOL causing visual symptoms	3 (0.112%) 1:890	3 (0.225%) 1:445	0%
Posterior uveitis	3 (0.112%) 1:890	2 (0.150%) 1:668	I (0.075%) I:I335
Retinal detachment	I (0.037%) I:2670	I (0.075%) I:I335	0%
Wound leak Post-surgical wound leak requiring management.	I (0.037%) I:2670	I (0.075%) I:I335	0%
Macular hole	I (0.037%) I:2670	I (0.075%) I:I335	0%
Retinoschisis	I (0.037%) I:2670	I (0.075%) I:I335	0%
Endophthalmitis	0%	0%	0%
Toxic anterior segment syndrome	0%	0%	0%

Notes: ^aNumber of patients who experienced the adverse event at least in one eye. ^bNumber of patients with the same adverse event occurring in both eyes. **Abbreviations**: CME, cystoid macular edema; IOP, intraocular pressure; IOL, intraocular lens.

534 eyes; per patient incidence 0.375% or 1 in 267 patients). Of the 5 eyes with PC tears, 2 needed a vitrectomy, and 1 eye was already vitrectomised following previous retinal detachment surgery. At the last postoperative appointment, 3 eyes had UDVA of 20/20, 1 had a UDVA of 20/25 corrected to 20/20, and 1 eye had a UDVA and CDVA of 20/25.

There was one eye with a dropped nucleus that underwent a vitrectomy, lensectomy, and anterior chamber-fixated implant with the final postoperative UDVA and CDVA of 20/25 compared to the pre-operative CDVA of 20/100.

Other intraocular events (occurring in one eye each) were zonule dialysis, zonule rupture, and surgical equipment failure. Torn iris was recorded in 5 eyes of 4 patients, and it was the only intraoperative AE that was recorded bilaterally in one patient.

Postoperative Adverse Events

A total of 86 postoperative adverse events occurred in 80 eyes of 53 patients (per-eye incidence 2.996% or 1 in 33 eyes, per-patient incidence 3.970% or 1 in 25 patients). No patient developed endophthalmitis.

Most of the postoperative events were those expected after cataract surgery, with cystoid macular edema and corneal edema having the highest occurrence (Table 2).

Loss of More Than Two Lines of Corrected Distance Vision

Of all patients who attended a minimum of one month follow-up, only three eyes had CDVA reduced by more than two Snellen lines compared to preoperative CDVA. The reasons for CDVA loss were as follows: case 1 - worsening of preexisting age-related macular degeneration, case 2 - displaced IOL postoperatively, requiring intervention, case 3 - development of central retinal artery occlusion. All three cases were unilateral and had the UDVA 20/25 or better in the fellow eye at the last available visit.

Discussion

The aim of this study was to report adverse events rates, as well as refractive and visual outcomes in a cohort of ISBCS cataract patients with preoperative reduced CDVA of 20/32 or less. Historically, concerns in offering same-day surgery to cataract patients revolved around safety, visual outcomes, and refractive surprise post-treatment, with the delayed approach allowing for adjustments to the IOL power on the second eye.^{10,11}

In the literature reports, safety concerns have largely been mitigated by the dramatic reduction in endophthalmitis rates with the adoption of intracameral antibiotics^{12–14} and with adherence to the ISBCS General Principles for Excellence.⁸ The remaining outstanding major criticism of ISBCS has been the refractive accuracy.^{15,16}

While this study included cataract patients with CDVA worse than 20/32, our results demonstrate that 89.1% of patients achieved UDVA of 20/32 or better monocularly, improving to 96.6% achieving at least 20/32 UDVA binocularly. Of all eyes, 83.6% had their postoperative monocular UDVA within one Snellen line of their postoperative CDVA.

Refractive predictability was good, with 83.8% of all eyes within ± 0.50 D, while 96.4% were within ± 1.00 D of emmetropia. The mean postoperative manifest spherical equivalent of the study group was $\pm 0.02 \pm 0.47$ D. Only 0.84% (n=10) of patients had postoperative bilateral ametropia of more than 1.00 D in each eye, with eight out of 10 patients with postoperative bilateral ametropia still achieving postoperative binocular UDVA of 20/40 or better. This is within the expected outcomes of surgery utilizing modern biometry and formulas performed with DSBCS.¹⁷

A study utilizing the Intelligent Research in Sight (IRIS) database in the United States found that patients undergoing ISBCS had, on average, a slight reduction in postoperative UDVA and CDVA compared to DSBCS patients.¹⁶ These study results are likely not generalizable to the wider population as the adoption of ISBCS in the US has been hampered by reimbursement issues, and many practitioners confine the use of ISBCS to medically complex cases.¹⁸ In contrast, a study of ISBCS versus DSBCS in the Kaiser population in the US found no difference in refractive outcomes.¹⁹

These risks, whether substantiated or not, must be weighed against the risks of delayed surgery. This includes the risk of induced anisometropia and worsened stereopsis leading to the risk of falls following first eye surgery, especially in the elderly population. In a study by Keay et al,²⁰ the risk of injurious falls halved after the second eye surgery in a population of ≥ 65 years old patients with bilateral visually significant cataracts. The authors concluded that first eye surgery substantially improved vision in older patients with cataracts, but second eye surgery is required to minimize fall incidence. In a large population of almost 30,000 elderly patients, Meuleners et al²¹ found that the risk of injurious falls requiring hospitalization was the highest between first and second eye surgery, with the greatest risk being within the first five months after the first eye surgery.

Other studies also reported numerous benefits after the second eye surgery, such as improved stereopsis^{22,23} or better patient-reported outcomes.^{22,24} Additionally, Lundstorm et al²⁴ evaluated the reasons why some patients reported more difficulties following cataract surgery and found that approximately a third of the cases reporting "no benefit" of cataract surgery were those who had anisometropia and problems with the non-operated eye following the first eye surgery. Another commonly discussed aspect is the effect of time delay of cataract surgery on mental health. A population-based study found that shortening the time interval between the first and second eye operation had a positive impact on mental health and was significantly correlated with the reduced number of mental health consultations.²⁵

Our study reports relatively low incidence of adverse events; however, the population was not large enough to establish the rates of some rare adverse events, such as endophthalmitis. The per-eye intra-operative adverse event rate was 0.524%, and the postoperative per-eye incidence was 2.996%. This is in line with prior studies of ISBCS, with the exception of a reduced posterior capsular rupture rate in our study.^{5,19,26} Postoperative events in our study population were those that are expected following cataract surgery in this particular age group. Although we have not performed a direct comparison to a DSBCS group, various studies reported the intra-operative and post-operative complication rates being similar when comparing ISBCS to DSBCS.^{19,27,28}

Only 3 eyes had a CDVA reduced by more than two Snellen lines compared to preoperative CDVA. Two of these were not related to the cataract surgery (pre-existing age-related macular degeneration and development of central retinal artery occlusion). However, the loss of CDVA in 1 eye was attributed to a displaced IOL post-operatively that required surgical intervention. More important, there was no bilateral vision loss of more than two Snellen lines.

Recognizing that the occurrence of endophthalmitis has historically remained a barrier to many surgeons adopting an ISBCS approach, in this study, there was no occurrence of endophthalmitis. However, a larger study group may be needed to reveal the true rate of this sight-threatening complication in cataract patients with reduced CDVA undergoing ISBCS. Although there have been sporadic reports of bilateral endophthalmitis following ISBCS, most of them were related to inappropriate aseptic techniques.^{29,30} To date, there have been very few cases of bilateral endophthalmitis in ISBCS patients where all surgical recommendations have been followed,²⁹ making the calculation of the true incidence rate difficult.

Some study limitations need to be acknowledged. The retrospective design of the study has its inherent limitations and provides a lower level of evidence compared to prospective studies. A comparison to a control group of patients with delayed sequential surgery would be beneficial, especially for the comparison of bilateral ametropia rates. However, most patients who undergo DSBCS in our clinical practice are those who are unsuitable for immediate sequential surgery, and their preoperative characteristics are not comparable to ISBCS patients. The sample was relatively homogenous in terms of IOL selection, as most of the patients had monofocal IOLs. This is due to the fact that monofocal IOLs are often the main choice in patients with poorer preoperative corrected visual acuity in our practice. Assessing the refractive accuracy of ISBCS in patients with premium IOLs would be beneficial, but this has already been addressed in our previous study in a population of refractive lens exchange patients.³

A small proportion of patients included in the adverse event count did not reach 1-month postoperative visit, and this could be a potential limitation of this study. However, these patients were mostly those who achieved very good outcomes in the early postoperative period and did not want to return for further follow-ups. Quite often (mainly during the Covid-19 pandemic), these patients were followed with a telemedicine consultation (a phone call), questioned about changes in their visual acuity and symptoms, and were advised to return to the clinic when experiencing any problems. However, a larger study population is needed to yield the true rate of endophthalmitis.

Conclusions

In a relatively large cohort of patients with visually significant cataracts, we have not observed any complications that would lead to bilateral vision loss. We believe the growing literature evidence of ISBCS safety will add to the acceptance of this approach among surgeons and increase the efficiency of cataract surgery.

Disclosure

Dasi Raju, Stephen Hannan, Mirna Belovari, Noelle Hannan, Colin Berry, Jan Venter, and David Teenan are employees of Optical Express. Steven Schallhorn is a chief medical officer for Carl Zeiss Meditec and a chairman of medical

advisory board for Optical Express. Julie Schallhorn received personal fees from Carl Zeiss Meditec, Allergan, ViaLase, Long Bridge, and Forsight V6 and has a financial interest in Journey 1, Neurotrigger, and Novus Vision. The authors report no other conflicts of interest in this work.

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