Evaluation of clinical outcomes following implantation of a sub-2-mm hydrophilic acrylic MICS intraocular lens

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Abstract

Purpose To evaluate clinical outcomes following sub-2-mm microincision cataract surgery (MICS) and intraocular lens (IOL) implantation.

Setting Five EU clinical sites.

Design Prospective, multicenter, open-label, single arm, non-randomized.

Methods Preoperative assessment involved visual acuity (VA), intraocular pressure and biometry measurements. 1.4-mm wound-assisted or 1.8-mm MICS was performed. Follow-up visits were made 1 day, 1–2 weeks, 1–2 and 4–6 months after surgery. The incision size, corrected distance VA (CDVA), uncorrected distance VA, manifest refraction spherical equivalent (MRSE), refraction predictability/stability and IOL decentration were assessed. At 12-, 18-, and 24-month, long-term centration, posterior capsular opacification (PCO) and Nd:YAG capsulotomy rates were investigated.

Results A total of 103 eyes were implanted with the study IOL (INCISE, Bausch & Lomb), 96 of which were included in visual outcome analysis. A mean 6-month CDVA of - 0.02 logMAR (20/20 ? 1) was observed and 75 eyes (79.8%) and 93 eyes (98.3%) achieved a visual acuity of at least 20/20 or 20/40. Mean MRSE was - 0.20 ± 0.60 D. Mean absolute predictive error was 0.44 ± 0.36 D, with 90.4% within 1.00 D of target. Mean total decentration was 0.35 ± 0.36 mm at 6 months and 0.32 ± 0.14 mm at 24 months (p[0.05). 24-month evaluation of posterior capsular opacification score was 0.03 for the central area. A Nd:YAG rate of 3.4% was observed at 24 months.

Conclusions The new MICS IOL provided excellent visual outcomes and was safe and effective for the sub- 2-mm procedure. The MICS IOL demonstrated longterm centration, stability and a low rate of PCO development.

Keywords Intraocular lens _ Implantation _Microincision cataract surgery

Introduction

Cataract surgery remains a curative intervention for restoring visual clarity and quality to cataract patients. However, it is a procedure that carries a risk of adverse effects, including surgically induced astigmatism, iris prolapse and decreased corneal optical quality due to higher-order aberrations (HOAs) [1]. Microincision cataract surgery (MICS), performed through an incision of less than 2 mm, has been developed as a method of minimizing corneal trauma and providing better postoperative outcomes than standard small incision phacoemulsification [2]. There are several forms of MICS available, and all have varying incision sizes. Biaxial microincision (BMICS) allows 1.5 mm or smaller incisions, while coaxial microincision (C-MICS), which is similar to the usual standard phacoemulsification technique, is used for incisions of 1.8 mm [3–6]. Published literature has shown that MICS offers improved control of surgically induced astigmatism and effective phacoemulsification time compared with standard small incision phacoemulsification [7]. Additionally, the control of surgically induced HOAs and better preservation of the optical quality of the cornea allow for further advantages of MICS, such as reduction in surgical trauma and less corneal biomechanical changes leading to an improvement in visual outcomes and patient satisfaction [8, 9].

However, current injection constraints (i.e., IOLs, inserters, and cartridges) make implantation of IOLs only possible via a wound-assisted technique. In this technique, the cartridge bevel does not enter the anterior chamber and it is currently the only injection technique that allows for the smallest incisions (i.e., \ 1.8 mm). A new microincision acrylic aspheric one-piece IOL (INCISE, Bausch & Lomb, USA) is optimized for implantation in the capsular bag through incisions of less than 2 mm. The lens has a lower water content (22%) than most MICS hydrophilic lenses on the market (25–26%). It is thought that this makes it stiffer and more resistant to tearing while passing through a 1.4-mm incision. It was designed to minimize PCO as evidenced by its sharper 360 degree posterior barrier edge with a 5 micron radius. The purpose of this study was to prospectively evaluate clinical outcomes following sub-2 mm MICS IOL implantation in cataract surgery using both conventional and wound-assisted implantation techniques.

Methods

Eligible subjects were scheduled to undergo microincision phacoemulsification cataract surgery and IOL implantation. Five clinical sites in the European Union (EU) were enrolled in this clinical investigation. The study eye was designated at the discretion of the investigator. All investigative sites had Ethics Committee (EC) approval before recruiting potential subjects. All patients provided a signed informed consent.

This study was conducted in compliance with the protocol and in accordance with the Declaration of Helsinki, ISO 14155 (2011) Clinical Investigation of Medical Devices for Human Subjects, 42 USC 282(j), ICH GCPs, and applicable local regulations. The study included patients who met the following criteria: age 40 years or above with clinically significant cataract requiring phacoemulsification and IOL implantation with IOL power from 15 to 30 D. A clear cornea media and ability for the pupil to dilate to at least 6.5 mm in diameter (as measured with the pupil gauge) were also inclusion criteria in this study. Exclusion criteria included predisposing sightthreatening ocular conditions, evidence of iris or choroidal neovascularization, a history of corneal or retinal surgery, glaucoma, optic atrophy, anterior segment pathology, associated ocular conditions which could affect the stability of the intraocular lens in the study eye (zonulolysis, defect zonules, evident zonular weakness or dehiscence), those taking medications known to potentially

complicate cataract surgery (e.g., a 1a-selective alpha blocker), as well as patients with preoperative corneal astigmatism [1.5 D and cataract severity grade 4 (Table 1).

Table 1 Patient demographics for safety set and Per-Protocol Set

	Safety set (n = 103)	Per-Protocol Set (n = 96)
Age (years)		
Mean (SD)	71.5 (7.6)	72.1 (6.9)
Median	72	73
Min, max	48, 86	53, 86
< 60	7 (6.8%)	5 (5.2%)
60–69	31 (30.1%)	28 (29.2%)
70–79	52 (50.5%)	51 (53.1%)
≥ 80	13 (12.6%)	12 (12.5%)
Gender		
Female	61 (59.2%)	57 (59.4%)
Male	42 (40.8%)	39 (40.6%)
Study eye		
OD	58 (56.3%)	54 (56.3%)
OS	45 (43.7%)	42 (43.8%)
Fellow eye		
Normal	7 (6.8%)	7 (7.3%)
Cataract	68 (66.0%)	63 (65.6%)
Pseudophakic	27 (26.2%)	25 (26.0%)
Aphakic	1 (1.0%)	1 (1.0%)

Preoperative assessment

All patients had a complete preoperative ophthalmic examination including corrected distance visual acuity (CDVA), subjective refraction, biomicroscopy of the anterior and posterior eye segments, dilated pupil size diameter and IOP measurement. Optical biometry (IOL-Master, Jena, Carl Zeiss Meditec AG) was performed in 96.1% of cases. Immersion ultrasound and the contact ultrasound technique were used in 1 and 3 eyes. The SRK/T formula was used for calculating the IOL power and target refraction was aimed as close to emmetropia as possible. Cataracts were classified preoperatively using the 4 grading scales of lens opacities classification system (LOCS) III: nuclear opalescence (NO), nuclear color (NC), cortical cataract (C), and posterior subcapsular cataract (P).

Study intraocular lens

The microincision IOL (INCISE, Bausch & Lomb, USA) is a one-piece foldable hydrophilic acrylic aspheric lens that must be implanted in the capsular bag (Fig. 1 a, b). The lens material is a copolymer of HEMA, and MMA, with water content lower than that of other

hydrophilic acrylic IOLS (22%). It has an ultraviolet (UV) absorber allowing a 10% UV cutoff C 370 nm for a lens of 20 D. The lens has aberration free aspheric optics on both the anterior and posterior surface and four angulated haptics. It also has two orientation features (on a topright– bottom-left axis) to aid in appropriate loading of the lens. The lens has a 5 l m radius 360_ posterior square barrier edge (Fig. 1 c).

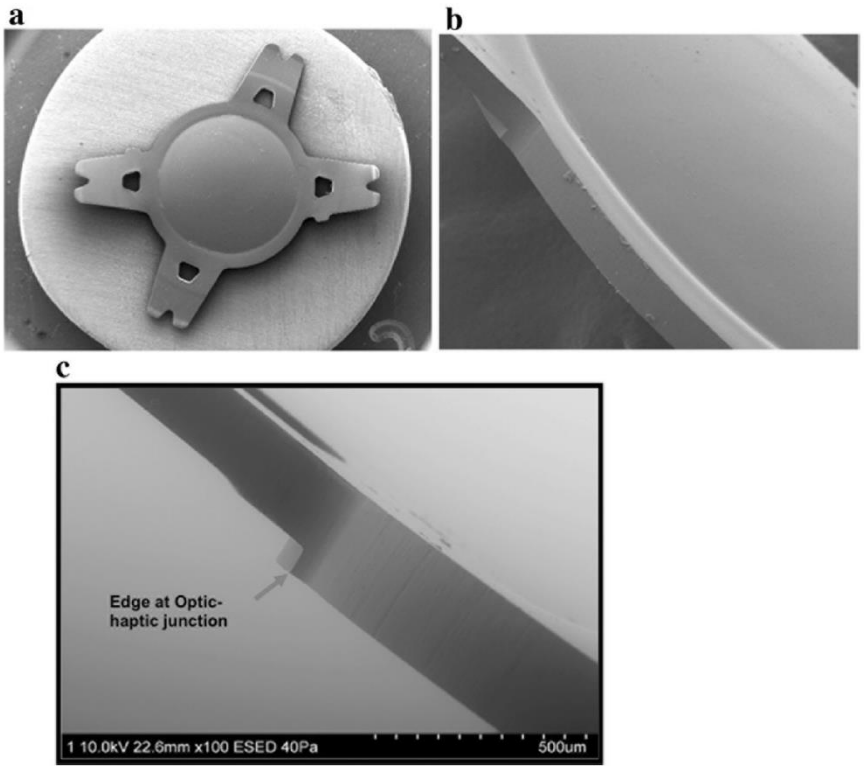

Fig. 1 SEM schematic of the microincision INCISE IOL (high magnification). **a** Overview, by courtesy of Prof B. Dick. **b** Details of optic, by courtesy of Prof B. Dick. **c** Detail of posterior sharp-edge design, by courtesy of Prof D.J. Spalton

Surgical technique

All cataract surgeries were performed using the Stellaris Vision Enhancement System (Bausch ? Lomb, USA), and the study lens was implanted through a clear corneal incision, using the VISCOJECT 1.5 single-use injector (Medicel, Switzerland). All eyes either underwent B-MICS or C-MICS. For B-MICS, the lens was implanted using the wound-assisted technique (tip of the cartridge at the edge of the incision) through an approximate 1.4-mm incision using either the 1.4-mm angled (Beaver- Visitec, UK) or the 1.5–1.7-mm angled (Storz, Germany) calibrated knives. For C-MICS, the study lens was implanted with the tip of the cartridge entering in the anterior chamber through an approximate 1.8-mm incision using 1.6–1.8-mm angled calibrated knives (Storz, Germany). The incision

size chosen for each patient was determined by the current surgical technique of the operating surgeon: biaxial (1.4 mm) and coaxial (1.8 mm) technique. Incision size was measured using gauges from 1.0 to 2.5-mm by 0.1-mm step (ASICO Gauges—Ref AE-1574T) before phacoemulsification before and after IOL insertion. Before and after INCISE IOL injection the anterior chamber was filled with ophthalmic viscosurgical device.

Postoperative assessment

Four comprehensive postoperative follow-up visits at 1 day, 1–2 weeks, 1–2 months, and 4–6 months following surgery were performed in all participants. During these visits, corrected (CDVA; primary study endpoint) and uncorrected distance visual acuity (UDVA) were assessed using logMAR visual acuity scales. Manifest refraction spherical equivalent (MRSE), predictability of refraction (assessed as deviation from targeted refraction), and stability of refraction [refraction results at month 6 vs. month 2 (defined using the ANSI criteria)] [10] were also assessed. Horizontal and vertical lens decentration relative to the limbus (measured in millimeters from retroillumination photographs taken at postoperative visits 2–7), total decentration, posterior capsular opacification (EPCO) score (3 mm central and within the capsulorhexis area), Nd:YAG capsulotomy rate and ocular adverse events were recorded during follow-up visits.

EPCO scores were determined by a single evaluator (P.B) who graded all photographs. These scores, along with Nd:YAG rates, were determined at further visits at 12, 18 and 24 months postoperatively.

Statistical analysis

Following ISO 11979-7 the null hypothesis was that the proportion of eyes with CDVA of 20/40 or better (p) was equal to or greater than the historical control proportion (p 0). The alternative hypothesis was that the proportion of eyes with CDVA of 20/40 or better was less than the historical control proportion. Regarding overall postoperative CDVA of 20/40 or better, an exact binomial test with a nominal 0.050 one-sided significance level and 80% power to detect the difference between the null hypothesis proportion, p 0 of 0.925 and the Alternative proportion, p A, of 0.839 the required sample size was 90 subjects. Following assessment of normality, all continuous variables were summarized using descriptive statistics and categorical measures using counts and percentages.

For the primary endpoint a one-sided exact binomial test was used with a Type 1 (alpha) error rate of 0.05 for comparison between the observed proportion of subjects with CDVA of 20/40 or greater and the historical control proportion. All other statistical analyses were performed using a two-sided hypothesis test at the 5% level of significance. No adjustments for Type I error were made for multiple comparisons. Unless otherwise noted, confidence intervals (CI) were two-sided with a 5% alpha risk (i.e., 95% confidence intervals). CIs for continuous variables are based on the t-distribution. CIs for dichotomous variables are exact binomial (Clopper–Pearson) confidence intervals.

All summaries and analyses were prepared using SAS software (SAS Institute, Cary, N.C., version 9.2 or higher).

Results

Table 1 outlines the demographics of all subjects. A total of 111 patients and eyes (58 right eyes) were enrolled in the study. Of these, 103 were successfully implanted with the study IOL and were labeled the Safety Set because their outcomes were used in safety analyses. These patients also comprised the Implanted set as they were all implanted with the IOL. An additional group called the Per-Protocol Set was also classified in the study and used for analysis of the visual outcomes achieved with the lens. This group consisted of 96 patients who were successfully implanted with the IOL and did not have any notable protocol deviations (defined as exclusion criteria arising after enrollment). Of the 103 patients implanted with the study IOL, 43 were implanted via B-MICS and 60 via C-MICS. The average age of the overall cohort (i.e., the Implanted Set) was 71.5 ± 7.6 years (range 48–86 years) of which 61 (i.e., 59.2%) subjects were female and 42 (i.e., 40.8%) subjects male. 83.5% (n = 86 eyes) of the subjects enrolled presented with nuclear or cortico-nuclear cataract, evaluated as moderate or dense in 82.6% (n = 85) of eyes. Target refraction was—0.20 ± 0.19 D. Looking specifically at the 96 eyes in the Per- Protocol Set, 39 eyes of these underwent IOL implantation using the wound-assisted technique (tip of the cartridge of the inserter at the edge of the incision) through an incision size of 1.4 ± 0.1 mm on average. Mean wound stretch was 0.2 ± 0.2 mm. In 57 eyes of the Per-Protocol Set, the study lens was implanted using the standard injection technique (tip of the cartridge of the inserter entering in the anterior chamber) through an incision size of 1.9 ± 0.1 mm on average. Mean wound stretch in this case was 0.1 ± 0.1 mm.

Visual performance data

The visual performance for the Per Protocol set, i.e., 96 eyes, for each visit is presented in Table 2 . There was a mean CDVA improvement of 3 lines at 1–2 weeks from preoperative visit, and then CDVA remained stable at 20/20 ? 1 Snellen on average. Furthermore, mean CDVA was - 0.02 logMAR (20/ 20 ? 1), and was 20/20 or better in 79.8% of eyes and 20/40 or better for 93 eyes (98.3%) at 6 months postoperative. The 6-month postoperative results showed a mean UDVA of ? 0.12 logMAR (20/25 Snellen), with 92.6% of eyes achieving 20/40 or better. There was an improvement of 5 lines on average from the preoperative visit.

The 6-month mean MRSE was - 0.20 ± 0.60 diopters (D), mean absolute Predictive Error was 0.44 ± 0.36 D with 90.4% of the eyes within 1.00 D of the targeted refraction. Refractive stability, as indicated by the difference in refraction from the 4–6-month and 1–2-month postoperative visits, was 0.02 ± 0.32 diopters with an absolute refractive change of 0.20 ± 0.25 D. 98.9% of the eyes had a change B 1.00 D in MRSE between V3 and V4 showing refractive stability was achieved 4–6 months after implantation.

Table 2 Patient recruitment demographics for each study site

Subject status	Overall *n* (%)	Site 1 #200043 Sweden *n* (%)	Site 2 #220251 France *n* (%)	Site 3 #230252 Italy *n* (%)	Site 4 #818328 Spain *n* (%)	Site 5 #822324 Germany *n* (%)
Number enrolled	111	21	23	26	8	33
Completed phase I	101 (91.0)	20 (95.2)	19 (82.6)	25 (96.1)	8 (100.0)	29 (87.9)
Discontinued after implant	2 (1.8)	0	1 (4.3)	0	0	1 (3.0)
Subject lost to follow-up	2 (1.8)	0	1 (4.3)	0	0	1 (3.0)
Subject withdrew consent	0	0	0	0	0	0
Subject explanted	0	0	0	0	0	0
Subject death	0	0	0	0	0	0
Other	0	0	0	0	0	0
Discontinued before implant	8 (7.2)	1 (4.8)	3 (13.0)	1 (3.8)	0	3 (9.0)
Screen failure[a]	1[a] (0.9)	0	0	0	0	1 (3.0)
Subject withdrew consent	5 (4.5)	1 (4.8)	1 (4.3)	1 (3.8)	0	2 (6.0)
Surgical complications	0	0	0	0	0	0
Subject death	0	0	0	0	0	0
Other[b]	2[b] (1.8)	0	2 (8.7)	0	0	0

Percentages are based on the total number of enrolled subjects

[a]Exclusion criteria #17: subject using prostaglandin analog eye drops

[b]Maximum number authorized by the EC was reached

Table 3 Visual performance results

	Preoperative	1 day	1–2 weeks	1–2 months	4–6 months
CDVA (logMAR)	0.31 ± 0.24		− 0.00 ± 0.11	− 0.02 ± 0.08	− 0.02 ± 0.09
UDVA (logMAR)	0.60 ± 0.26	0.21 ± 0.20	0.11 ± 0.14	0.11 ± 0.14	0.12 ± 0.15
MRSE (D)	− 0.11 ± 2.19		− 0.06 ± 0.58	− 0.19 ± 0.60	− 0.20 ± 0.60
Absolute predictive error (D)			0.46 ± 0.35	0.38 ± 0.36	0.44 ± 0.38

Safety parameters

All eyes implanted with the MICS IOL (n = 103 eyes) were included in the safety analysis.

Lens decentration

Mean total decentration is presented in Table 3 (relative to the limbus). As shown in Fig. 2 , on a consistent cohort of 77 eyes (all implanted with no missing data at any visit), there were no statistically significant differences among visits (p = 0.07). The MICS IOL was

positioned on average at 0.30–0.35 mm from the superior nasal position, 12 months following implantation (Fig. 3).

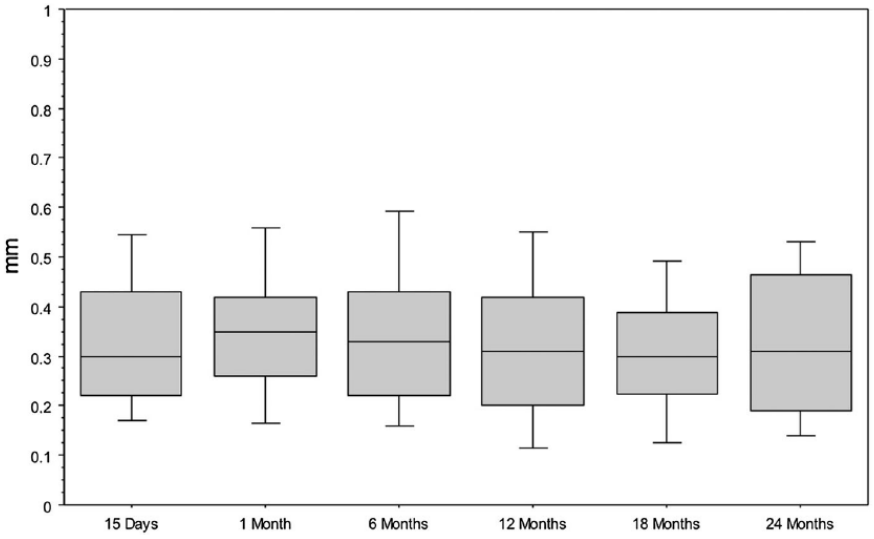

Fig. 2 Mean total IOL decentration (mm) relative to the limbus (n = 77)

Table 4 Mean lens decentration values (mm) relative to the limbus in all implanted subjects

	1–2 weeks	1–2 months	4–6 months	11–13 months	17–19 months	22–25 months
Lens decentration relative to limbus (mm)						
Horizontal	0.17 ± 0.19	0.20 ± 0.22	0.19 ± 0.22	0.15 ± 0.23	0.13 ± 0.19	0.14 ± 0.21
Vertical	0.20 ± 0.16	0.21 ± 0.14	0.19 ± 0.17	0.18 ± 0.16	0.18 ± 0.15	0.19 ± 0.15
Total	0.33 ± 0.15	0.35 ± 0.16	0.35 ± 0.17	0.32 ± 0.17	0.30 ± 0.13	0.32 ± 0.14

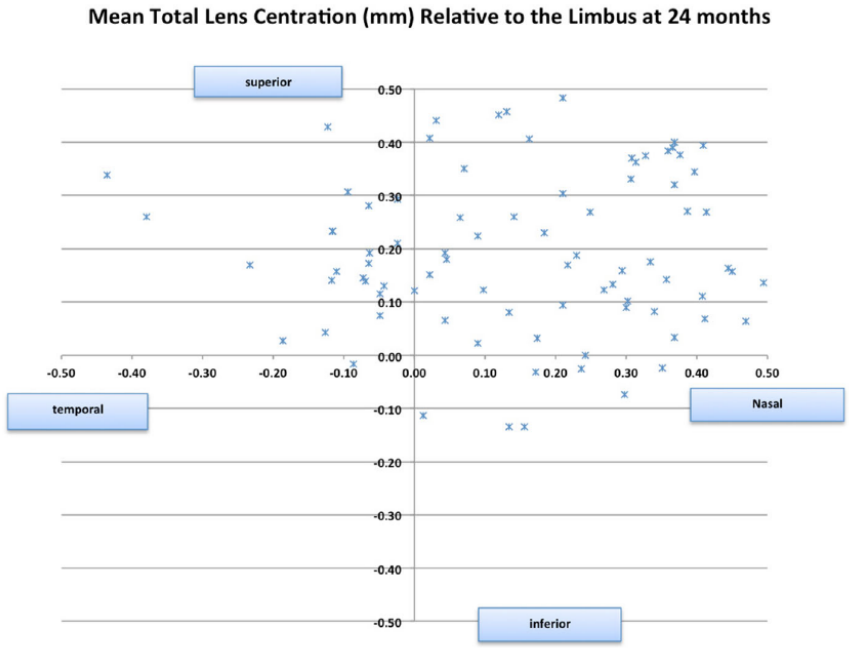

Fig. 3 Mean total IOL decentration (mm) relative to the limbus (n = 77) at 24-month postoperative visit

Evaluation of posterior capsular opacification (EPCO) score and Nd:YAG rate

The data for all implanted eyes that did not receive a capsulotomy before the visit are presented in Table 4. Both 3 mm central and within the capsulerhexis areas EPCO scores were on average close to zero during the course of the 24 months following surgery, respectively (Fig. 4). EPCO score findings were 0.01, 0.03 and 0.07 within the capsulorhexis with no significant differences between study sites (p[0.05). Nd:YAG rates were 0% until 12 months postoperative (11–13-month visit window), when thereafter three eyes among the 103 implanted eyes (2.9%) underwent a Nd:YAG capsulotomy for posterior capsule opacification visual disturbance. Nd:YAG rates were 3.4% (3/88 eyes were followed up to 24 months) (Table 5).

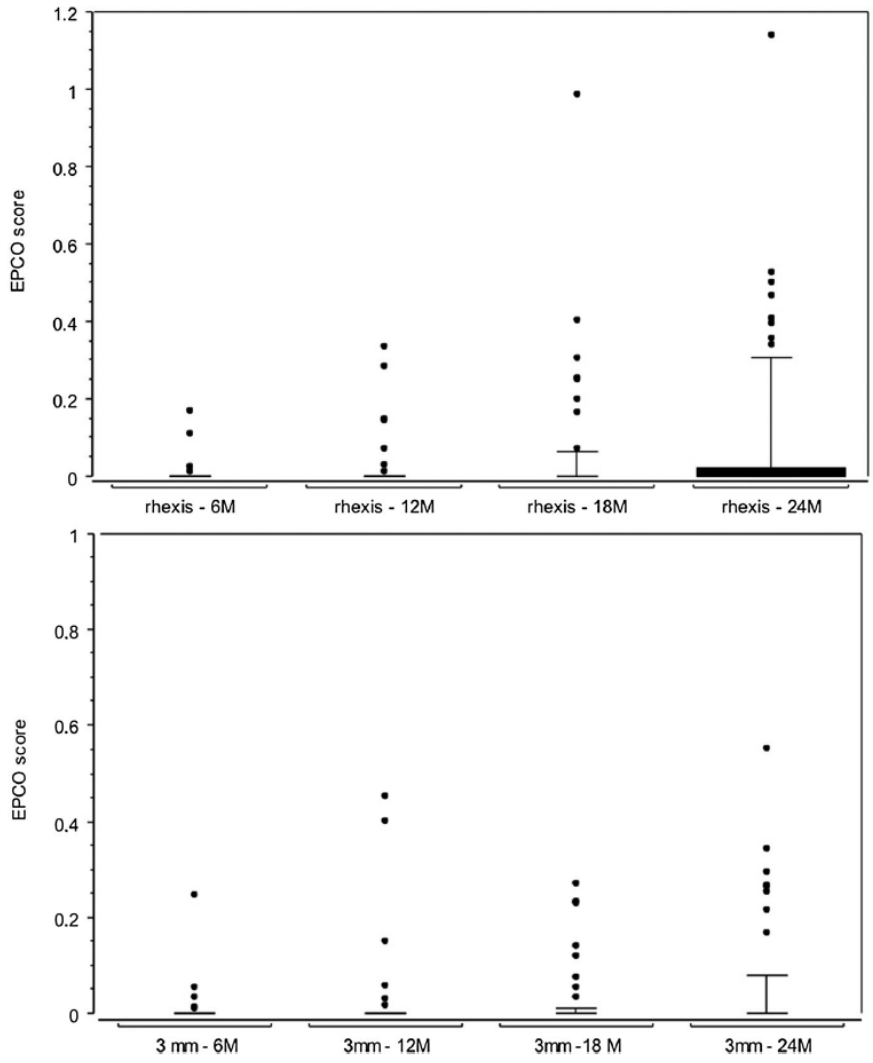

Fig. 4 Mean EPCO scores for within capsulorhexis (above) and central 3 mm (below) for each postoperative visit

Table 5 Mean evaluation of EPCO scores in all eyes

	1–2 weeks	1–2 months	4–6 months	11–13 months	17–19 months	22–25 months
n	103	102	102	99	99	99
EPCO score—3 mm central	0.00 ± 0.00	0.00 ± 0.02	0.00 ± 0.03	0.01 ± 0.07	0.01 ± 0.05	0.03 ± 0.09
EPCO score—within the capsulorhexis	0.00 ± 0.01	0.00 ± 0.03	0.00 ± 0.02	0.01 ± 0.05	0.03 ± 0.13	0.07 ± 0.17

Adverse events

One patient experienced low visual acuity and reported glare. Laser capsulotomy was performed before 2 months to treat a primary posterior capsular plaque that was observed intraoperatively and at the day 1 postoperative visit. Two cases of cystoid macular edema (CME), one still persistent at 4–6 months postoperatively, were recorded. No other

adverse events, i.e., posterior capsular tear, IOL malposition, iris damage, Descemet's membrane detachment, or retinal detachment were noted. No relationship between the surgical technique and occurrence of adverse events was noted.

Discussion

This prospective, multicenter study demonstrates that the used microincision IOL provides good visual and refractive outcomes. Specifically, the mean CDVA achieved with the IOL was - 0.02 logMAR (20/20), and 80% of eyes obtained a CDVA of 20/20 or better. Additionally, the CDVA was 20/40 or better for 93 eyes (98.3%) in the Per-Protocol Set and for all eyes (100%) in the Safety Set at the 6-month postoperative visit. This exceeds the historical control ISOGrid [11] of 92.5 and 96.7%, respectively, for CDVA of 20/40 or better. The visual performance data of this study also show that the mean MRSE was - 0.20 ± 0.60 D, while mean absolute predictive error was 0.44 ± 0.36 D within 1.00 D of the targeted refraction for 90.4% of eyes.

These outcomes are consistent with the recommendations based on the EUREQUO registry [11] and the UK NHS benchmark data [12] with 87.0 and 85.0% of eyes within 1.00 D, respectively. Of course, better outcomes may be achieved with greater experience and personalizing the A constant for this MICS IOL. A constant optimization performed by Dr Wolfgang Haigis reported that the A constant should be slightly decreased from 119.1 to 118.9 [13]. Applying this optimized A constant to the study data set would have slightly improved the refraction predictability with 92.0% of cases within 1.00 D of expected refraction. It is understood that postcataract surgery, MICS provides the opportunity to achieve an advanced refractive result with less perioperative injury. This is thought to be because, unlike with coaxial cataract surgery technique, MICS does not induce further incision healing process, inflammation of the anterior chamber, corneal endothelial loss, or corneal edema [14 , 15]. However, due to the very high technical and optical requirements needed to meet the sub-2-mm incision demand, there are only very few MICS IOLs commercially available. The refractive outcomes achieved in the current study suggest that the used microincision IOL meets these technical requirements. A further technical requirement of a MICS IOL is to exhibit long-term stability in the bag to ensure consistently high visual clarity, quality and patient satisfaction long after surgery. The microincision IOL demonstrated a predictable and stable centration with a mean total

decentration of 0.32 ± 0.14 mm in a superior nasal direction 24 months following implantation. These results are consistent with those previously reported with conventional one or three-piece IOLs, falling within a range of 0.20–0.60 mm[16 –21]. The location of the IOL was assessed in relation to the geographical center of the cornea rather than the visual axis; also located nasally. Despite advances in IOL designs and modern surgical techniques, posterior capsule opacification (PCO) remains the most common complication after cataract surgery. Experimental works by Nishi et al. [22 –24] on physiopathology and mechanisms of PCO have shown that the most important feature of midterm PCO prevention is the square edge design. This was clinically confirmed by Buehl et al. [25] in a metaanalysis which followed prospective controlled randomized trials in a 12-month follow-up period. A Cochrane review by Findl et al. [26] analyzed the roles that IOL material, lens geometry, pharmacology therapy, and surgical technique have on PCO development. PCO score was found to be significantly lower with sharp-edge design IOLS, whereas there was no evidence of the optic material having an influence. However, limited long-term follow-up and large variation in the PCO score systems led to difficulties pooling the data. Using scanning electron microscopy (SEM), several experimental studies have evaluated the square edge profile of a variety of IOLs [27 –29]. Despite the different quantification methods used by these in vitro studies (i.e., deviation from a perfect square [27 , 28] or mean radius curvature [29]) their conclusions were comparable: hydrophilic acrylic IOLs appear to have relatively rounder edges than silicone and hydrophobic IOLs. But these results suggest that variation in PCO incidence is more reflective of differences in manufacturing processes rather than the IOL material. For example, during the polishing process, hydrophilic lenses may experience abrasion of the square edges. Thus, the polishing process adopted by the manufacturer can determine the level of the edge sharpness. Hydrophobic lenses in comparison, however, are usually molded with no polishing step.

Owing to the specific manufacturing process and its 5 l m radius 360_ sharp posterior optic edge, the microincision IOL used in this study demonstrated a low score of PCO development with mean 3 mm central and within the capsulorhexis area EPCO scores of 0.03 ± 0.09 and 0.07 ± 0.17, respectively, 24 months after surgery. To quantify PCO, different methods of automated analysis and digital imaging are available, but the most

common measurement in clinical trials remains the Nd:YAG capsulotomy rate. The 24-month incidence of Nd:YAG capsulotomy was 3.4%. This compares favorably with the results obtained with other hydrophilic lenses with incidence rates reported from 4.2 to 50% [30 –34], and especially other microincision lenses, with an incidence reported from 8.0 to 64.5% [35 –39]. All reported adverse events and complications during the 4–6-month follow-up were expected events anticipated after any cataract surgery with IOL implantation and not unique or specifically associated with the IOL. A key limitation of the current study is the absence of investigation of patient satisfaction or corneal higher-order aberrations. However, as there are previous reports on studies investigating aberrations with MICS [8 , 40 , 41], the current study design instead allows for an effective review of the visual performance and long-term safety profiles of a MICS IOL. Study size is another limitation of the current study. While approximately 100 eyes give good indication of the outcomes achievable with the INCISE IOL, further larger-scale studies will be valuable in corroborating and building on the findings seen in the current study. It is also worth noting that the follow-up period of 24 months used in the current study is an additional limitation. Literature shows that PCO can develop long after cataract surgery. As such, while the current study provides indication of the short- and mediumterm PCO rates associated with the INCISE IOL, studies with longer follow-up in the range of 10 years are required to determine whether these rates remain the same long term. Finally, as no toric version of the IOL was available at the time of the study, subjects with an astigmatism[1.5 D were excluded. Both this population as well as those with a cataract severity grade 4 should be evaluated in a future study.

Conclusion

The results of this study show, for the first time, the visual performance and long-term safety data for the MICS INCISE IOL, demonstrating good visual acuity and excellent lens stability alongside low PCO rates and adverse events.

Author contribution

The authors confirm that they have made a significant contribution to this study and have read and approved the final version of the manuscript.

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Compliance with ethical standards

Conflict of interest

There are no conflicts of interest to disclose.

Ethical approval

All procedures performed in this study were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments.

Informed consent

Informed consent was obtained from all individual participants included in the study.

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