

Clinical evaluation of a new hydrophobic acrylic preloaded intraocular lens with a novel delivery system

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Abstract

Purpose: To evaluate clinical outcomes of patients implanted with the Clareon® monofocal intraocular lens (IOL) with AutonoMe™, an automated disposable preloaded delivery device.

Design: Retrospective review.

Methods: One hundred and eight eyes of 88 patients underwent uneventful phacoemulsification cataract surgery and implantation with the Clareon IOL. The primary endpoints were best-corrected distance acuity (BCDA), uncorrected distance acuity (UCDA), and proportion of patients achieving UCDA of logarithm of Minimal Angle of Resolution (logMAR) 0.18 or better at 1 month. Secondary endpoints included refractive stability and predictability, contrast sensitivity as well as wound stretch and surgically induced astigmatism (SIA).

Results: The mean BCDA and UCDA at 1 month were logMAR 0.06 ± 0.08 and 0.18 ± 0.17 , respectively. 93.8% of eyes had BCDA of logMAR 0.18 or better, and all eyes had BCDA of logMAR 0.3 or better. 80.9% of eyes had UCDA of 0.18 or better, and 97.8% of eyes had UCDA of 0.3 or better. All eyes were within 0.75 D of refractive target, 90.9% were within 0.5 D, and 68.7% were within 0.25 D. The mean contrast values (logMAR) were 1.73 ± 0.18 at 3 cpd, 1.91 ± 0.24 at 6 cpd, 1.62 ± 0.25 at 12 cpd, and 1.09 ± 0.28 at 18 cpd. Mean wound stretch and centroid SIA for a 2.2 mm incision was 0.04 ± 0.05 mm and 0.10 D, respectively. There was no wound stretch for a 2.4 mm incision and centroid SIA was 0.23 D.

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Conclusion: The Clareon IOL provided excellent visual outcomes and good refractive predictability. The AutonoMe delivery system did not cause significant corneal wound stretch or astigmatism.

Keywords: Clareon AutonoMe, hydrophobic acrylic, Malaysia, preloaded intraocular lens

Abstrak

Pengajian klinikal kanta intraokular hidrofobik baru yang dimuatkan dengan sistem penghantaran novel

Tujuan: Untuk menilai keputusan klinikal pesakit yang menerima kanta Clareon® intraokular monofokal (IOL) dengan AutonoMe™, sistem penghantaran IOL yang automatik.

Jenis kajian: Retrospektif.

Kaedah: 108 mata daripada 88 pesakit menjalani pembedahan katarak phacoemulsification yang tiada komplikasi dan diimplantasi dengan Clareon® IOL. Titik akhir utama adalah ketajaman visual yang terbaik diperbetulkan (BCDA), ketajaman visual yang tidak dibetulkan (UCDA) dan perkadaran pesakit yang mencapai UCDA logaritma Sudut Minimum Resolusi (logMAR) 0.18 atau lebih baik pada 1 bulan. Titik akhir sekunder termasuk kestabilan dan ramalan refraktif, sensitiviti kontras serta regangan luka dan astigmatisme yang disebabkan pembedahan (SIA).

Keputusan: Purata BCDA dan UCDA pada 1 bulan masing-masing adalah logMAR 0.06 ± 0.08 dan 0.18 ± 0.17 . 93.8% mata mempunyai BCDA logMAR 0.18 atau lebih baik, dan semua mata mempunyai BCDA logMAR 0.3 atau lebih baik. 80.9% mata mempunyai UCDA 0.18 atau lebih baik, dan 97.8% mata mempunyai UCDA 0.3 atau lebih baik. Semua mata berada dalam lingkungan 0.75D sasaran refraktif, 90.9% berada dalam lingkungan 0.5D dan 68.7% berada dalam lingkungan 0.25D. Purata sensitivity kontras (logMAR) adalah 1.73 ± 0.18 pada 3 cpd, 1.91 ± 0.24 pada 6 cpd, 1.62 ± 0.25 pada 12 cpd dan 1.09 ± 0.28 pada 18 cpd. Purata regangan luka dan centroid SIA untuk hirisan 2.2 mm adalah 0.04 ± 0.05 mm dan 0.10D, masing-masing. Tiada regangan luka untuk hirisan 2.4 mm dan centroid SIA adalah 0.23 D. *Kesimpulan:* Clareon IOL memberikan hasil visual yang sangat baik dan ramalan refraktif yang baik. Sistem penyampaian AutonoMe tidak menyebabkan regangan luka kornea yang ketara atau astigmatisme.

Kata kunci: Clareon Autonome, hidrofobik akrilik, kanta intraokular pramuat, Malaysia

Introduction

The Clareon® intraocular lens (IOL) is a new, single-piece, hydrophobic acrylic IOL manufactured by Alcon Laboratories (Fort Worth, TX, USA) that became available for use in Malaysia in early 2019. This IOL is made from a new biomaterial, which is a hydrophilic copolymer (2-hydroxyethylmethacrylate)¹ with a water content of 1.5% (at 35°C), refractive index of 1.55, and glass transition temperature of 9.1°C.² Its overall design is based on the single-piece Acrysof IOL platform (water content of 0.4%), with the same 6.0 mm biconvex optic and 13.0 mm length. Clareon has an aspheric anterior surface with precision edge design for reducing edge glare and positive dysphotopsia, as well as a posterior square optic edge for reducing posterior capsular opacification. Clareon comes preloaded in an automated, disposable lens delivery system AutonoMe™ that is designed with a carbon dioxide-powered delivery mechanism. The tip of the injector has a depth guard, which prevents excessively deep insertion of the device into the incision and therefore, minimizes wound stretch.

This study presents our initial experience with the Clareon® CNA0T0 monofocal IOL and clinical outcomes in a routine cohort of cataract patients in Malaysia.

Methods

This study was a retrospective review of patients who underwent uneventful cataract surgery with implantation of the Clareon CNA0T0 monofocal IOL in three private ophthalmic surgical centres in Malaysia from March 2019 to March 2020. Ethics approval was not required as this study was an audit and patient identifiers were removed accordingly.

Patient selection

Eligible patients were those aged 18 years or older in good general and ocular health with significant cataract who underwent phacoemulsification and implantation of the Clareon CNA0T0 monofocal IOL. Eyes with previous refractive surgery and patients with pre-existing ocular diseases which may significantly impact visual acuity or in the opinion of the surgeon, compromise the stability of the IOL, were excluded. Eyes with greater than 1 D of corneal astigmatism as well as patients who had experienced intraoperative complications were also excluded.

Cataract surgery

The study authors, who were based in different ophthalmic centres, performed the surgeries on all the eyes assessed in this study. All eyes had sutureless phacoemulsification under topical anaesthesia through a 2.2 mm (MW Lee and KC Yeo) or a 2.4 mm corneal incision (FM Cheong) using the Centurion machine (Alcon Laboratories). All patients had optical biometry and the Barrett Universal II formula was used for IOL selection targeting emmetropia. If optical biometry was unsuccessful and immersion ultrasound was used instead, KC Yeo used the SRK-T formula to guide IOL selection. Patients were reviewed postoperatively on Day 1, Week 1, Month 1, and Month 3.

Study endpoints

The primary endpoints were uncorrected distance visual acuity (UCDA), best-corrected distance visual acuity (BCDA), and the proportion of patients achieving UCDA of logarithm of Minimal Angle of Resolution (logMAR) 0.18 or better at 1 month. Snellen visual acuities were converted to logMAR for analysis.

The secondary endpoints were refractive outcome and predictability (difference between postoperative spherical equivalent at 1 month and target spherical

Table 1. Demographics and preoperative characteristics of patients who received the Clareon IOL

Patients (n)	88
Age (years)	
Mean ± SD	65.15 ± 7.14
Range	49 to 86
Eyes implanted with Clareon (n)	108
Right (n)	61
Left (n)	47
Axial length (mm)	
Mean ± SD	23.58 ± 0.98
Range	21.49 to 26.15
Corneal astigmatism (mm)	
Mean ± SD	0.53 ± 0.22
Range	0 to 0.93
BCDA (logMar)	
Mean ± SD	0.58 ± 0.62
Range	0.18 to 1.78
UCDA (logMar)	
Mean ± SD	0.77 ± 0.67
Range	0.1 to 2

BCDA: best-corrected distance acuity; IOL: intraocular lens; SD: standard deviation; UCDA; uncorrected distance acuity

equivalent), refractive stability (difference between postoperative spherical equivalent at 1 week and 1 month), contrast sensitivity measured under photopic conditions with the Vector Vision CSV-1000E contrast acuity chart (Greenville, USA) at 1 month, wound stretch (measured with the Memmen incision gauge [Terrebonne, Canada] before and immediately after IOL implantation), and surgically induced astigmatism (centroid SIA calculated with preoperative keratometry readings and postoperative keratometry measurements at 1 month using the <http://sia-calculator.com/> website). Patients who had bilateral Clareon implants also underwent the Visual Function Index-14 (VF-14) Quality of Life questionnaire,³ which was administered by telephone at 1 month. The VF-14 is often used to assess the outcomes of cataract surgery and consists of a series of 14 questions to assess the degree of difficulty faced by a patient when performing specific visual tasks.

Adverse events

All intraoperative or postoperative complications were also recorded. Eyes with intraoperative complications were excluded from analysis.

Data collection and analysis

Data was gathered on a Microsoft Excel database specifically designed for the study. Descriptive statistics which included mean, median, standard deviation (SD), and minimum and maximum values were used to analyse the data. Tests of statistically significant differences were performed using one-way ANOVA to compare postoperative manifest refraction (spherical equivalent) at 1 week, 1 month, and 3 months to assess the refractive stability of the Clareon IOL.

Results

A total of 125 eyes underwent phacoemulsification with implantation of Clareon monofocal IOL in the three centres from March 2019 to March 2020. Two eyes with posterior polar cataract had intraoperative capsular compromise and were therefore excluded from the study. Another 15 eyes did not complete the 1-month follow-up and were also excluded. Data from the remaining 108 eyes (from 88 patients) were available for analysis. The preoperative parameters of these patients are described in Table 1. Only data from 53 eyes were available for analysis at 3 months.

Visual outcomes

The mean logMAR UCDA improved from 0.77 ± 0.67 preoperatively to 0.18 ± 0.17 at 1 month postoperatively. The mean logMAR BCDA also improved from 0.58 ± 0.62 preoperatively to 0.06 ± 0.08 at 1 month postoperatively (Fig. 1). One hundred and five eyes (97.2%) had UCDA of logMAR 0.3 (Snellen 6/12) or better and 86 eyes

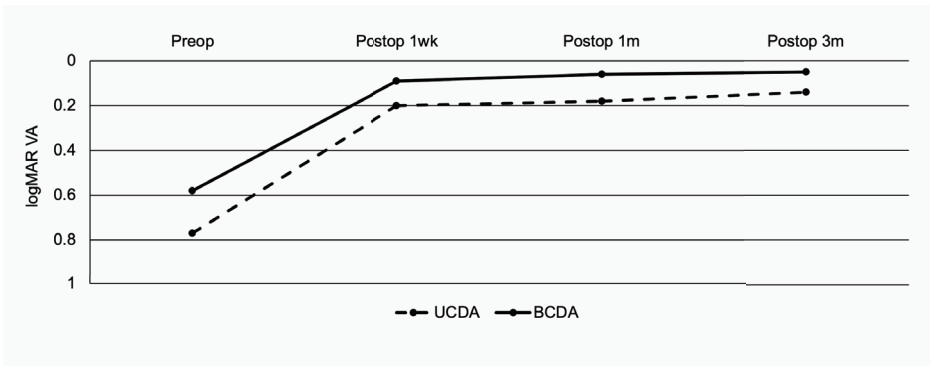


Fig. 1. Best corrected and uncorrected mean logMAR visual acuity of patients preoperatively at week 1, month 1, and month 3.

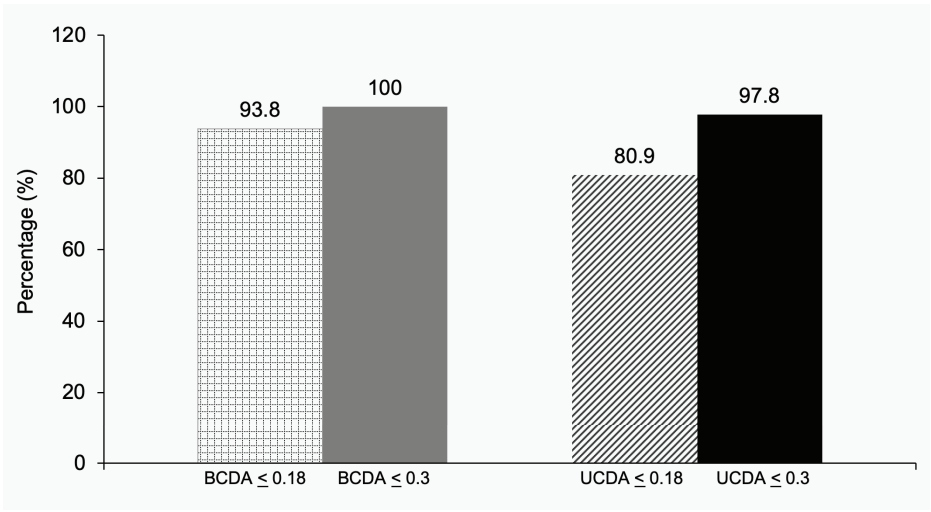


Fig. 2. Percentage of eyes with best corrected and uncorrected logMAR visual acuities of 0.3 or better and 0.18 or better.

(79.6%) had logMAR 0.18 (Snellen 6/9) or better. All eyes had BCDA of log MAR 0.3 or better and 101 eyes (93.5%) had logMAR 0.18 or better (Fig. 2).

The mean logMAR UCDA and BCDA at 3 months were 0.14 ± 0.11 and 0.05 ± 0.06 , respectively. Fifty eyes (94.3%) had UCDA of logMAR 0.3 or better, 41 eyes (77.4%) had UCDA of logMAR 0.18 or better, and all eyes had BCDA of logMAR 0.18 or better.

Refractive outcomes

Postoperative spherical equivalent (SE) at 1 month was compared with preoperative target SE while refractive predictability was assessed by subtracting the pre-

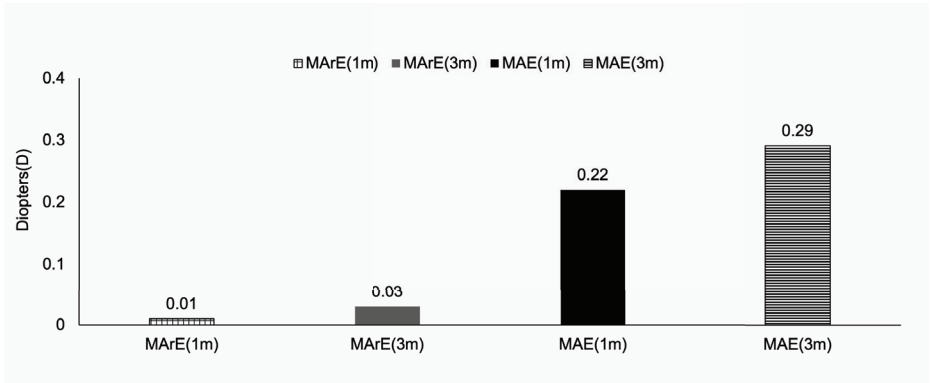


Fig. 3. Percentage of eyes with postoperative spherical equivalent within 0.25 D, 0.5 D, and 0.75 D of target.

operative SE from the postoperative SE and calculating the mean arithmetical error (MArE) as well as the mean absolute error (MAE). The MArE at 1 month was 0.01 ± 0.27 and the MAE was 0.22 ± 0.16 . All eyes were within 0.75 D of target, 98 eyes (90.7%) were within 0.5 D, and 74 eyes (68.5%) were within 0.25D (Fig. 3). At Month 3, MArE was 0.03 ± 0.34 , MAE was 0.29 ± 0.19 and 48 eyes (90.6%) of eyes were still within 0.5D of target SE.

Refractive stability was assessed by calculating the difference between the postoperative SE at 1 week and 1 month. Mean change in SE from 1 week to 1 month was -0.07 ± 0.31 and mean absolute change was 0.25 ± 0.20 . All eyes had $\leq 1D$ change in SE from 1 week to 1 month. 100 eyes (92.6%) had $\leq 0.5D$ and 73 eyes

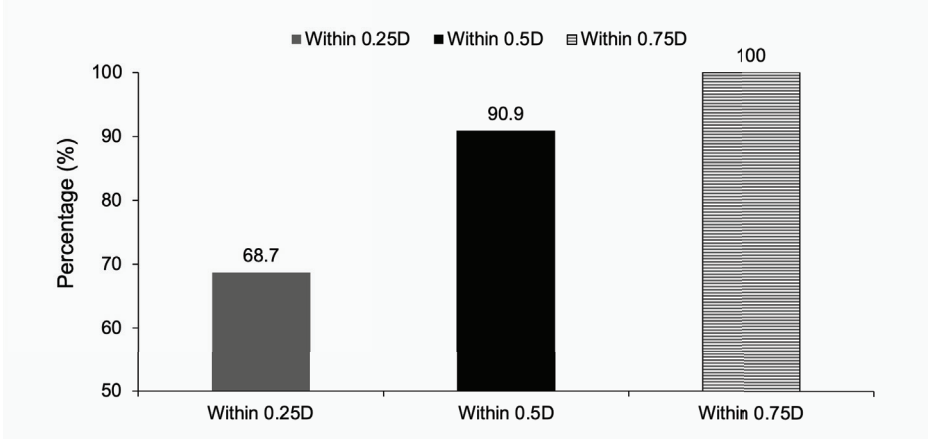


Fig. 4. Change in refraction (mean spherical equivalent) from 1 week to 3 months postoperatively.

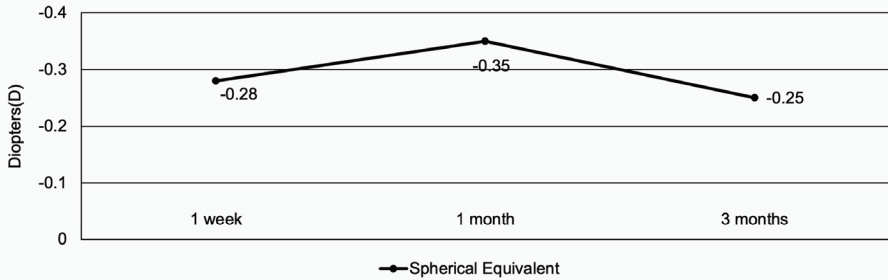


Fig. 5. Comparison of contrast sensitivity between aged-matched controls, Clareon, and other monofocal intraocular lenses.

(67.6%) had $\leq 0.25\text{D}$ change. Mean change in SE from 1 month to 3 months was -0.03 ± 0.32 and mean absolute change was 0.23 ± 0.22 . All eyes at 3 months had $\leq 0.5\text{D}$ change in SE. The mean SE at 1 week, 1 month and 3 months were -0.28 ± 0.43 , -0.35 ± 0.41 and -0.25 ± 0.32 respectively (Fig. 4). There was no statistically significant difference in SE at 1 week, 1 month or 3 months, postoperatively ($P = .364$).

Contrast sensitivity

Contrast sensitivity for all eyes was performed at 1 month postoperatively with the Vector Vision CSV-1000E under photopic conditions at spatial frequencies of 3, 6, 12 and 18 cycles per degree (cpd). For purposes of analysis, linear values were converted to log units. The mean contrast values were 1.73 ± 0.18 at 3 cpd, 1.91 ± 0.24 at 6 cpd, 1.62 ± 0.25 at 12 cpd and 1.09 ± 0.28 at 18 cpd (Fig. 5).

Wound stretch and surgically induced astigmatism

Wound stretch was measured intraoperatively as previously described. The mean size (for the 2.2 mm incision) was 2.2 ± 0.02 mm pre-IOL implantation and 2.25 ± 0.06 mm post-implantation. There was no change in incision size for the 2.4 mm incision.

When assessed by individual surgeons, the centroid SIA for the right and left eyes were 0.10 D and 0.09 D, respectively (for MW Lee), 0.10D and 0.08D (for KC Yeo), and 0.23 D and 0.22 D (with FM Cheong).

VF-14 Questionnaire

Twenty patients had bilateral Clareon implants. The mean VF-14 score within this cohort was 95.2 ± 6.29 (range 80.56 to 100). Ten patients recorded a score of 100 (full marks).

Adverse events

Two eyes (in the same patient) with posterior polar cataract had intraoperative posterior capsular rupture with vitreous loss. In both eyes, reverse optic capture with the Clareon IOL was possible, with one eye requiring a return trip to the operating theatre for the removal of vitreous wick through the side-port incision. Both eyes achieved a final BDVA of Snellen 6/9 and 6/6, respectively but were excluded from analysis.

Three eyes had postoperative cystoid macular oedema, and all responded well to treatment with topical steroids and topical nonsteroidal anti-inflammatories. A final BCDA of logMAR 0 was achieved in two eyes and logMAR 0.3 in the remaining eye at 1 month.

One eye had raised intraocular pressure noted at 1 week which was attributed to a response to steroid treatment. The topical steroid was changed from prednisolone to loteprednol and intraocular pressure returned to normal with this eye achieving BCDA of logMAR 0 at 1 month.

Discussion

The Clareon IOL is made from a new biomaterial and previous *in vitro*⁴⁻⁶ and *in vivo*² studies that evaluated the Clareon IOL have reported low levels of glistenings and surface haze compared with other commercially available IOLs. Initial clinical studies⁷⁻¹⁰ have also shown this IOL to be safe and effective with good postoperative outcomes and minimal complications.^{11,12} This retrospective study documents the initial clinical experiences using the Clareon IOL in Malaysian patients.

This study demonstrated that this IOL provided good visual and refractive outcomes in the early postoperative period with a high proportion of patients achieving UCDA of logMAR 0.3 or better and all eyes achieving BCDA of logMAR 0.3 or better. A previous study¹ evaluated the refractive stability of the Clareon IOL and showed little change in SE after 1 week and up to 3 months postoperatively. In this study, refractive stability was achieved early with no statistically significant change in SE from 1 week to 3 months postoperatively.

There was also very good refractive predictability with more than 90% of eyes within 0.5 D of target using the SRK-T or the Barrett Universal II formulae. This was achieved despite the lack of 'A' constant optimization. These good refractive outcomes could be attributable to the positional stability of this IOL. Previous publications on the three-piece version of the Clareon IOL⁸ had reported excellent visual outcomes and a low rate of posterior capsular opacification.

The mechanical stability of this IOL was also evaluated in an experimental study¹³ that compared Clareon IOL with other monofocal IOLs. Clareon IOL had very low levels of axial displacement. The corresponding simulated dioptric power shift likely offered better positional stability and optimized refractive outcomes for patients.

Stanojcic *et al.*¹⁰ previously reported no difference in contrast sensitivity when comparing the Clareon IOL with the Tecnis PCB00 IOL (New Brunswick, USA). For practical purposes, contrast sensitivity in this study was tested under photopic conditions since most daily activities are conducted during daylight. The mean contrast sensitivity of all eyes under photopic conditions was found to be better than aged-matched normal controls as shown on the manufacturer's website (Population norms, Age group 50 to 75 years of age (<http://www.vectorvision.com/csv1000-norms/>)). The mean contrast sensitivity was also comparable to other monofocal IOLs when the logMAR values were plotted together using data from an earlier study¹⁴ comparing contrast sensitivity between three different aspheric IOLs. While comparisons across different studies were not recommended given the differing testing conditions, this provides an idea of how Clareon IOL compares with other monofocal IOLs.

The Clareon IOL comes preloaded in a disposable automated injector system (AutonoMe). In a previous study¹⁵ assessing corneal tissue trauma, AutonoMe injector resulted in significantly less endothelial cell loss and misalignment as well as less tissue inflammation compared with the Monarch III injector.

In our study, implantation of the Clareon IOL through a 2.2 mm incision required a wound assisted approach with a second instrument to stabilize the eye as the injector tip did not fit through the incision. This approach resulted in minimal and likely insignificant wound stretch (average increase in wound size of less than 0.05 mm). For 2.4 mm incisions, the injector tip fit snugly into the incision up to the nozzle guard. No wound stretch was evident at all.

There was no significant surgically induced astigmatism as the postoperative centroid SIA values were comparable with each individual surgeon's previous calculated centroid SIA values (MW Lee, KC Yeo = 0.1 D and FM Cheong = 0.2 D).

Patients with bilateral implants ($n = 20$) were very satisfied with their visual function as evidenced from the high scores reported with the VF-14 questionnaire that evaluated the difficulty in performing visually dependent common daily tasks. In this study, 10 out of the 20 patients who had bilateral implants scored full marks. Three individuals scored below 90 and all had BCDA of \geq logMAR 0.18 but reported moderate difficulty with near tasks (even with glasses). Further evaluation of their symptoms showed that they had significant dry eyes, which may have contributed to the difficulties they experienced.

The surgeons did not experience any adverse events with regards to the use of this novel injector system. Specific recommendations and training videos provided by the manufacturer flattened out the learning curve very quickly. Interestingly, in the two eyes with posterior capsular compromise, both Clareon IOLs remained well-centred and stable with a reverse optic capture technique. The surgeon (MW Lee) noted that Clareon IOLs were easier to manipulate compared with Acrysof and this could be related to its increased water content, which reduced stiffness.

The limitations of this study are related to its retrospective design and the inconsistent nature of data collection. Confounding factors were also introduced with the enrolment of patients under the care of different surgeons; variations in surgical practices could influence outcomes. Another limitation was the relatively short follow-up period, with only a small proportion of patients having at least 3 months of follow-up data. With the inclusion of a new biomaterial in the Clareon IOL, longer follow-up would be useful to identify the rates of posterior capsular opacification and more importantly, presence of surface scatter or sub-surface nanoglistenings which had been reported in other hydrophobic acrylic IOLs. Nevertheless, in this cohort of patients, no glistenings were found in the Clareon IOL up to 3 months of follow-up.

In summary, initial experience with the Clareon IOL in this cohort of Malaysian patients showed excellent visual outcomes, refractive stability and predictability, as well as safety with the use of the novel AutonoMe fully automated disposable injector system.

Declarations

Ethics approval and consent to participate

Ethics approval was not required as this study was an audit and patient identifiers were removed accordingly.

Competing interests

All three authors are paid speakers for Alcon Laboratories and all received grant support for the study.

Funding

This study was conducted with a grant from Alcon Laboratories (M) Sdn Bhd. The grant was used for the research assistants used by each centre for data collection and handling, presentations at meetings, and for the services of a medical writer to prepare the manuscript for submission.

Acknowledgements

Eve Lyn Chong (optometrist) and Eunice Poh Sum Hiew (optometrist) provided support with data collection and analysis.

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