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ORIGINAL RESEARCH

Clinical Evaluation of a Hydrophobic Intraocular Lens Using a Preloaded Automated Injector in a Korean Population

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Purpose: This study assessed post-market clinical outcomes of the Clareon monofocal intraocular lens (IOL) preloaded in the AutonoMe Delivery System in a real-world setting of Korean patients.

Methods: This prospective, multicenter, single-arm study in Korea was conducted from July 2020 to December 2021. Patients were ≥20 years old with unilateral or bilateral cataracts who received Clareon IOLs (CNA0T0) preloaded in an automated injector system. Best corrected distance visual acuity (BCDVA) and uncorrected distance visual acuity (UCDVA) were evaluated under photopic conditions. Surgeon delivery system preference was assessed using a survey questionnaire. Glistenings, surface haze, adverse events, posterior capsule opacification (PCO), and Nd:YAG capsulotomy rates were also assessed during the 12-month postoperative follow-up.

Results: Mean ± SD monocular BCDVA was 0.02 ± 0.11 and 0.00 ± 0.10 logMAR at 1 month and 12 months, respectively. BCDVA of 0.2 logMAR or better was achieved by 94.4% and 99.1% of eyes at 1 month and 12 months after implantation, respectively. Mean monocular UCDVA was 0.11 ± 0.14 and 0.07 ± 0.13 logMAR at 1 month and 12 months, respectively. UCDVA of 0.3 logMAR or better was achieved by 97.4% of eyes at 12 months after implantation. Preparation of the automated injector system was rated as "very easy" or "easy" and CNA0T0 IOL delivery was rated as "very controllable" or "controllable" by all surgeons. Only grade 0 glistenings and no surface haze were observed during the 12-month follow-up. No clinically significant PCO or Nd:YAG capsulotomy were reported throughout the study; clinically nonsignificant PCO was reported in 23% of eyes.

Conclusion: This 12-month real-world study of the CNA0T0 IOL and the automated injector system demonstrated excellent visual outcomes and high surgeon satisfaction.

Keywords: visual acuity, intraocular lens delivery, glistenings, surface haze, surgeon's preference questionnaire

Introduction

Cataract surgery using phacoemulsification followed by intraocular lens (IOL) implantation is the most common surgical procedure worldwide.[1] Monofocal IOLs are frequently implanted lenses because of their relatively low cost, optimal distance visual acuity outcomes, and fewer associated photic phenomena, including halos and glare.[2,3]

The Clareon® Aspheric Hydrophobic Acrylic Monofocal IOL (Alcon Vision LLC, Fort Worth, TX, USA; CNA0T0 IOL) was launched in Korea in 2020. The CNA0T0 IOLs are foldable, 1-piece IOLs that use flexible acrylic material (PEA/HEMA copolymer) with 1.5% water content. The CNA0T0 IOL optics and architecture were based on the AcrySof® IOL platform (Alcon), and the material and manufacturing were modified to improve lens clarity, minimize

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edge glare, and reduce the risk of posterior capsule opacification (PCO).[4–6] Recent studies with Clareon IOLs in the United States, Europe, India, and Japan demonstrated good visual outcomes and improved lens clarity characteristics, including low levels of surface haze and grade 0 glistenings (according to a 4-grade scale adapted from Miyata et al, grade 0 glistenings were defined as 0–25 microvacuoles/mm^2 on the glistenings assessment subjective scale).[4–8]

In additional to advancements in IOL technology, there have been innovations in IOL delivery systems. The CNA0T0 IOL is available preloaded in the AutonoMe® Automated Preloaded Delivery System (Alcon; automated injector system). The use of preloaded delivery systems may improve cataract surgery outcomes by eliminating the IOL loading phase. In contrast with manually loaded IOLs, preloaded delivery systems allow for reduced device preparation time,[9,10] which can significantly shorten total surgical case times and potentially increase efficiency of surgical centers and help meet the increased demand for cataract surgery.[9,11–13] Preloaded delivery systems can also improve the consistency of IOL haptic folding and reduce the risk of IOL damage[9,10,14,15] by eliminating loading variability or user error and reducing the risk of contamination by eliminating the need to handle the IOL.[12,16–18] A prospective, randomized, comparative study reported that the AutonoMe Delivery System provided safe and easy IOL delivery; no haptic misconfigurations were observed.[19] Furthermore, preloaded delivery systems are pre-packaged sterile single-use devices that have demonstrated increased microbiologic safety and reduced risk of patient inflammatory reactions (eg, toxic anterior segment syndrome and endophthalmitis).[14,18]

The AutonoMe Delivery System was designed to protect the corneal incision and provide a safer IOL delivery (Figure 1).[6,20,21] It has a proprietary 3-mm nozzle tip and depth guard designed to minimize corneal tissue damage and corneal incision stretch.[21,22] Compared with a manual delivery system, the automated injector system demonstrated a smaller wound enlargement and less damage to the device nozzle.[22,23] The CO_2-powered mechanism of the automated injector system allows for a single-handed surgical technique, improving surgeon's control over the IOL advancement speed compared with the mechanism of action of other delivery systems (ie, push-type [syringe-style] or screw-type [twist-style] advancement).[15,22] Additionally, the use of single-handed IOL delivery allows the surgeon's second hand to stabilize the eye or manipulate the IOL as needed.[22]

The AutonoMe Delivery System was reported as safe and effective in studies in Japan, India, and Europe;[4,5,8,24] however, at the time of this report, there were no published outcomes from Korean patients implanted with Clareon IOLs or feedback on the use of the AutonoMe Delivery System from Korean surgeons. As this device was recently launched in Korea, there is a need to evaluate clinical outcomes specific to the Korean population. The purpose of this postmarket clinical study was to describe real-world efficacy and safety outcomes in Korean patients implanted with CNA0T0 IOLs preloaded in the automated injector system through 1 year after implantation and to assess IOL delivery performance and real-world experience from surgeons in Korea.

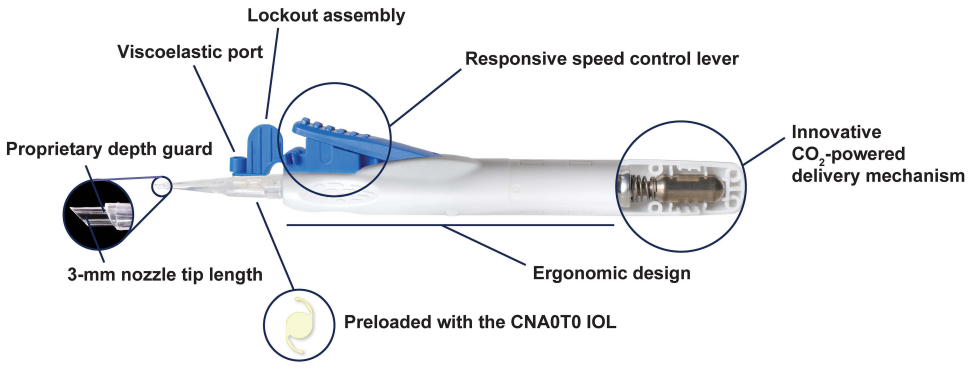

Figure 1 The automated injector system components and features.
Abbreviation: IOL, intraocular lens.

Methods

Study Design

This was a prospective, multicenter, single-arm study that assessed the clinical outcomes, safety, and IOL delivery performance of the CNA0T0 IOL preloaded in the automated injector system at 7 sites in Korea. Similar methods were used as described by Titiyal et al.[8] The study was conducted from July 2020 to December 2021, with the final database lock on 19 January 2022. The study was registered with the Clinical Research Information Service on 26 December 2019 (KCT0004634). Patients attended up to 10 visits over 1 year. Study visits included a screening visit, an operative visit, and postoperative visits on day 1, week 1, and months 1, 6, and 12.

Patients were 20 years or older with age-related unilateral or bilateral cataracts requiring an IOL implantation with calculated lens power between +15.0 and +30.0 D and preoperative regular corneal astigmatism of <1.00 D. Patients with clinically significant corneal abnormalities, ocular trauma, previous refractive surgery, previous corneal transplant, history of retinal conditions or degenerative eye disorders, or amblyopia were excluded from the study. Patients who were pregnant or breastfeeding were also excluded from the study.

The study was conducted in compliance with Good Clinical Practice and with international and national regulations, laws, and guidelines such as ISO 14155:2011 and in accordance with the ethical medical research principles outlined in the Declaration of Helsinki. This study was approved by the Chonnam National University Hospital Institutional Review Board (IRB), Yonsei University Health System Severance Hospital IRB, Seoul National University Bundang Hospital IRB, Samsung Medical Center IRB, Kangbuk Samsung Hospital IRB, The Catholic University of Korea Seoul St. Mary's Hospital IRB, and Kyungpook National University Hospital IRB. All patients included in this study signed informed consent.

Surgical Procedure

Standard phacoemulsification procedure was performed for cataract removal using surgeon's preferred methodology (including femtosecond laser) per local standard of practice. The AutonoMe Delivery System was used to implant the Clareon monofocal IOL (model CNA0T0) into the capsular bag in the posterior chamber of the eye. IOL power was calculated targeting emmetropia (±0.50 D). Personalized A-constants were not allowed in this study; all surgeons used the manufacturer's recommended A-constant of 119.1. Surgeons selected the most suitable IOL power using the same IOL power calculation formula at each site for all cases. For patients implanted bilaterally, an IOL power adjustment based on the refractive outcomes of the first operated eye was allowable for the second eye.

Surgeons used their own discretion for the initial incision size. Ophthalmic viscosurgical devices allowed during the surgery included Viscoat® (Alcon), DisCoVisc® (Alcon), or Provisc® (Alcon).

Efficacy Assessments

Best corrected distance visual acuity (BCDVA) and uncorrected distance visual acuity (UCDVA) were evaluated at 4 m using an Early Treatment of Diabetic Retinopathy Study chart under photopic conditions at 1 week, 1 month, 6 months, and 1 year after the implantation. Absolute prediction error was calculated as the absolute difference between the spherical equivalent of the preoperative predicted refraction and the postoperative manifest refraction.

The primary effectiveness endpoint was the percentage of eyes achieving monocular BCDVA of 0.2 logMAR or better at 1 month post-implantation. Secondary effectiveness endpoints included monocular BCDVA, monocular UCDVA, and absolute prediction error at 1 month after surgery.

Exploratory assessments included IOL clarity characteristics, such as glistenings and surface haze. Glistenings were graded according to a 4-grade scale adapted from Miyata et al, and grade 0 glistenings were defined as 0–25 microvacuoles/mm^2 on the glistenings assessment subjective scale.[7] The presence or absence of IOL surface haze was assessed using slit-lamp examination. PCO and neodymium-doped yttrium aluminium garnet (Nd:YAG) capsulotomy rates were also evaluated.

Surgeon's Preference of New Delivery System

Surgeon preference regarding the AutonoMe Delivery System was assessed with a survey questionnaire conducted after the completion of all surgeries at each site. A survey response was obtained from a single surgeon at sites where

a minimum of 14 implantations had been performed. The questionnaire assessed the surgeon's current method of cataract surgery (ie, preferred delivery system, typical incision size and architecture, and insertion technique) and asked the surgeons to rate their overall experience with the performance of the AutonoMe Delivery System (ease of preparation, ease of insertion, control of the IOL, ergonomics, intuitiveness/ease of use, and device preference).

Safety

Safety endpoints included ocular and nonocular adverse events (AEs), PCO and Nd:YAG capsulotomy, device deficiencies, IOL tilt and decentration, intraocular pressure, and surgical problems. AEs were reported from the time patients signed informed consent to study exit and were summarized using descriptive statistics.

Results

Patients

Of the 98 patients enrolled in the study, 12 discontinued because of screening failures before implantation. Of the 86 patients with attempted implantation, 125 eyes of 85 patients were successfully implanted with CNA0T0 IOLs. Of these patients, 40 were bilaterally implanted. Baseline demographic data are summarized in Table 1. Mean age ± SD was 69.1 ± 6.7 years, 46/85 patients (54%) were female, and all patients were Korean.

Table 1 Patient Demographics and Baseline Characteristics (All-Implanted Analysis Set)

Parameter	Patients (N = 85)
Age, years	
Mean ± SD	69.1±6.7
Range	51–88
Sex, n (%)	
Female	46 (54)
Male	39 (46)
Race, n (%)	
Asian	85 (100)
	All Eyes (N = 125)
Axial length, mm	
Mean ± SD	23.5±0.85
Range	20.9–25.6
Axial length category, n (%)	
Short (<21 mm)	1 (1)
Medium (21–26 mm)	124 (99)
Long (>26 mm)	0
Anterior chamber depth, mm	
Mean ± SD	3.10±0.38
Range	2.22–3.86
Corneal astigmatism, D	
Mean ± SD	0.54±0.26
Range	0–1.19
Monocular BCDVA, logMAR	
Mean ± SD	0.28±0.22
Range	−0.10 to 1.00
Monocular UCDVA, logMAR	
Mean ± SD	0.46±0.25
Range	0.08–1.24

Abbreviations: BCDVA, best corrected distance visual acuity; UCDVA, uncorrected distance visual acuity.

There were 7 patients who discontinued from the study (due to AEs [n = 4], loss to follow up [n = 1], or withdrawal by the patient [n = 2]); 79 patients completed the study and were included in the analysis. There were 116/125 eyes (93%) that completed the 1-year postoperative visit.

Surgical Procedure

The mean final corneal incision size after implantation of the CNA0T0 preloaded in the automated injector was 2.39 ± 0.26 mm (range, 2.2–2.8 mm). Most final incisions (87/125; 70%) were within the 2.2–2.4 mm range. The implanted IOLs ranged in power from +15.0 to +27.0, and the most frequently implanted IOL powers were +21.5 (16/125; 13%) and +22.0 (12/125; 10%).

Visual Acuity Outcomes

Mean ± SD monocular BCDVA for all eyes was 0.02 ± 0.11 logMAR at 1 month and 0.00 ± 0.10 logMAR at 12 months after implantation (Figure 2A). The primary effectiveness endpoint, BCDVA of 0.2 logMAR or better, was achieved by 94.4% of eyes at 1 month after implantation; at 12 months, 99.1% of eyes had BCDVA of 0.2 logMAR or better. Most eyes (83.1% and 87.8%) achieved BCDVA of 0.1 logMAR or better at 1 month and 12 months after implantation, respectively (Figure 2B).

Mean ± SD monocular UCDVA for all eyes was 0.11 ± 0.14 logMAR at 1 month and 0.07 ± 0.13 logMAR at 12 months after implantation (Figure 3A). More than half of all eyes (60.8% and 68.7%) achieved UCDVA of 0.1 logMAR or better at 1 and 12 months, respectively. Most eyes (97.4%) achieved UCDVA of 0.3 logMAR or better at 12 months after implantation (Figure 3B).

Mean absolute prediction error ± SD for all eyes was 0.33 ± 0.27 D at 1 month and 0.31 ± 0.29 D at 12 months after implantation (Figure 4).

Surgeon-Reported Preferences

One site was not included in the questionnaire analysis because the minimum number of study eye implants (14) was not met. Most surgeons indicated they were currently using the manually loaded Monarch Delivery System (Alcon) in their practice (4/6; 67%), with a 2.0–2.4 mm incision size (4/6; 67%), 2-plane incision architecture (4/6; 67%), and a wound-assisted insertion technique (4/6; 67%).

All surgeons (100%) rated both the preparation of the automated injector system before implantation and incision site insertion as "very easy" or "easy" and reported that the CNA0T0 IOL was "very controllable" or "controllable" during delivery (Supplementary Table 1). All surgeons (100%) rated the comfort of the hand posture when using the automated injector system during IOL delivery as "very comfortable" or "comfortable." Most surgeons found the automated injector system to be "more intuitive" or "much more intuitive", easier to use compared with their current delivery systems, and preferred the automated injector system to their current delivery system (Supplementary Table 1).

Safety Outcomes

There were no glistenings and no surface haze observed at any time throughout the 12 months of the study. There were no reports of clinically significant PCO or Nd:YAG capsulotomy for the duration of the study (Table 2).

One ocular serious AE (cystoid macular oedema) was reported in 1 eye (0.8%; Supplementary Table 2). Ocular AEs occurred in 11/126 eyes (9%). Four of 85 patients who received the CNA0T0 IOL (4.7%) discontinued due to a serious AE (fatal cardiac arrest, fatal tuberculosis, fatal malignant lung neoplasm, and fatal recurrent lung cancer). There were device deficiencies because of a plunger issue (ie, under or overriding IOL) in 2/126 eyes (1.6%); in 1 of these instances, the study IOL did not advance in the injector, and the eye was implanted with a nonstudy IOL and included in the safety analysis only. There were no eyes with IOL position change; no IOL tilt ≥1° or decentration ≥0.5 mm was reported at any visit.

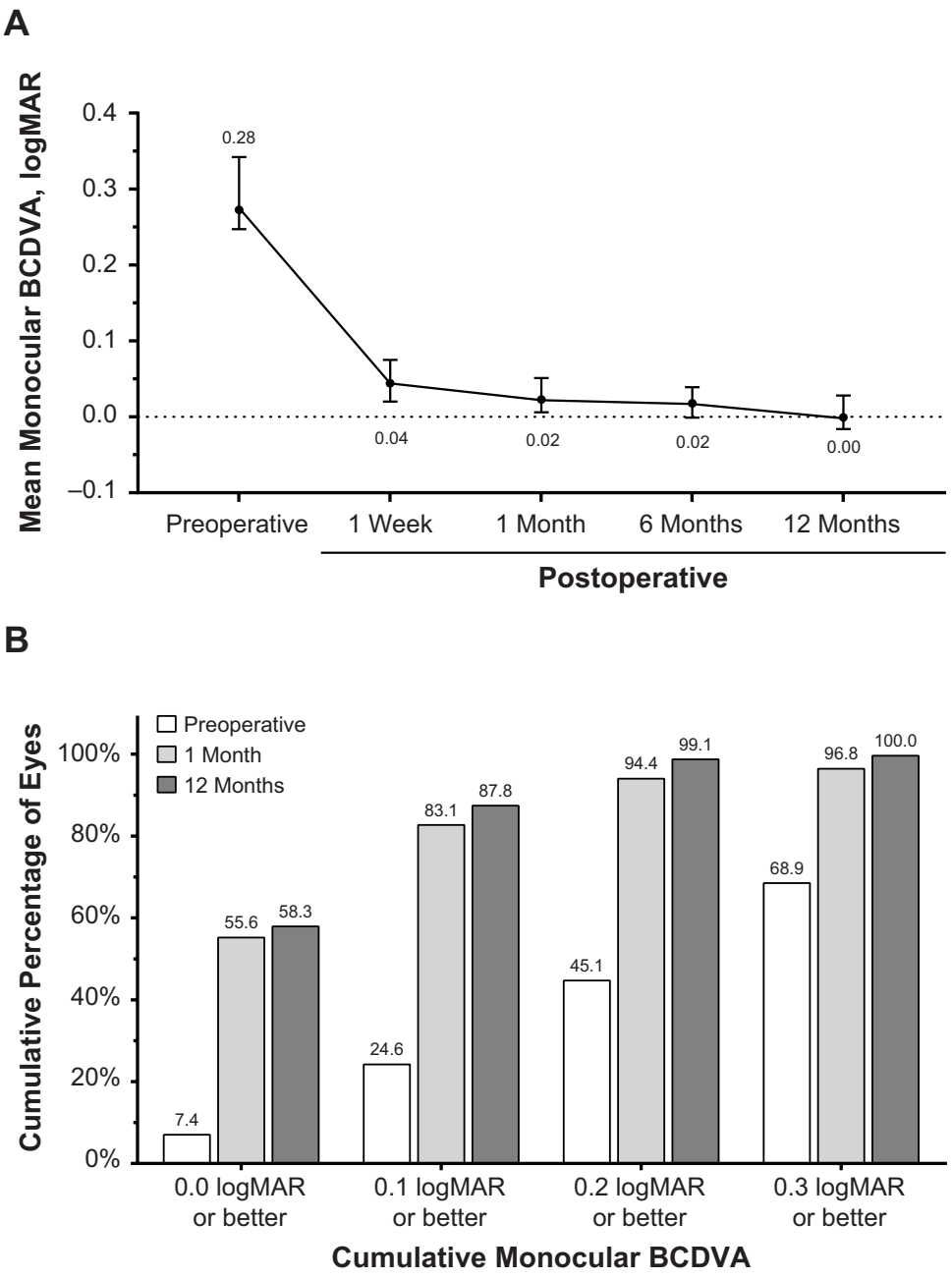

Figure 2 Mean monocular BCDVA (**A**) and cumulative distribution of monocular BCDVA (**B**) in all eyes implanted with the CNA0T0 IOL. Error bars represent 95% CI.
Abbreviations: BCDVA, best corrected distance visual acuity; IOL, intraocular lens.

Discussion

This was the first clinical evaluation of the performance and safety of the CNA0T0 IOL preloaded in the automated injector system in a Korean population in a real-world setting. The results from a Korean population provide valuable insights into the clinical effectiveness and safety of CNA0T0 IOLs, particularly in the context of a specific country and a distinct group of surgeons. This emphasis on a Korean population helps contextualize the real-world applicability and performance of the CNA0T0 IOL in this specific demographic group, contributing to the broader understanding of its clinical utility. The CNA0T0 IOL demonstrated good visual outcomes during the 12-month follow-up. There were no findings of clinically significant PCO or Nd:YAG capsulotomies at 12 months after implantation. Furthermore, there were no reports of surface haze, and only grade 0 glistenings were reported throughout the 12-month follow-up. The use of the

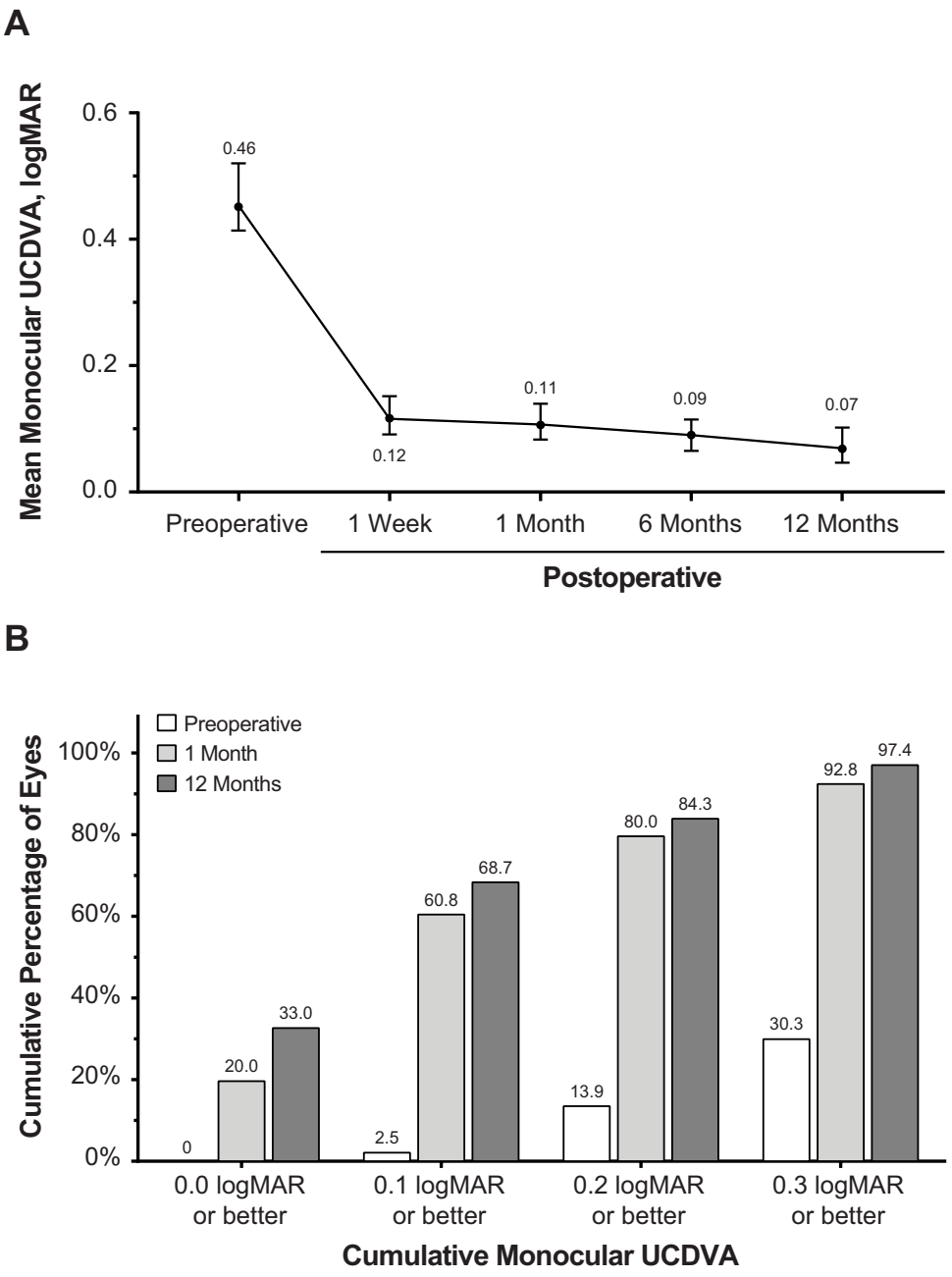

Figure 3 Mean monocular UCDVA (A) and cumulative distribution of monocular UCDVA (B) in all eyes implanted with the CNA0T0 IOL. Error bars represent 95% CI.
Abbreviations: IOL, intraocular lens; UCDVA, uncorrected distance visual acuity.

CNA0T0 IOL preloaded in the automated injector system resulted in high surgeon satisfaction and positive feedback on ease of use.

In the current study, mean monocular BCDVA improved from 0.28 logMAR preoperative to −0.002 logMAR 12 months after implantation, and all eyes achieved BCDVA of 0.3 logMAR or better. Mean monocular UCDVA for all eyes improved from 0.46 logMAR preoperative to 0.07 logMAR at 12 months after implantation, and 97.4% of eyes achieved UCDVA of 0.3 logMAR or better at 12 months. The visual acuity outcomes in the Korean population were consistent with outcomes from several 1-year studies conducted in other regions. In a multicenter Clareon IOL clinical trial in the United States (n = 350), mean monocular BCDVA at 12 months after implantation was −0.05 logMAR, and BCDVA of

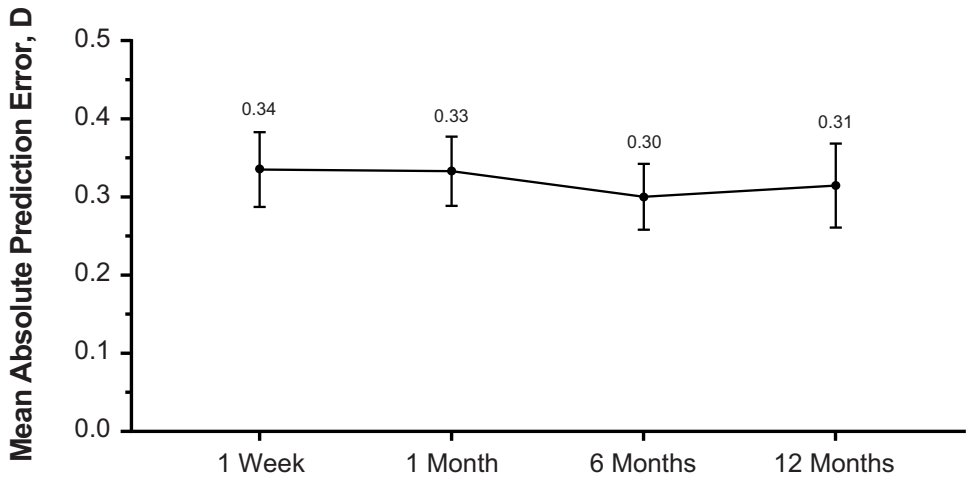

Figure 4 Mean absolute prediction error in all eyes with the CNA0T0 IOL. Prediction error = MRSE – predicted residual refractive error. Error bars represent 95% CI.
Abbreviations: IOL, intraocular lens; MRSE, manifest refraction spherical equivalent.

0.3 logMAR was achieved by 99.7% of patients.[5] There were similar visual acuities reported in 1-year studies conducted in Japan (n = 384) and India (n = 111) with the Clareon IOL preloaded in the AutonoMe Delivery System.[4,8]

Short-term results for this study were also consistent with findings from other studies. At 1 month post-implantation, the current study reported mean BCDVA of 0.02 logMAR. Similarly, in a study of 144 eyes implanted with the Clareon IOL preloaded in the AutonoMe Delivery System, mean BCDVA was 0.03 logMAR at 4 to 6 weeks after implantation in patients without ocular comorbidities.[24] Another study (n = 50) reported that BCDVA of −0.09 logMAR was achieved at 3 months after implantation with Clareon IOLs preloaded with the AutonoMe Delivery System.[20]

The Clareon IOLs were manufactured with the goal to improve clarity (ie, reduce surface haze, sub-surface nano-glistenings [SSNGs], and glistenings). The smoother surface of the Clareon IOLs was associated with lower surface haze, fewer SSNGs, and fewer glistenings compared with other IOLs in vitro.[6] A clinical study reported that at 12 months after Clareon IOL implantation, glistenings were rarely observed and were graded 0 on the Miyata scale.[25] The current study observed no surface haze and only grade 0 glistenings during 12 months of follow-up. The square-edge design and fibronectin binding of the Clareon IOL were intended to reduce PCO. In this study, there were no reports of clinically significant PCO or Nd:YAG capsulotomy (Table 2). There were 29/125 eyes (23%) with clinically nonsignificant PCO. Overall, 96/125 eyes (77%) had no observed PCO at 12 months postoperatively. This was consistent with previous findings from 2 studies in Japan that reported a 1% to 5% rate for Nd:YAG capsulotomy,[4,26] as well as Clareon IOL studies in other populations.[5,8]

Advancements in the design of IOL delivery systems have improved efficiency and outcomes of cataract surgery, including shorter total surgical case time and reduced risk of loading variability and device contamination.[11–13] The automated injector system used in this study is the first preloaded delivery system to use an automated mechanism of action. It provides intuitive ergonomic single-handed control of IOL delivery designed to benefit the surgeon, such that

Table 2 Eyes with Subjective Posterior Capsule Opacification

	All Eyes (N = 125)
Subjective posterior capsular opacification, n(%)	
None	96 (77)
Clinically nonsignificant	29 (23)
Clinically significant	0
Clinically significant requiring Nd:YAG	0

Note: Category represents maximum rating for an eye during the study.
Abbreviations: Nd:YAG, neodymium-doped yttrium aluminium garnet.

the second hand can be used to stabilize the globe during IOL delivery. Overall, the automated injector system received high satisfaction feedback from surgeons in Korea. Most surgeons found the automated injector system to be "more intuitive" or "much more intuitive" and reported that it was easier to use compared with their current delivery systems. These findings were consistent with surgeon responses from previous studies that assessed surgeon satisfaction in Japan and India.[4,8]

Based on the 2018 and 2020 national surveys of surgical practice in Korea, the majority of surgeons used phacoemulsification, and 64% to 66% used an incision size of 2.8 mm when performing surgery.[27,28] The automated injector system allows for IOL delivery through initial incisions as small as 2.2 mm; in this study, most final incisions (87/125; 70%) were within the 2.2–2.4 mm range (mean, 2.39 ± 0.26 mm), indicating minimal wound stretch. Previous studies have shown that a smaller incision would result in smaller postoperative surgically induced astigmatism.[29,30] Although data on incision wound architecture were not collected as part of this study, other studies have assessed effects of the automated injector system on wound healing. A clinical study (n = 40) that assessed corneal morphology with different IOL delivery systems reported less trauma to the wound, reduced wound retraction, and a more regular architecture of the corneal incision with the automated injector system compared with other delivery systems.[22] Additionally, the automated injector system demonstrated a smaller enlargement of the corneal wound during implantation and smaller corneal thickness increase compared with another delivery system.[15,31] In a study that evaluated corneal tissue trauma in patients with grade 4 cataract (n = 40), the use of the automated injector system resulted in less corneal thickness increase at the incision site and less endothelial cell loss 1 hour and 1 day after surgery.[15] The results of these studies suggest that the automated injector system is able to deliver IOLs through a small incision with minimal wound enlargement.

This study has a number of limitations, including the single-arm study design without a control group. Six eyes implanted with the Clareon IOL were not targeted for emmetropic postoperative refraction with the predicted residual refraction outside of ±0.50 D. Additionally, 3 eyes included in the analyses had preoperative regular astigmatism >1.00 D (Table 1). However, these deviations did not affect the results of the primary endpoints, and these eyes were included in the analysis. These deviations could have affected the secondary effectiveness endpoint of monocular UCDVA.

Because of the real-world setting, some patients in this study had ocular comorbidities, such as diabetic retinopathy, dry eye syndrome, meibomian gland dysfunction, and epiretinal membrane. Investigators judged that the outcomes of the study would not be confounded by the presence of these comorbidities. The inclusion of patients with ocular comorbidities increased the generalizability of these results to the larger "real-world" population. Restrictions related to COVID-19 (ie, travel limitations, quarantine, and social distancing) affected visit schedules and assessments; some visits may have been conducted late. However, 79 of the 85 patients with successful implantation completed the current study despite COVID-19–related disruptions. Other strengths of this study included the real-world setting with Korean patients and high patient retention through the 12-month follow-up period.

In conclusion, this 12-month real-world study of the CNA0T0 IOL preloaded in the automated injector system in Korea demonstrated visual outcomes consistent with studies in other regions; 100% of eyes experienced no surface haze and 100% of eyes had grade 0 glistenings. High surgeon satisfaction was reported for the automated preloaded injector based on a questionnaire that assessed device ease of use, control of the IOL delivery, and ergonomics. Overall, good visual outcomes were achieved with the CNA0T0 IOL preloaded in the automated injector system in a Korean population.

Abbreviations

AE, adverse event; BCDVA, best corrected distance visual acuity; IOL, intraocular lens; Nd:YAG, neodymium-doped yttrium aluminium garnet; PCO, posterior capsule opacification; SSNG, sub-surface nano-glistenings; UCDVA, uncorrected distance visual acuity.

Data Sharing Statement

The data used to support the primary findings of this study are available upon reasonable request from the study sponsor, Alcon Research LLC.

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Author Contributions

All authors made a significant contribution to the work reported, whether that was in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; agreed on the journal to which the article has been submitted; and agreed to be accountable for all aspects of the work.

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This study was funded by Alcon Research LLC. Alcon assisted with the design and conduct of the study; collection, management, analysis, and interpretation of the data; and preparation, review, and approval of the manuscript.

Disclosure

Hong Kyun Kim, Kyoung Yul Seo, Joon Young Hyon, and Hyun Seung Kim were consultants to Alcon. Kyung Chul Yoon and Chul Young Choi were consultants and clinical investigators for Alcon. Tae-Young Chung was a consultant/speaker and a clinical investigator for Alcon. Alexis Rendon is an employee of Alcon Research LLC. The authors report no other conflicts of interest in this work.

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