

One-year multicenter evaluation of a new hydrophobic acrylic intraocular lens with hydroxyethyl methacrylate in an automated preloaded delivery system



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Purpose: To assess a single-piece monofocal hydrophobic acrylic intraocular lens (IOL) with hydroxyethyl methacrylate (HEMA) (Clareon) contained in automated preloaded delivery system (AutonoMe).

Setting: 18 surgical sites in Japan.

Design: Observational study.

Methods: In patients undergoing phacoemulsification and IOL implantation of a new hydrophobic acrylic IOL using an automated injector, clinical data were collected preoperatively and at 1 day, 1 week, and 1 month, 6 months, and 12 months postoperatively. The degree of glistenings was graded on a 4-point scale. The surgeons rated usability and performance of the IOL delivery system on a 5-point scale.

Results: The study enrolled 384 eyes of 384 patients, ranging in age from 41 to 93 (73.8 ± 8.2, mean ± SD) years. The percentage of

eyes with corrected distance visual acuity of 20/25 or better at 1 day, 1 week, and 1 month, 6 months, and 12 months postoperatively was 82.6%, 91.9%, 92.8%, 96.6%, and 95.2%, respectively. Refractive error was within 1.0 diopter in approximately 90% of cases. No glistenings were found in all cases throughout the study period. The rate of Nd:YAG laser posterior capsulotomy was 0.9% at 1 year. The IOL delivery system received high ratings on its usability and performance by the surgeons.

Conclusions: The new hydrophobic acrylic IOL with HEMA showed excellent visual and refractive outcomes without developing glistenings throughout the 1-year study period. The surgeons gave high marks for usability and performance of the automated preloaded delivery system.

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Tireless efforts have been made to improve the performance of intraocular lenses (IOLs), such as refinement of lens materials and sophistication of delivery systems. Among them are the development of a single-piece hydrophobic acrylic IOL that contains hydroxyethyl methacrylate (HEMA) (Clareon CNA0T0; Alcon Laboratories, Inc.) and the introduction of an automated preloaded delivery system (AutonoMe; Alcon Laboratories, Inc.). The Clareon IOL, a modified version of AcrySof (Alcon Laboratories, Inc.), is manufactured using a new hydrophobic acrylic material to provide greater resistance to glistening formation, enhanced lens clarity characteristics, and a minimum level of surface haze.^{1,2} A hydrophilic copolymer, HEMA, is introduced instead of phenylethyl methacrylate that was used in AcrySof, giving a higher water content (1.5% at 35°C) than other hydrophobic acrylic materials. Experimental and clinical studies demonstrated that

the new hydrophobic acrylic IOL with HEMA is free from glistenings and surface light scattering.^{2–7} Large-scale clinical evaluation of this IOL, however, has not been reported.

AutonoMe is an automated preloaded IOL delivery system, which features CO₂-powered delivery mechanism. The depth guard attached to the cartridge nozzle confers mechanical resistance of the nozzle and prevents the excessive penetration of the nozzle tip into the incision. Experimental and clinical studies evaluated the influence of this injector on wound architecture.^{8–11} However, there have been no clinical studies on the usability and performance of this automated preloaded delivery system. In addition, to our knowledge, assessment of the actual products combining the Clareon IOL and AutonoMe has not been reported until now, except for 2 small studies with a short follow-up period after surgery, in which development of glistenings was not evaluated.^{12,13}

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We conducted the current multicenter study to investigate the intraoperative and postoperative performance of the monofocal Clareon IOL and AutoMe by analyzing surgeons' subjective ratings of this system and postoperative clinical parameters including the occurrence of glistenings for 1 year.

METHODS

Patient Selection

This trial was a single-arm, multicenter study involving 18 surgical sites in Japan. Patients were selected from consecutive cases among the clinic population who were eligible for routine cataract surgery and had undergone phacoemulsification and IOL implantation with Clareon and AutoMe from February to August 2019. Patients were enrolled to this observational study after finishing the cataract surgery. Inclusion criteria included good visual potential, corneal astigmatism less than 1.5 diopters (D), and no previous history of eye surgery. Exclusion criteria included coexisting ocular conditions that might affect vision, performance of combined surgery, and age younger than 20 years.

The study protocol was reviewed and approved by the ethics committees of the respective surgical sites or a nonprofit organization institutional review board (MINS IRB, Tokyo). A written informed consent was obtained from each patient before enrollment. This study adhered to the tenets of the Declaration of Helsinki and was conducted according to Ministerial Ordinance on Standards for Post Marketing Investigation and Studies of Medical Devices (Ministerial Ordinance of the Ministry of Health, Labour and Welfare No. 38 of 2005) and Ethical Guidelines for Medical and Health Research Involving Human Subjects (Ministry Notification of MEXT and MHLW No. 3 of 2014). This study was registered at ClinicalTrials.gov ID: NCT03824028, <https://clinicaltrials.gov/ct2/show/NCT03824028> (January 31, 2019).

Surgery

Surgeons from 18 surgical sites performed surgeries. Each surgeon used their standard, small-incision sutureless phacoemulsification cataract extraction technique to implant an IOL. Continuous curvilinear capsulorhexis of the anterior capsule approximately 5.0 to 5.5 mm in diameter was created manually, and the Clareon IOL was implanted into the capsular bag using the AutoMe injector.

Examinations

The ophthalmological examinations were performed before and 1 day, 1 week, and 1 month, 6 months, and 12 months after surgery. Preoperative examination included measurements of corrected distance visual acuity (CDVA), manifest refraction, intraocular pressure, slitlamp anterior segment examination, optical biometry, keratometry, and retinal evaluation under pupil dilation. IOL power calculation was performed using the Sanders-Retzlaff-Kraff/Theoretical formula or the Barrett Universal II formula with A-constant of 119.1. Postoperatively, CDVA was evaluated at all postoperative visits. Occurrence of postoperative adverse events

related to surgery or IOLs was checked at all postoperative visits. Under pupil dilation, the degree of glistenings in the IOL optic was assessed using a 4-point scale (0 to 3) based on the Miyata grading system in which grade 0 represents <25 microvacuoles/mm², and grade 3 represents ≥151 microvacuoles/mm².¹⁴

After surgery, surgeons were asked to evaluate the performance and usability of the IOL delivery system. Table 1 lists the parameters that the surgeons rated on a 5-point scale from very good to very poor.

Statistical Analysis

The sample size was determined as 300 to have 95% statistical power to detect the events of 1% probability.

RESULTS

The study enrolled 384 eyes of 384 patients, ranging in age from 41 to 93 (73.8 ± 8.2, mean ± SD) years. There were 156 men and 228 women. Because of the pandemic of new coronavirus and so on, considerable number of patients failed to return to the predetermined postoperative visits, especially at 6 months and later. The number of eyes examined at each time point was 384 (100%) at 1 day, 371 (96.6%) at 1 week, 376 (97.9%) at 1 month, 321 (83.6%) at 6 months, and 230 (59.9%) at 1 year postoperatively. Even with 230 eyes at 1 year, however, the statistical power to detect 1% events still maintained at 90.1%.

The performance and usability of the AutoMe injector were evaluated by the surgeons following surgery. As summarized in Table 1, the automated preloaded delivery system received relatively favorable ratings, and more than 90% of responses were rated very good or good for parameters such as ease of preparation, ease of nozzle tip insertion into the incision, and controllability of IOL delivery speed. On the other hand, parameters such as controllability of IOL behavior during implantation and usability in comparison with manual preloaded injectors received slightly lower marks.

The time course of changes in postoperative CDVA is shown in Figure 1, and its breakdown is summarized in Figure 2. The percentage of eyes with CDVA of 20/25 or better at 1 day, 1 week, and 1 month, 6 months, and 12 months postoperatively was 82.6%, 91.9%, 92.8%, 96.6%, and 95.2%, respectively. The amount of refractive error was calculated as the absolute difference between postoperative manifest refraction and the targeted refraction. The refractive error was small and stable (Figure 3), and approximately 90% of cases presented refractive errors within 1.0 D (Figure 4). The time course of changes in the simple residual refractive error is shown in Figure 5.

Table 1. Parameters Evaluated by Surgeons After Each Injection Regarding the Automated Preloaded Injector System.

	Very good	Good	Fair	Poor	Very poor
A. Ease of preparation	184 (47.9)	181 (47.1)	16 (4.2)	3 (0.8)	0 (0.0)
B. Ease of nozzle tip insertion into the incision	145 (37.8)	212 (55.2)	21 (5.5)	6 (1.6)	0 (0.0)
C. Controllability of IOL delivery speed	163 (42.4)	187 (48.7)	26 (6.8)	8 (2.1)	0 (0.0)
D. Controllability of IOL behavior during implantation	144 (37.5)	151 (39.3)	63 (16.4)	24 (6.3)	2 (0.5)
E. Comfort of hand posture during handpiece manipulation	123 (32.0)	205 (53.4)	52 (13.5)	4 (1.0)	0 (0.0)
F. Usability in comparison with manual preloaded injectors	159 (41.4)	145 (37.8)	70 (18.2)	9 (2.3)	1 (0.3)
G. Overall ease of use	152 (39.6)	160 (41.7)	61 (15.9)	10 (2.6)	1 (0.3)
H. Preference in your practice	110 (28.6)	223 (58.1)	47 (12.2)	4 (1.0)	0 (0.0)

n (%) of scores out of 384 cases

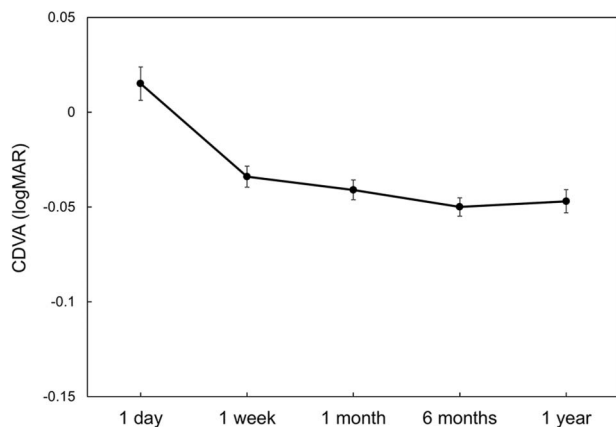


Figure 1. Time course of changes in CDVA. Mean \pm standard error.

The degree of glistenings rated on a 4-point scale (grade 0 to 3) remained grade 0 in all cases throughout the study period. Two eyes (2/230, 0.9%) underwent Nd:YAG laser posterior capsulotomy for posterior capsule opacification, 6 months and 1 year after surgery, respectively. There were no other intraoperative and postoperative complications related to the IOL or the delivery system.

DISCUSSION

The current 1-year multicenter study indicates that the new hydrophobic acrylic IOL with HEMA, Clareon, is associated with highly satisfactory clinical outcomes after surgery, including excellent visual acuity, stable refraction, low incidence of posterior capsule opacification, and no glistening formation throughout the study period. A previous 1-year clinical study reported that the Clareon IOL had excellent refractive stability and visual acuity.¹¹ Another comparative study demonstrated that there were no differences in visual outcomes between the Clareon IOL and the Tecnis PCB00 IOL at 12 months postoperatively.⁵ A clinical study to evaluate 2 hydrophobic acrylic single-piece IOLs showed that there was no clinically relevant difference in anterior chamber depth between Clareon and AcrySof IQ in patients

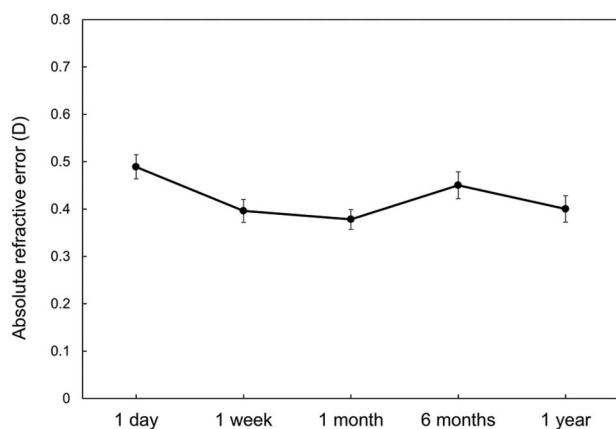


Figure 3. Time course of changes in the amount of absolute refractive error. The refractive error was calculated as the absolute difference between postoperative manifest refraction and targeted refraction. Mean \pm standard error.

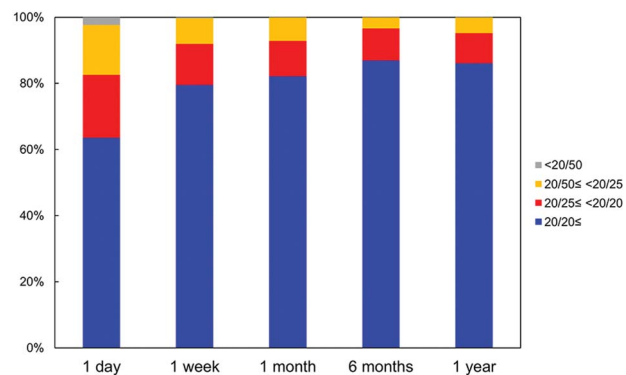


Figure 2. Distribution of CDVA.

after uneventful cataract surgery, and both IOLs yielded good refraction and visual acuity outcomes.¹⁵ The findings in our study are in good agreement with these previous reports.

As for clarity of the optic, an in vitro study reported that the Clareon IOL exhibited among the lowest levels of surface haze and roughness, surface light scattering, and glistenings compared with other commercially available hydrophobic acrylic IOLs.² In a laboratory setup, Wang et al. investigated changes in the predisposition for glistening formation in 1 type of hydrophobic acrylic IOL material and demonstrated that a high number of glistenings were induced in the explanted IOLs from the 1990s.³ The propensity for glistening formation decreased considerably after that decade, and the current Clareon material is essentially glistening free. Long-term clinical observation confirmed that surface light scattering is suppressed in Clareon IOLs up to 7 years and that glistenings and surface light scattering did not develop with Clareon IOLs during 9-year observation.^{4,6} The current larger cohort study supports these previous findings.

Clareon is a modified version of AcrySof for enhanced clarity and greater resistance to glistenings.^{1,2} AcrySof was made of a copolymer of phenylethyl acrylate and phenylethyl methacrylate crosslinked with 1.4 butanediol diacrylate. In Clareon, phenylethyl methacrylate is replaced by a hydrophilic copolymer, 2-HEMA. It is speculated that introduction of 2-HEMA in the acrylic backbone of Clareon creates an interface

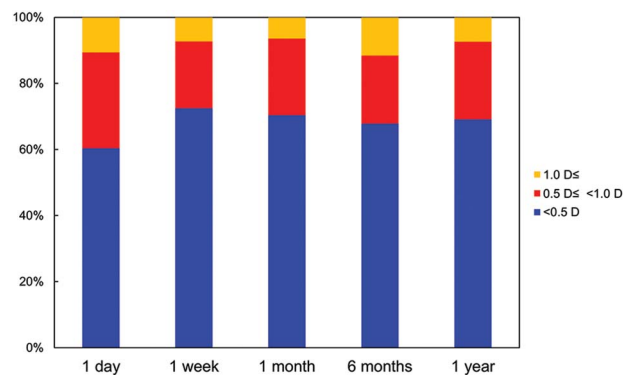


Figure 4. Distribution of refractive error. The refractive error was calculated as the absolute difference between postoperative manifest refraction and targeted refraction.

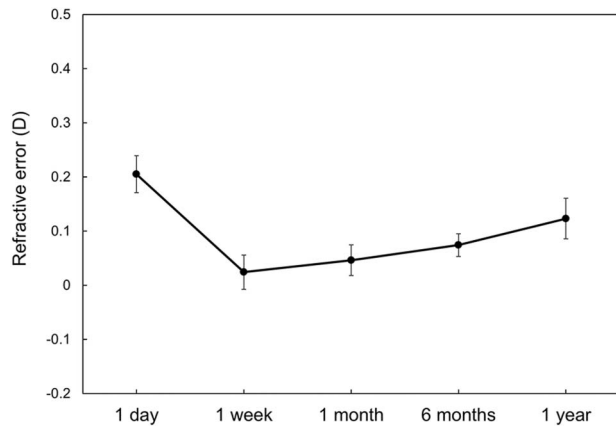


Figure 5. Time course of changes in the amount of simple refractive error. The refractive error was calculated by subtracting target refraction from postoperative manifest refraction. Mean \pm standard error.

for the interaction of water molecules in the optic, preventing microvacuole formation, thereby reducing the chances of glistenings.¹ The in situ water content of 1.5%, which is higher than the 0.23% of AcrySof, is also thought to help reduce the optical phenomena caused by microvacuoles and nanovacules. In vitro and clinical studies of hydrophobic acrylic materials with a water content higher than standard hydrophobic acrylic materials (typically less than 0.5%) showed that they present advantages in terms of hydration-related phenomena, such as glistenings.^{16–18} The Clareon is produced from a hydrophobic copolymer formulation that uniformly distributes water throughout the polymer matrix using a proprietary manufacturing technology, which is likely to have a positive impact on clarity.² The present and previous studies clinically prove that Clareon carries a very low risk for surface and bulk inhomogeneities, such as glistenings and surface light scatterings.

Our study assessed the development of glistenings for 1 year. The incidence of glistenings reported in the literature appears to vary as a function of the postoperative time considered.¹⁹ In 115 eyes implanted with the 3-piece AcrySof MA60BM, Miyata et al. reported that no glistenings were found 1 month after surgery; the incidence was 20% at 3 months, 51% at 6 months, and 55% at 1 year.²⁰ In a study in which 42 eyes implanted with the AcrySof MA30BA or MA60BM were examined at 2.4 ± 0.3 years (range 6 to 46 months) postoperatively, all IOLs had glistenings.²¹ Regarding the single-piece AcrySof IOLs, Davison observed trace to 2+ glistenings in 11 of 100 consecutive patients with the SA30AL IOL examined 1 to 16 months postoperatively (mean 8 months).²² Waite et al. examined consecutive patients with the SA60 IOL at 12 months, 24 months, and 36 months and patients with the SN60 at 12 months.²³ All 53 IOLs included in the study showed some degree of glistenings. In a large series of cases with AcrySof IOL (SN60AT, SN60WF, SA60AT, and MA), glistenings occurred in 157 (60.4%) of 260 eyes, and comparison of the severity of glistenings stratified by duration of follow-up (≤ 24 months vs > 24 months) showed no statistically significant difference.²⁴ In addition, a 9-year clinical study reported complete absence of glistenings

and surface light scattering formation with Clareon.⁴ Although our observation period was only 1 year after surgery, none of the eyes developed glistenings in a large cohort. Thus, from the previous and current findings combined, we would conclude that Clareon has long-term resistance to microvacuole formation.

In our study, 2 eyes (2/230, 0.9%) underwent Nd:YAG laser posterior capsulotomy for posterior capsule opacification, 6 months and 1 year after surgery, respectively. This result is consistent with those of a previous meta-analysis, which demonstrated that the overall probability of performing Nd:YAG posterior capsulotomy within a year of implant for AcrySof was 1.44% (1.11% to 1.83%) and 0.62% (0.21% to 1.38%) for Clareon IOLs.²⁵

The current study, to our knowledge, represents the first clinical evaluation of usability and performance of the automated preloaded delivery system, AutoMe, by asking the surgeons to grade 8 parameters on a semiquantitative scale. As shown in Table 1, overall ratings were quite favorable, and more than 90% of responses were rated very good or good for parameters such as ease of preparation, ease of nozzle tip insertion into the incision, and controllability of IOL delivery speed. On the other hand, parameters such as controllability of IOL behavior during implantation and usability in comparison with manual preloaded injectors received slightly lower marks. The negative feedbacks from the surgeons on these parameters included difficulty in controlling the leading haptics which came out straight (not tucked) and delayed release of the trailing haptics from the injector, indicating that some surgeons preferred the manual injector system over the automated delivery system because of unpredictable behaviors of the haptics during insertion. More efforts are needed to improve these points and to further sophisticate the automated IOL delivery system. These minor events, however, did not cause any consequences in surgery, and IOL implantation was successfully completed without complications in all cases. With this automated delivery system, the speed of IOL advancement is easily controlled by varying the lever depression. Because this is a single-handed device, the surgeons can stabilize the eye with the second hand. There is a depth guard at the tip of the nozzle to enhance user-friendliness of the device. These features seem to contribute to the highly positive evaluations of this delivery system by the surgeons.

The present study has several limitations. First, 16.4% and 40.1% of eyes were lost to follow-up at 6 and 12 months postoperatively, respectively, due to the pandemic of new coronavirus and so on. Second, some important clinical data were not collected, such as IOL power, axial length, and incision size. The original study plan did not include these parameters because this was planned as a postmarket surveillance, of which primary purposes were to evaluate IOL delivery performance, visual outcomes, and refractive stability.

In conclusion, the current multicenter study evaluated new hydrophobic acrylic IOL with HEMA contained in the automated delivery system. The injector system received high ratings on its usability and performance by the surgeons. One-year postoperative visual outcomes and refractive stability were excellent, the rate of Nd:YAG laser

posterior capsulotomy was very low, and no IOL developed glistenings throughout the study period.

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WHAT WAS KNOWN

- The Clareon IOL, a modified version of AcrySof, is manufactured with a new hydrophobic acrylic material containing hydroxyethyl methacrylate for enhanced lens clarity characteristics.
- AutoNoMe is an automated preloaded IOL delivery system, which features CO₂-powered delivery mechanism.

WHAT THE PAPER ADDS

- The 1-year multicenter study indicated that the Clareon IOL contained in the AutoNoMe preloaded delivery system showed excellent visual and refractive outcomes, without glistening formation.
- The injector system received high ratings on its usability and performance by surgeons.

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