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Original Article

Clinical Outcomes of a New Hydrophobic Trifocal Intraocular Lens with Hydroxyethyl Methacrylate in Cataract Surgery: A Prospective Multicenter Study

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Purpose: To investigate the clinical outcomes of new hydrophobic trifocal intraocular lens with hydroxyethyl methacrylate in the Korean population

Methods: This prospective, multicenter, and observational study evaluated the clinical outcomes of 80 eyes of 40 patients with age-related cataract underwent cataract surgery using CNWT (Clareon PanOptix). Assessment included monocular and binocular uncorrected distance visual acuity, corrected distance visual acuity, uncorrected intermediate visual acuity (at 60cm), near visual acuity (at 40 and 33 cm), uncorrected defocus curves, questionnaires evaluating photic phenomena, spectacle independence, and spectacle free satisfaction.

Results: At postoperative 3 months, mean uncorrected binocular visual acuities were 0.04, 0.04, 0.03 logarithm of the minimum angle of resolution (logMAR) at far, intermediate, and near distances, respectively. All patients achieved uncorrected binocular visual acuity of 0.2 logMAR or better. Monocular and binocular defocus curve indicated a mean visual acuity of 0.2 logMAR or better at the defocus range of +1.0 to – 3.0 diopters (100 to 33 cm) and +1.0 to – 3.5 diopters (100 to 28 cm). High spectacle independence was observed at all distances, with 37.5% patients reporting photic phenomena.

Conclusions: The Clareon PanOptix intraocular lens has shown positive clinical outcomes, providing a viable option for cataract surgery. These lenses effectively address patients' visual needs, especially in intermediate and near distance tasks, reducing dependence on glasses.

Key Words: Cataract, Multifocal intraocular lenses, Presbyopia

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Recent advancements in intraocular lens (IOL) technology have led to the development of trifocal IOLs, designed to enhance visual acuity (VA) at varying distances. This innovation prioritizes maintaining clear vision at far distances, reducing discomfort for intermediate and near vi-

sion, and achieving a high level of spectacle independence. Trifocal IOLs have demonstrated superior improvement in near VA compared to extended depth of focus IOLs in previous studies [1–3]. Studies by Lubinski et al. [4] have reported significantly better near and intermediate vision with trifocal IOLs compared to extended depth of focus IOLs. This body of research consistently suggests that trifocal IOLs may outperform monofocal IOLs and other multifocal IOLs, especially in VA at near to intermediate distances [5–7].

As IOL technology has diversified, there have been advancements in IOL materials, particularly in the context of multifocal IOLs. TFNT (Acrysof PanOptix, Alcon), a globally used IOL, is the trifocal diffractive IOL based on SN60WF (Acrysof IQ, Alcon). However, it is known that long-term issues such as glistening and surface scattering are more associated with multifocal lenses, particularly those made of the Acrysof material [8]. Glistening refers to small, fluid-filled vacuoles that can scatter light, leading to visual disturbances like glare and halos. To address this, CNA0T0 (Clareon, Alcon) is an advanced IOL that incorporates improved material technology, transitioning from phenylethyl methacrylate (PEMA) to hydroxyethyl methacrylate (HEMA) [9]. A new diffractive hydrophobic multifocal IOL, CNWT (Clareon PanOptix, Alcon), aims to improve near and intermediate VA while minimizing the risk of glistening [10].

This study aims to evaluate the visual performances and patient satisfaction of individuals who underwent bilateral implantation of Clareon PanOptix IOLs, through a comprehensive analysis of monocular and binocular visual outcomes, defocus curves, and patient-reported experiences.

Materials and Methods

This study was approved by the Institutional Review Board of Kangbuk Samsung Hospital (No. 2022-10-033-003). Informed consent was obtained from all participants before enrollment. The study adhered to the principles outlined in the Declaration of Helsinki

This prospective study enrolled patients with age-related cataracts who underwent bilateral cataract extraction via phacoemulsification and received bilateral implantation of the trifocal CNWT IOL. All participants, aged 50 years or older, consented to undergo surgery for the second eye within a week following the initial surgery. Inclusion criteria comprised individuals with a postoperative visual po-

Fig. 1. Simulated images for subjective photic phenomena survey to patients. (A) None. (B) Mild. (C) Moderate. (D) Severe.

tential of 20 / 25 or higher and preoperative corneal astigmatism of 0.75 diopters (D) or less. Exclusion criteria were the same as in a previous study [11]: (1) pregnant and lactating women; (2) patients with a history of retinal disease, ocular trauma, or ocular surgery with evidence of keratoconus or significant irregular astigmatism; (3) patients who had worn rigid contact lenses within the past 6 months, gas-permeable lenses within the past month, or longer wearing times or daily soft contact lenses within 7 days of scheduled surgery; (4) patients with other diseases affecting capsule stability such as pseudoexfoliation syndrome, glaucoma, traumatic cataract, or Marfan syndrome; and (5) patients who were not able to read or understand the informed consent.

Table 1. Preoperative characteristic of 20 patients (40 eyes)

Characteristic	Value (n = 40)
Age (yr)	64.28 ± 5.76 (53–75)
Sex	
Male	5 (12.5)
Female	35 (87.5)
Sphere (D)	1.061 ± 1.850
Cylinder (D)	–0.744 ± 0.485
MR spherical equivalent (D)	0.691 ± 1.860
Axial length (mm)	23.511 ± 0.952
Pupil size (mm)	
Photopic pupil	3.896 ± 0.874
Mesopic pupil	4.750 ± 0.674
Preoperative refractive target (D)	–0.299 ± 0.159

Values are presented as mean ± standard deviation (range), number of eyes (%), or mean ± standard deviation.
D = diopters; MR = manifest refraction.

For preoperative assessment, all patients received ophthalmic examinations including uncorrected distance VA (UDVA), corrected distance VA (CDVA), uncorrected intermediate VA (UIVA) at 66 cm, uncorrected near VA (UNVA) at 40 and 33 cm, topography (Galilei G6, Ziemer Ophthalmic Systems AG), corneal aberration (OPD SCAN, NIDEK Inc), optical biometry and keratometry (IOLMaster 700, Carl Zeiss Meditec), slit-lamp examination, and funduscopy. All visual acuities were checked using ETDRS (Early Treatment Diabetic Retinopathy Study) charts (Vector Vision Ltd).

Table 2. Monocular and binocular visual outcomes at postoperative 3 months of 20 patients (40 eyes)

Variable	Before	After	Difference	*p*-value
Sphere (D)	1.07 ± 1.85	0.00 ± 0.38	1.06 ± 1.85	<0.001
Cylinder (D)	–0.73 ± 0.49	–0.49 ± 0.47	–0.25 ± 0.57	0.001
Spherical equivalent (D)	0.70 ± 1.86	–0.24 ± 0.33	0.94 ± 1.83	<0.001
Monocular				
UDVA (logMAR)	0.32 ± 0.27	0.04 ± 0.08	0.27 ± 0.29	<0.001
CDVA (logMAR)	0.14 ± 0.25	0.00 ± 0.04	0.14 ± 0.26	0.002
UIVA (logMAR)	0.38 ± 0.25	0.05 ± 0.07	0.32 ± 0.26	<0.001
UNVA (logMAR)				
At 40 cm	0.43 ± 0.27	0.04 ± 0.06	0.37 ± 0.29	<0.001
At 33 cm	0.47 ± 0.30	0.06 ± 0.08	0.41 ± 0.29	<0.001
Binocular				
UDVA (logMAR)	0.27 ± 0.20	0.04 ± 0.08	0.23 ± 0.19	<0.001
CDVA (logMAR)	0.11 ± 0.18	0.00 ± 0.04	0.11 ± 0.20	0.017
UIVA (logMAR)	0.30 ± 0.17	0.04 ± 0.08	0.26 ± 0.16	<0.001
UNVA (logMAR)				
At 40 cm	0.33 ± 0.16	0.03 ± 0.06	0.30 ± 0.15	<0.001
At 33 cm	0.36 ± 0.19	0.04 ± 0.07	0.31 ± 0.18	<0.001

Values are presented as mean ± standard deviation.
D = diopters; UDVA=uncorrected distance visual acuity; logMAR = logarithm of the minimum angle of resolution; CDVA = corrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity.

All surgeries were performed by two operators (CYC, KT) in two institutions, involved a 2.2-mm corneal incision, manual capsulorhexis, and phacoemulsification under topical anesthesia, with IOLs implanted in the bag. Postoperative refraction aimed at the nearest negative value from emmetropia using the Haigis formula for IOL power calculation.

Follow-up examinations were conducted at 1 week, 1 month, and 3 months after fellow eye IOL implantation. Main outcomes included VA, monocular and binocular defocus curves, and patient questionnaires. UDVA, CDVA, UIVA at 66 cm, and UNVA at 40 and 33 cm were measured. Uncorrected monocular and binocular defocus curves ranged from +1.00 to –4.00 D in 0.50 spherical D intervals. A questionnaire assessed subjective satisfaction, spectacle independence, spectacle-free vision satisfaction, and subjective photic phenomena. During the subjective assessment of photic phenomena, simulation images were given to the patients representing various types and degrees of photic phenomena (Fig. 1A–1D). Subsequently, they were instructed to indicate the severity level on a scale consisting of four options: none, mild, moderate, and severe.

Statistical analyses used IBM SPSS ver. 24.0 (IBM Corp), presenting continuous variables as means ± standard deviations. The Wilcoxon signed rank test analyzed preoperative and postoperative variables, considering a *p*-value less than 0.05 as statistically significant.

Results

This study involved 80 eyes from 40 patients, with an average age of 64.28 ± 5.76 years (range, 53 to 75 years). The participants included five men and 35 women. Table 1 outlines the preoperative patient characteristics.

Visual outcomes

The mean preoperative and postoperative spherical equivalent values, monocular and binocular UDVA, CDVA, UIVA, and UNVA are shown in Table 2. Additionally, mean preoperative refractive target was –0.299 ± 0.159 D and mean postoperative spherical equivalent was –0.24 ± 0.33 D. All postoperative values exhibited statistically significant improvements in VA compared to the preoperative state. The cumulative percentage of monocular VA, depicted in Fig. 2, revealed that 98% of patients achieved a mean monocular UDVA of 0.2 logarithm of the minimum angle of resolution (logMAR) or better (0.04 ± 0.08 logMAR). Additionally, all patients achieved monocular UIVA and CDVA of 0.2 logMAR or better (0.05 ± 0.07 and 0.00 ± 0.04 logMAR, respectively), also all subjects achieved monocular UNVA of 0.2 logMAR or better at 40 and 33 cm distance (0.04 ± 0.06 and 0.06 ± 0.08 logMAR, respectively). As shown in Fig. 3, all patients achieved bin-

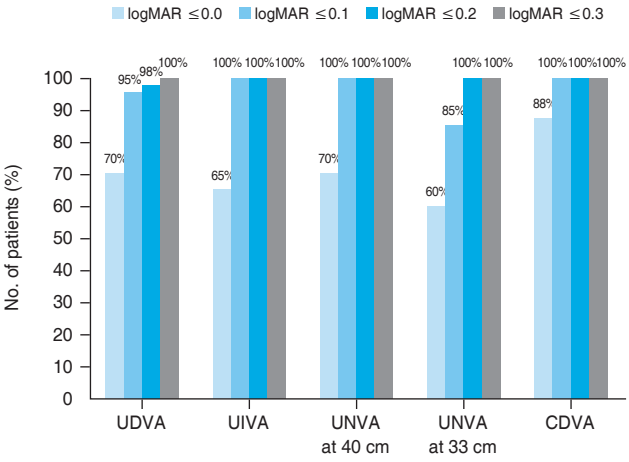

Fig. 2. Categorical statistics for monocular uncorrected distance visual acuity (UDVA), uncorrected intermediate VA (UIVA), uncorrected near VA (UNVA), and corrected distance VA (CDVA) at postoperative 3 months in 20 patients (40 eyes). logMAR = logarithm of the minimum angle of resolution.

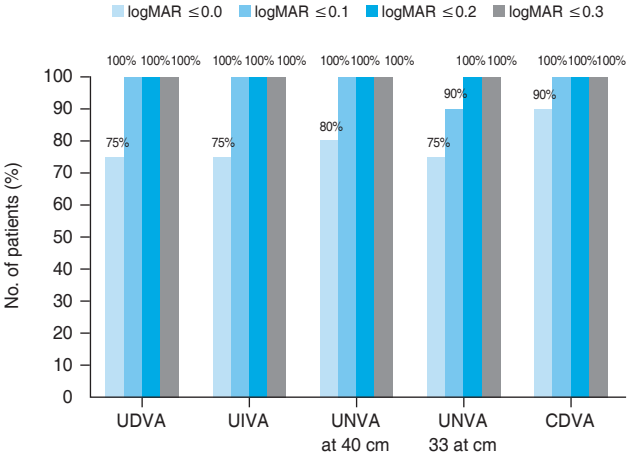

Fig. 3. Categorical statistics for binocular uncorrected distance visual acuity (UDVA), uncorrected intermediate VA (UIVA), uncorrected near VA (UNVA), and corrected distance VA (CDVA) at postoperative 3 months in 20 patients (40 eyes). logMAR = logarithm of the minimum angle of resolution.

ocular UDVA, CDVA, UIVA, and UNVA of 0.2 logMAR or better.

Uncorrected defocus curves

Uncorrected mean monocular and binocular defocus curves are shown in Fig. 4. In the uncorrected binocular defocus curve, a mean VA of 0.2 logMAR or better was maintained in the defocus range of +1.00 to – 3.50 D (corresponding visual distance of 100 and 28 cm). Notably, there was a plateau without a clearly evident trough in VA from +1.00 to –3.00 D (VA range, 0.090 to 0.070 logMAR). Uncorrected monocular defocus showed the best performance with vision of 0.022 logMAR at vergences corresponding to distances of approximately 1.0 m. The monocular defocus curve showed a mean VA of 0.2 logMAR or better at +1.00 to –3.00 D (VA range, 0.110 to 0.100 logMAR).

With an increase in negative defocus, simulating a reduced object distance (–3.00 to –4.00 D equivalent to distances of 33 and 25 cm), both monocular and binocular defocus curves displayed a gradual decrease in VA, with binocular visions of 0.07 logMAR at –3.00 D, 0.18 logMAR at –3.50 D, and 0.27 logMAR at –4.00 D, respectively. Additionally, the monocular defocus curve showed decreasing VA of 0.10, 0.21, and 0.34 logMAR at –3.0, –3.5, and –4.0 D, respectively.

Questionnaire

The questionnaire results regarding the perception of photic phenomena are presented in Fig. 5. Eight out of 40 patients (20.0%) did not report any photic phenomena such as glare, halo, or starburst. Among the 17 patients (42.5%) who reported mild photic phenomena, 50% frequency of photic phenomena was most commonly observed. The incidence of moderate to severe photic phenomena was reported by 37.5% of patients.

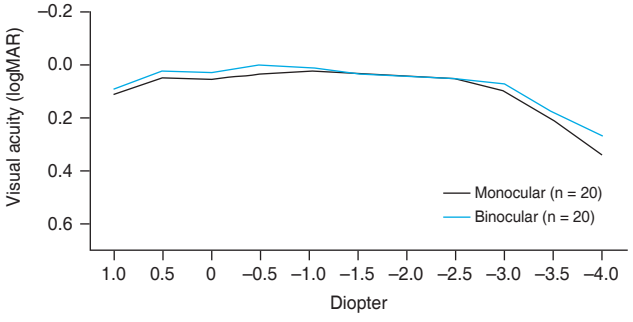

Fig. 4. Uncorrected mean monocular and binocular defocus curves in 20 patients (40 eyes). logMAR = logarithm of the minimum angle of resolution.

Spectacle independence

Regarding spectacle independence, more than 95% of subjects were able to function without glasses at all three distances in daily life. The proportions of patients never requiring eyeglasses was 100% at intermediate distance, 95% at near distance, and 97.5% at far. One patient reported using spectacles for far distance, and two patients did for near distance (Fig. 6).

Satisfaction

Ninety-five percent of patients reported being "very sat-

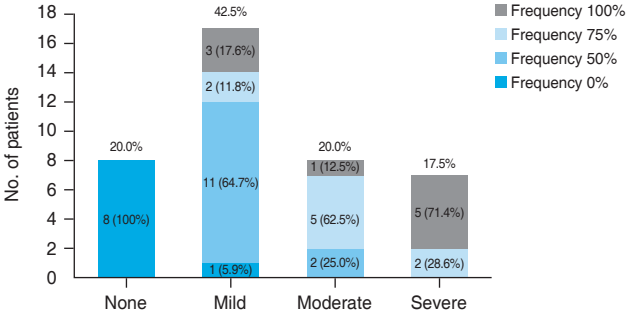

Fig. 5. Results of the questionnaire regarding severity and frequency of photic phenomena at postoperative 3 months.

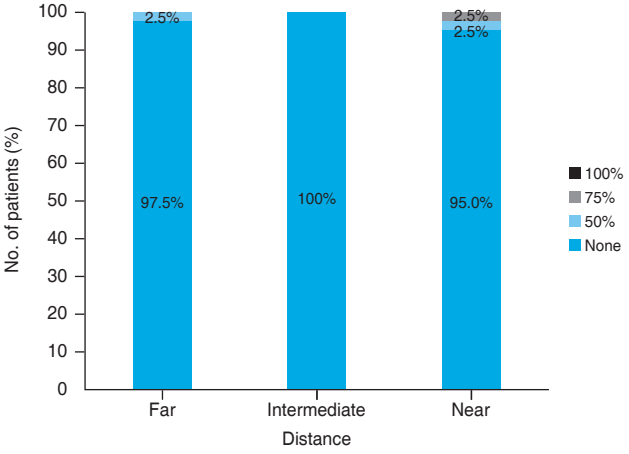

Fig. 6. Results of the questionnaire for spectacle use in daily life at postoperative 3 months.

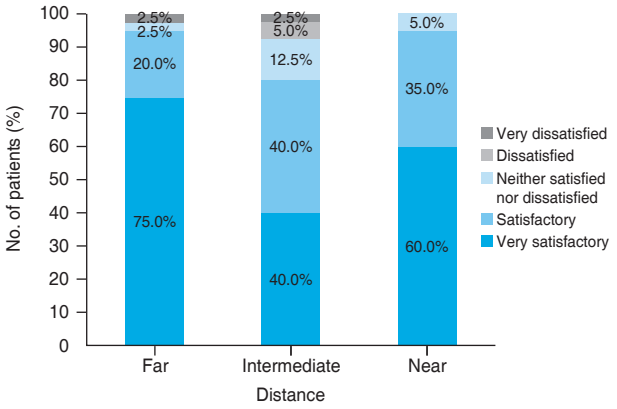

Fig. 7. Results of the questionnaire for spectacle free satisfaction at postoperative 3 months.

isfied" or "satisfied" with their vision without glasses or contact lenses at far and near distance. Eighty percent of patients reported satisfaction regarding spectacle-free vision at intermediate distance (Fig. 7).

Discussion

This study analyzed the outcomes of binocular implantation of the CNWT IOL, exploring monocular and binocular visual performance at diverse distances (4 m, 1.5 m, 40 cm, 33 cm), defocus curves, photic phenomena, and spectacle independence. Previous research indicates that multifocal IOL implantation extends the range of vision and enhances spectacle independence compared to monofocal IOLs [12–15].

In previous studies, some authors reported that Acrysof material is associated with glistening [16]. Tognetto et al. [17] showed higher percentage and greater density of glistening in Acrysof group compared to other intraocular lenses. Other study reported SN60WF showed mean glistening density (microvacuole [MV] per square millimeter) of 264.4 ± 110.3 MV/mm^2 and mean Miyata grading of 2.6 *in vitro* glistening formation [18]. Another study detected mean number of microvacuoles of Acysof model (47–650 MV/mm^2), in contrast to the Clareon model group (1 ± 1 MV/mm^2), showing Clareon materials greater resistance to glistenings compared to the Acrysof model [19]. In addition, long-term clinical observation study showed glistenings and surface light scattering did not develop with Clareon IOLs during 9-year observation [20].

To address the issue of glistening, CNA0T0, a novel IOL replacing material of PEMA to HEMA, was introduced. HEMA is a hydrophilic polymer that may contain 1.5% increased water content. Therefore, lens clarity with less glistening is gained [10]. According to this point, CNWT was released recently which is made of CNA0T0 material with optical structure of TFNT. The objective of this study is to assess the updated clinical results and gauge patient satisfaction among individuals receiving the trifocal IOL with new IOL material, providing valuable insights for ophthalmic clinicians and surgeons.

Patients with bilateral CNWT IOL implantation showcased enhanced visual acuities at far, intermediate, and near distances. The mean intermediate VA, illustrated in Fig. 2, exceeded 0.1 logMAR for all patients, indicating proficient vision for tasks like computer work. These findings align with previous studies reporting good VA at all distances, particularly excellent intermediate vision with TFNT IOL [14]. Additionally, trifocal IOLs, especially TFNT IOLs, exhibited superior intermediate performance compared to bifocal and other trifocal IOLs [15]. In terms of mean near VA at 33 cm distance, 85% and 90% of patients achieved monocular and binocular UNVA of 0.1 logMAR or better, respectively, indicating the common ability to read J2 letter size at near distances without glasses.

The study included an assessment of the uncorrected defocus curve, recognizing the limitation of the corrected defocus curve in representing real-life scenarios [21]. VA results were supported by the outcome of the binocular defocus curve which showed that the lens provided consistently excellent vision of approximately 0.1 logMAR or better between +0.50 and −2.50 D, from distance to near. The binocular uncorrected defocus curve showed a plateau without clearly evident peak in range between +1.00 and –3.00 D (corresponding in distance to the interval between 100 and 33 cm), suggesting stable intermediate vision. On the contrary, as the defocus diopter decreased (–3.00 to –4.00 D, corresponding to visual distances of 33 and 25 cm), a progressive decrease of the curve was observed, while the VA at near distance was remained between 0.07 and 0.27 logMAR. Previous studies have shown similar defocus curves to the ones obtained in our study [22]. Also, in previous studies, –2.50 to -3.00 D (corresponding to 40 to 33 cm) are often used as the near range in the defocus curve [23,24]. However, in this study, we assessed the patient's functional vision at even closer distances by ex-

panding the range of defocus curves to encompass up to –4.00 D (corresponding to 25 cm). We can speculate that our result of progressive decay of VA at near distance (–3.50 to –4.00 D) occurred due to the difference measuring range of near distance in this study compared to previous studies.

This broad range of good VA is important in reducing patients' reliance on glasses for daily activities. Spectacle independence at intermediate distances was achieved in all patients, while the rate of spectacle independence was just slightly lower at the near distance (95.0%) and far distance (97.5%) in this study. Out of 40 patients only two (5.0%) and one (2.5%) reported that they required glasses for near and far vision, respectively. In a previous study, over 80% of patients with Acrysof PanOptix IOL reported never needing eyeglasses to see [23]. In other study, 90% or more of subjects reported never wearing glasses or wearing them only a little [25]. Kohnen et al. [14] reported complete spectacle independence in 96% of patients. In line with previous studies, Clareon PanOptix IOL in our study exhibited a high level of spectacle independency.

A Cochrane review about multifocal IOLs found that photic phenomena are 3.5 times more likely with multifocal IOLs than with monofocal IOLs [13]. In this study, we evaluated the patients' experiences with optic phenomena to better understand their satisfaction in their real life. Mild optic phenomenon (43%) was the most common by the respondents in this study. The proportion of patients who did not experience photic phenomena was 20%. Nevertheless, patient satisfaction of spectacle-free remains high in all distances.

In prior studies, reported outcomes on photic phenomena have varied significantly. Kohnen et al. [14] found that 93% of patients experienced optic phenomena, whereas Ramamurthy et al. [24] reported 86.6% of patients indicating "none" to "only some of the time" for optic phenomena. Galvis et al. [22] noted 6.1% of participants expressing "some difficulties in daily life" related to photic phenomena. It is important to note that differences in question wording and discomfort level categorization among studies make direct comparisons challenging. In a study conducted in Germany by Kohnen et al. [14], may have yielded a higher proportion of bothersome responses due to factors like lighter iris color and larger scotopic pupil size. Additionally, the studies did not analyze the duration of optic phenomena; only their presence and frequency were assessed. Prior research suggests that neuroadaptation after multifocal IOL surgery could alleviate these optical phenomena over time. Typically, this process takes a minimum of 3 months and up to 1 year. However, our study's last follow-up was at 3 months, during the ongoing neuroadaptation process. It could be assumed that challenges related to optical phenomena might decrease over time; hence, further research with an extended follow-up is necessary. Subsequent studies should also investigate other visual disturbances linked with multifocal IOLs, including halo, glare, starbursts, hazy vision, blurred vision, distortion, and multiple images, providing a more comprehensive understanding of their impact on both vision quality and overall quality of life.

This study has several limitations, including a relatively short follow-up period, a small sample size, and a homogeneous Korean population. The absence of measurements for contrast sensitivity and reading speed, common limitations of multifocal IOL studies, is another drawback. Additionally, restricted patient participation in certain tests, with only 20 patients undergoing VA tests and a defocus curve, further limits the generalizability of the findings. As the follow-up period was short, confirming the long-term stability and superiority of the new material was not clearly feasible. Consequently, further follow-up observations and investigations are needed.

Prior studies on Clareon material IOLs have demonstrated reduced susceptibility to complications like glistening. Likewise, research on PanOptix IOLs has underscored the lens's ability to provide VA with wide range of distances. Our study demonstrated good uncorrected far and intermediate visual acuities. Our results show that the Clareon PanOptix IOL's new composition, which combines the optical characteristics of Clareon material IOLs and the multifocal characteristics of PanOptix trifocal IOLs, demonstrates outcomes consistent with prior investigations conducted using each individual composition [11,22,24,26].

In conclusion, bilateral implantation of Clareon PanOptix CNWT IOL demonstrated excellent visual outcomes at distance, intermediate and near. Spectacle independence was high at all distances. Thus, these IOLs can offer patients a good option for cataract surgery that aligns with their visual needs and expectations seeking to reduce their dependence on spectacles across a wide range of vision especially a specific visual quality for near tasks.

Conflicts of Interest: None.
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