

# A Novel Intraocular Lens Simulator that Allows Patients to Experience the World Through Multifocal Intraocular Lenses Before Surgeries

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**Purpose:** The purpose of this study was to investigate whether the intraocular lens (IOL) simulator can simulate how the world appears to patients with multifocal IOLs by allowing the patients to see far and near objects through the IOL simulator.

**Methods:** Twenty eyes from 20 patients (age = 50–70 years old) were included in the study. The IOL simulator we developed consists of a trial lens frame adapter, a lens tube, a concave lens, a spacer, a wet cell, and an IOL. We used two IOLs: Tecnis monofocal and Tecnis bifocal IOL (add +3.25 diopter [D]). Patients wore a trial lens frame with an IOL simulator on distant corrected trial lenses and underwent the following tests: defocus curve, satisfaction with distance and near vision, halo around the light, and near point accommodation (NPA). To check how the world appears to the patients through this simulator, a machine vision lens and a scientific camera were attached to the simulator, and far and near objects were photographed.

**Results:** In the defocus curve of multifocal IOL, the visual acuity showed the second peak at –4 D. Compared to monofocal IOL, satisfaction with distant vision was slightly worse, more halos were felt, satisfaction with near vision was higher, and the NPA was shorter in multifocal IOL. In the scientific camera test, through the multifocal IOL, the waiting room was blurry, the halo around the ceiling light was prominent, and the characteristics on the near visual acuity chart were clear.

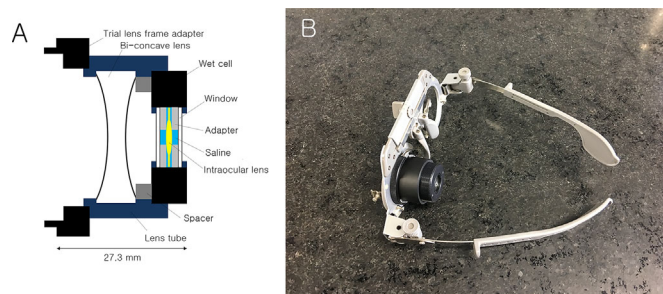
**Conclusion:** Subjects could experience the functions of multifocal IOLs with our newly developed IOL simulator.

**Translational Relevance:** This IOL simulator using geometric optics allows patients to experience the function of multifocal IOLs before cataract surgery.

## Introduction

Multifocal intraocular lenses (IOLs) have been widely used in cataract surgery for several years and allow patients to see both far and near objects clearly. However, it is not understood how the world appears to patients with multifocal IOLs, whether they can see both far and near objects as clearly as expected, whether they see far objects less clearly compared to patients with monofocal IOLs, and whether they see a halo around a light at night.

Many clinical studies have reported satisfaction or spectacle independence with questionnaires, and near, intermediate, and distant visual acuity of patients with multifocal IOLs.<sup>1–12</sup> However, these are all subjective tests that solicit patients. Although some studies have objectively simulated this using the optical bench test,<sup>13–17</sup> it is difficult for clinicians or patients to intuitively understand the results. Only a simple target, such as the United States Air Force 1951 resolution target used in the optical bench test, has limitations in expressing how the world appears to patients with multifocal IOLs.



**Figure 1.** The intraocular lens (IOL) simulator. **(A)** The IOL simulator we developed consists of a trial lens frame adapter, lens tube, concave lens, spacer, wet cell, and IOL, and is mounted on a trial lens frame. **(B)** This IOL simulator was stably fixed to the trial lens (spherical) slot, at the back-side of the trial lens frame, by a trial lens frame adapter.

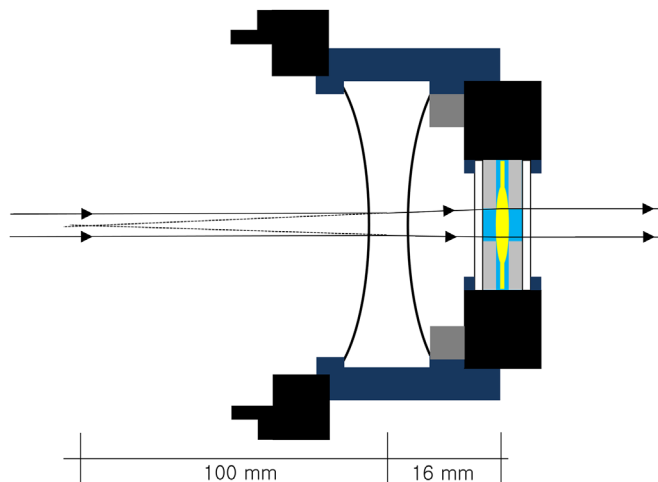
To solve this problem, we developed a mobile model eye with a camera. We took photographs of far and near objects through IOLs to demonstrate how the world appears to patients with monofocal or multifocal IOLs.<sup>18</sup> We could objectively show the images we took with the mobile model eye to other patients or researchers. However, it would be ideal if the patients could experience their own world through the IOLs in real time.

We recently developed an IOL simulator that combines a concave lens and a wet cell with a commercially available multifocal IOL. This IOL simulator can be mounted on a trial lens frame and worn like glasses. In this study, we investigated whether the IOL simulator can simulate how the world appears to patients with multifocal IOLs by allowing the patients to see far and near objects through the IOL simulator.

## Methods

The IOL simulator we developed consists of a trial lens frame adapter, a lens tube, a concave lens, a spacer, a wet cell, and an IOL, and is mounted on a trial lens frame (Fig. 1).

A concave lens is needed to neutralize the base power of the multifocal IOL. The concave lens used in this study was a biconcave lens (Thorlabs, Newton, NJ) with a diameter of 1 inch and a diopter power of  $-10$  D (focal length =  $-100$  mm). We used two IOLs: a Tecnis monofocal (9 D, aspheric, ZCB00; Johnson & Johnson, Santa Ana, CA) and a Tecnis bifocal IOL (9 D, add  $+3.25$  D, ZLB00). The wet cell has two, 0.5-inch diameter windows (thickness = 1 mm, N-BK7) and is filled with 0.9% normal saline. The IOL was held between two lens adapters with a 3.8 mm aperture.<sup>18</sup> The IOL loading was performed while checking the IOL concentration using a dissection microscope. The focal lengths



**Figure 2.** The function of concave lens ( $f = -100$  mm) of the intraocular lens (IOL) simulator. The Tecnis monofocal (9 D) in the wet cell had a focal length of 116 mm. We kept the distance between the centers of the concave lens and monofocal intraocular lens (IOL; 9 D) at  $116 \text{ mm} - 100 \text{ mm} = 16 \text{ mm}$ . Therefore, both lenses were positioned to have a common focal point. The collimated beam entering the concave lens becomes the collimated beam again after passing through the IOL. Thus, this concave lens neutralizes the power of the monofocal IOL (9 D).

of the IOL in the wet cell were measured using a collimated beam of laser (CPS532-C2; Thorlabs) with a wavelength of 532 nm. The Tecnis monofocal (9 D) IOL in the wet cell had a focal length of 116 mm. The focal length by the base power (9 D) of the multifocal IOL (9 D, add 3.25 D; Johnson & Johnson) in the wet cell was also 116 mm. The focal length of the 12.25 D by the 3.25 D added power of the multifocal IOL (9 D, add 3.25 D) was measured as 88 mm.

We kept the distance between the centers of the concave lens and monofocal IOL (9 D) at  $116 \text{ mm} - 100 \text{ mm} = 16 \text{ mm}$ . Therefore, both lenses were positioned to have a common focal point. The collimated beam entering the concave lens becomes the collimated beam again after passing through the IOL; thus, this concave lens neutralizes the power of the monofocal IOL (9 D; Fig. 2).

In the same way, we kept the distance between the centers of the concave lens and multifocal IOL (9 D, add 3.25 D) at  $116 \text{ mm} - 100 \text{ mm} = 16 \text{ mm}$ , so this concave lens neutralizes the base power of the multifocal IOL (9 D, add 3.25 D). At this time, the additional power  $+3.25$  D is changed to  $+3.9$  D (near distance 256 mm) because of the  $-10$  D concave lens according to the lens equation (Supplementary Fig. S1).

Using a spacer, the distance between the center of the IOL and the concave lens was maintained at 16 mm. The wet cell containing the IOL and the concave lens was fixed in the lens tube, so alignment was not

necessary. This IOL simulator was stably fixed to the trial lens (spherical) slot, at the back-side of the trial lens frame, by a trial lens frame adapter. The overall length of the IOL simulator was 27.3 mm (see Fig. 1A).

## Patients' Test

This prospective study was reviewed and approved by the Institutional Review Board (IRB) of the Catholic University of Korea Yeouido St. Mary's Hospital (SC19OISI0176). This study followed the principles of the Declaration of Helsinki. Before testing, the purpose and method of this study were explained to the patients, and informed consent was obtained. Among the patients who came to the hospital for cataract examination, patients aged 50 to 70 years old were selected based on the results of a previous study that reported that patients over 50 years of age only have minimal power of accommodation.<sup>19</sup> Among them, patients who had at least one eye with cataracts of NO1NC1 by the Lens Opacities Classification System III (LOCS III),<sup>20</sup> cortical opacity, or posterior subcapsular opacity (PSCO) that did not block the visual axis, and corrected visual acuity better than 0.1 logMAR were included in the study. As exclusion criteria, patients who had corneal abnormalities or corneal surgery, whose pupils were too small (<1.5 mm) or too large (>5.0 mm), and those who had a poor understanding of the examination were excluded.

A researcher (author H.H.S.) loaded IOLs into wet cells. He did not mark "monofocal IOL" or "multifocal IOLs" on the outside of the simulator. Instead, he arbitrarily marked A and B on the outside of the simulator. Therefore, this was a double-blind test because neither the examiner nor the patients were informed about the type of IOL.

An automatic refraction test (KR-1; Topcon, Tokyo, Japan) was performed, and the fully corrected distance visual acuity of the patients was measured. Visual acuity was measured using a liquid crystal display (LCD) visual acuity chart (LC-R1; Rice Co., Goyang, Korea), and a mode in which one character was displayed per screen was used. Near point accommodation (NPA) was measured in cm with full correction of the refractive error to measure the amplitude of accommodation. At this time, Arabic numbers of 10 point-size were used for the target. The amplitude of the accommodation was calculated using the amplitude of accommodation ( $D$ ) =  $1/\text{NPA}$  (m).

The IOL simulator was mounted in the spherical lens slot of the trial lens frame. At this time, the concave lens faced forward, and the IOL wet cell faced the patient's eye (see Fig. 1B). A spherical

and cylinder lens that corrects the refractive error of the patient was inserted in the two front slots where the cylinder lens and prism lens are usually inserted. The spherical and cylindrical diopters were converted because the vertex distance was changed from 13 mm to 27.3 mm. Patients were allowed to see the world through the 3.8 mm aperture of the IOL adapter. The fellow eye was covered by inserting a blank into the other slot of the trial lens frame.

Patients wore the trial lens frame with an IOL simulator on distant corrected trial lenses and underwent the following tests. These tests were repeated for monofocal and multifocal IOLs.

## Defocus Curve

After placing the spherical trial lens with +1.0 to -7.0 D in 1.0 D increments in front of the trial lens frame, the distance of the visual acuity was repeatedly measured using an LCD visual acuity chart and a mode in which one character was displayed per screen.

We calculated the sample sizes of patients for comparing the distance of the visual acuity with the monofocal IOL and the multifocal IOL at defocus -4 D. We estimated the mean of paired differences and the standard deviation of the paired differences to calculate the sample size following a literature review. As in our study, we found a previous study comparing near visual acuity with a monofocal IOL and a multifocal IOL using an IOL simulator in the same eye.<sup>21</sup> However, according to their results, the monofocal IOL achieved relatively good visual acuity at near distances. The Tecnis monofocal (ZCB00) and Tecnis bifocal IOL (ZLB00) were not tested in their study, so we did not use them for estimation. In a study comparing the distance-corrected near visual acuity in the Tecnis monofocal (ZCB00) and the Tecnis bifocal IOL (ZLB00), the distance-corrected near vision was  $0.555 \pm 0.609$  logMAR in the monofocal (ZCB00) and  $0.179 \pm 0.129$  logMAR in the multifocal (ZLB00) IOL. We estimated the mean of paired differences as being  $0.555 \text{ logMAR} - 0.179 \text{ logMAR} = 0.376 \text{ logMAR}$ . We estimated the standard deviation of the paired differences as a mean of 0.609 logMAR and 0.19 logMAR. Then, a sample size of 15 achieves 95% power to detect a mean paired differences of 0.376, with an estimated standard deviation of differences of 0.369, and with a significance level of 0.05 using a two-sided paired  $t$ -test.<sup>22</sup> Twenty eyes from 20 patients were included in this study.

## Satisfaction With Distance Vision

The patients were allowed to see the waiting room of the clinic through the IOL simulator. Regarding satisfaction with distant vision, the patients were asked



**Figure 3.** The standard photograph for distance vision and halo. The standard photograph was taken by a mobile model eye. The mobile model eye consists of an achromatic lens for the cornea, a wet cell containing a Tecnis 9 D multifocal IOL (add +3.25 D, ZLB00) and a Nikon camera (D610).

to check between 0 and 10 points after reviewing the following standard photograph (Fig. 3).

The standard photograph was taken by a mobile model eye. The mobile model eye consists of an achromatic lens for the cornea, a wet cell containing a Tecnis 9 D multifocal IOL (add +3.25 D, ZLB00) and a Nikon camera (D610). This is a modification of the method described in a previous study.<sup>18</sup>

0 points: It looks hazy, like the standard photograph (see Fig. 3).

10 points: It looks clear when viewed, with trial lenses fully correcting the refractive error and without the IOL simulator.

The satisfaction with distance vision through the monofocal IOL and satisfaction with distance vision through the multifocal IOL was not normally distributed (Kolmogorov–Smirnov test,  $P < 0.001$ , and  $P = 0.002$ , respectively). The Wilcoxon signed-rank test was used for comparison.

### Halo Around the Light

The patients were allowed to see the lights on the ceiling of the waiting room through the simulator. For the halo around the light, the patients were asked to check between 0 and 10 points after reviewing the standard photograph (see Fig. 3).

The standard photograph was taken by a mobile model eye, which consisted of an achromatic lens for the cornea, a wet cell containing a Tecnis 9 D multifocal IOL, and a Nikon camera. This is a modification of the method described in a previous study.<sup>18</sup>

0 points: No significant halo around the light is observed, such as when viewed with trial lenses fully

correcting the refractive error and without the IOL simulator.

10 points: A significant halo around the light is observed, as shown in the standard photograph (see Fig. 3).

### Satisfaction With Near Vision

The patient was allowed to see the near visual acuity chart (25 cm, 10 points, Arabic number) through the simulator. Although the additional power of the Tecnis bifocal IOL used in the study was +3.25 D, the additional power is changed to +3.9 D (near distance = 256 mm) because of the -10D concave lens by the lens equation (see Supplementary Fig. S1). Therefore, we used 25 cm ( $1/3.9 \text{ D} = 25.6 \text{ cm}$ ) instead of 33 to 40 cm for the near visual acuity chart. Regarding the satisfaction of near vision, the patients were asked to check between 0 and 10 points.

0 points: It appears blurry when viewed with distant corrected trial lenses without the IOL simulator.

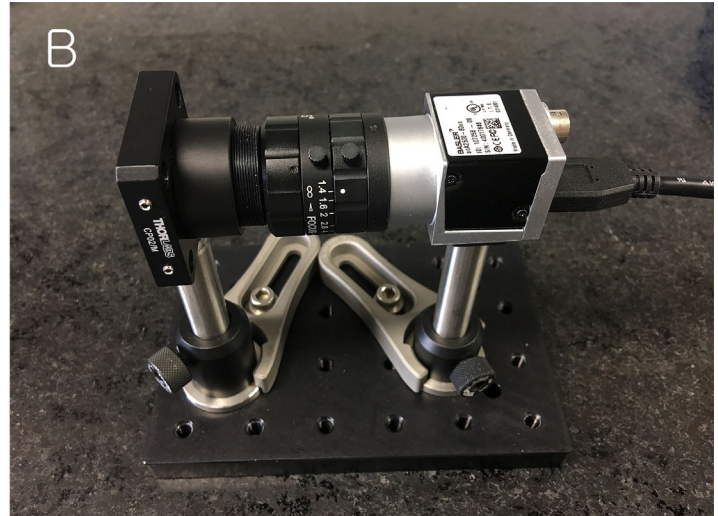
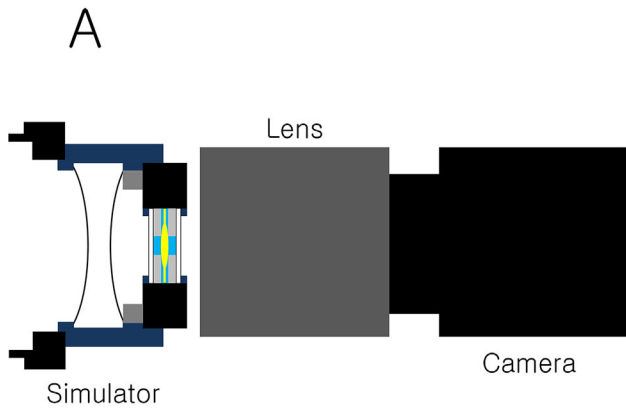
10 points: It appears clear when viewed with distant corrected trial lenses plus a reading glass (4 D).

### Near Point Accommodation

The NPA was measured in cm using a 10 point-sized Arabic number in the near visual acuity chart while wearing a trial lens frame with an IOL simulator on distant corrected trial lenses.

### Scientific Camera Test

To check how far and near the objects appeared to the patients through this simulator, a machine vision lens and a scientific camera were attached to the simulator instead of the human eye, and far and near objects were photographed. A fixed focal length 25 mm lens (Edmund Optics, Barrington, NJ) was used for the machine vision lens, and a complementary metal-oxide semiconductor (CMOS) camera (Basler acA2500-60uc; Ahrensburg, Germany) was used for the camera (Fig. 4). We did not make any gap between the IOL simulator and the machine vision lens to block ambient light. At this time, the aperture of the machine vision lens was set to a maximum, and the focus was set to infinity. The waiting room and the ceiling light of the waiting room were photographed, which the patient saw through the simulator. Apart from the patient experience, the long-distance scenery during the day, the near visual acuity chart (early treatment diabetic retinopathy study [ETDRS] 2000 Series chart “2”; Precision Vision, La Salle, IL), and the traffic light, headlight, and taillight of cars at night were also photographed. This was tested for the Tecnis monofocal IOL and the multifocal IOL. The camera



**Figure 4.** Scientific camera test. To check how the far and near objects appear to the patients through this simulator, a machine vision lens and a scientific camera were attached to the simulator instead of the human eye, and far and near objects were photographed. A fixed focal length 25-mm lens (Edmund Optics, Barrington, NJ) was used for the machine vision lens, and a complementary metal-oxide semiconductor (CMOS) camera (Basler acA2500–60uc, Ahrensburg, Germany) was used for the camera (A). We did not make any gap between the IOL simulator and the machine vision lens to block ambient light (B).

settings, such as exposure time and gamma correction, were maintained during monofocal and multifocal IOL experiments.

test for comparison. Statistical analysis was performed with SPSS 21.0 and,  $P < .05$  was defined as statistically significant.

### Statistical Analysis

We performed Kolmogorov–Smirnov test for the age, spherical equivalent, cylindrical error, best corrected distance visual acuity (logMAR), NPA, amplitude of accommodation, satisfaction with distant vision, halo score, satisfaction with near vision, and NPA with the IOL simulator to check whether they were normally distributed or not. If they were normally distributed, they were expressed as the mean  $\pm$  standard deviation. If they were not normally distributed, they were expressed as the median (interquartile range).

We compared the distance visual acuity with the monofocal IOL and multifocal IOL at defocus 0 D. Because neither were normally distributed (Kolmogorov–Smirnov test,  $P = 0.009$ , and  $P = 0.012$ , respectively), we used the Wilcoxon signed rank test for comparison. We compared the distance visual acuity with the monofocal IOL and the multifocal IOLs at defocus  $-4$  D. Because the distance visual acuity with the monofocal IOL at  $-4$  D was not normally distributed (Kolmogorov–Smirnov test,  $P = 0.020$ ) and the distance visual acuity with the multifocal IOL at  $-4$  D was normally distributed (Kolmogorov–Smirnov test,  $P = 0.065$ ), we used the Wilcoxon signed rank

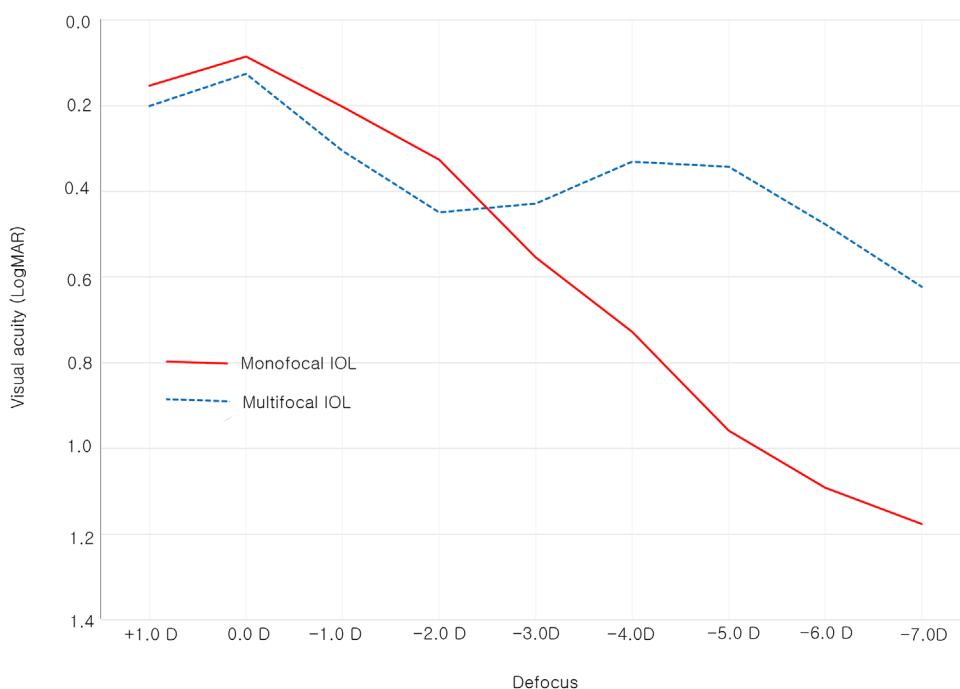
## Results

Twenty eyes from 20 patients were included in this study. Table 1 shows the demographics of the patients included in the study. The median age of the patients was 61.0 years old, and there were 9 men and

**Table 1.** Demographics and Characteristics of the Subjects

	Mean $\pm$ SD	Median (IQR)
Age, years		61.0 (6.0)
Gender, men:women	9:11	
Spherical equivalent, D	$+0.406 \pm 1.4$	
Cylindrical, D		$-0.75 (1.00)$
BCVA (LogMAR)		0.000 (0.097)
NPA, cm	$47.1 \pm 5.1$	
Amplitude of accommodation, D	$2.1 \pm 0.2$	

BCVA, best corrected visual acuity; D, diopter; IQR, interquartile range; LogMAR, logarithm of the minimum angle of resolution; NPA, near point of accommodation; SD, standard deviation.



**Figure 5.** Defocus curves of monofocal intraocular lens (IOL) and multifocal IOL using the IOL simulator. In the case of monofocal IOL, the visual acuity showed a maximum at 0 D, and then the visual acuity decreased continuously. In the case of multifocal IOL, the visual acuity showed a maximum at 0 D, then decreased and increased again, showed the second peak at -4 D, and then decreased again.

**Table 2.** Patients’ Experiences of Monofocal and Multifocal Intraocular Lens Through Intraocular Lens Simulator

	Monofocal IOL	Multifocal IOL	P Value
Satisfaction with distant vision	10.0 (1.0) <sup>a</sup>	5.0 (3.8) <sup>a</sup>	<0.001 <sup>b</sup>
Halo around a light	1.3 ± 1.1 <sup>c</sup>	9.0 (3.8) <sup>a</sup>	<0.001 <sup>b</sup>
Satisfaction with near vision	2.4 ± 1.9 <sup>c</sup>	7.6 ± 1.6 <sup>c</sup>	<0.001 <sup>d</sup>
NPA (cm)	44.5 ± 7.0 <sup>c</sup>	24.0 ± 3.8 <sup>c</sup>	<0.001 <sup>d</sup>

IOL, intraocular lens; NPA, near point of accommodation.

<sup>a</sup>Median (interquartile range).

<sup>b</sup>Wilcoxon signed rank test.

<sup>c</sup>Mean ± standard deviation.

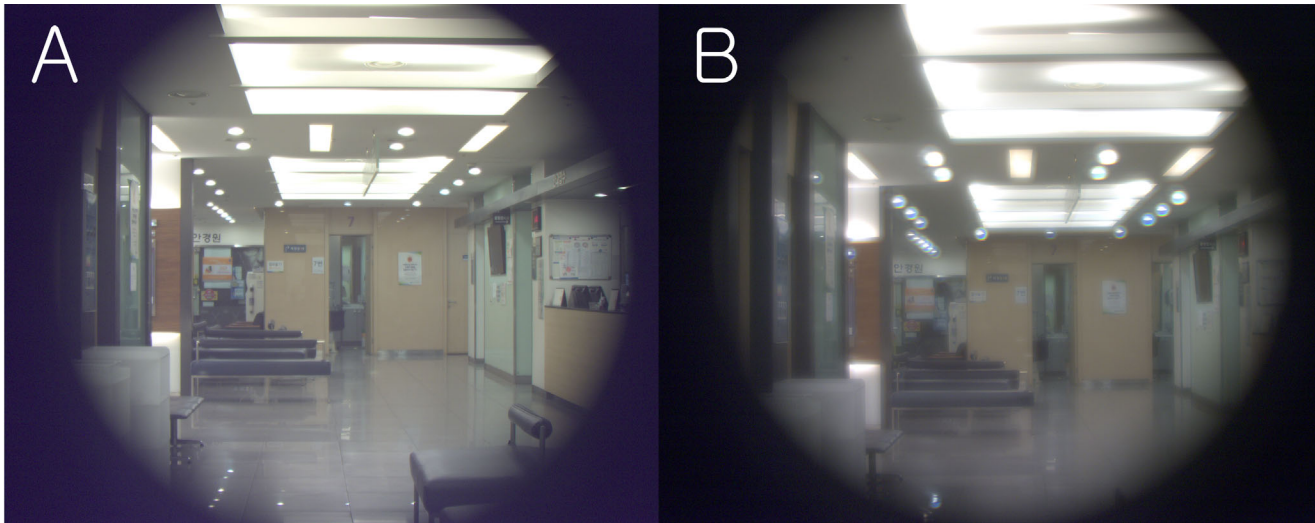
<sup>d</sup>Paired *t*-test.

11 women. The mean of NPA was 47.1 cm, and the mean amplitude of the accommodation was 2.1 D.

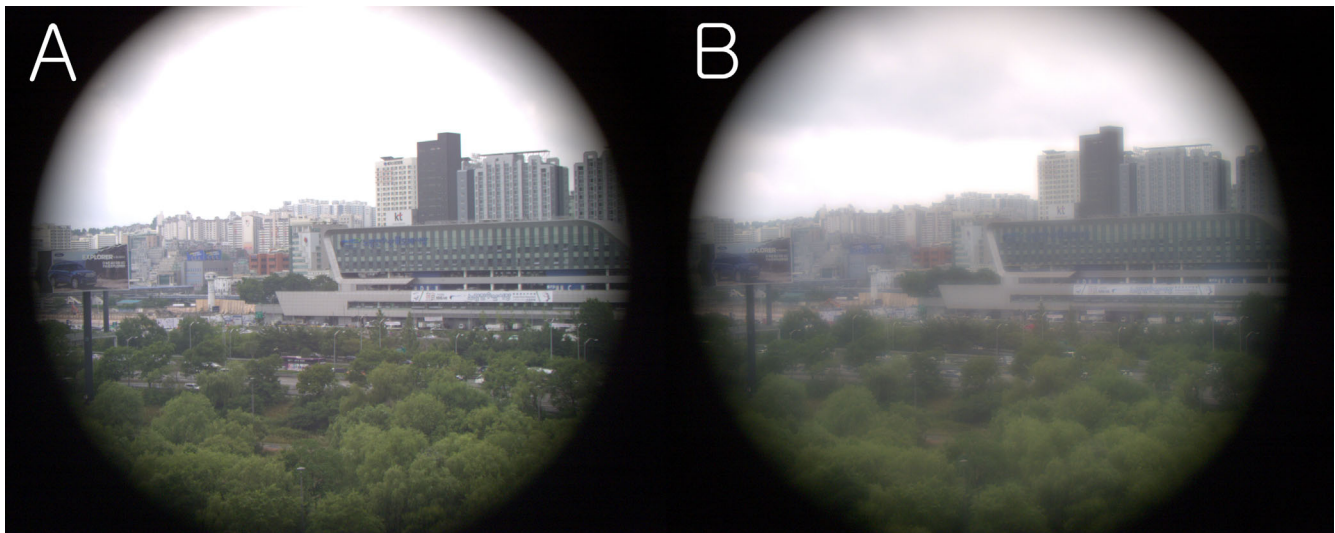
Figure 5 shows the defocus curves of the monofocal IOL and multifocal IOL using the IOL simulator. In the case of monofocal IOL, the visual acuity showed a maximum at 0 D, and then the visual acuity decreased continuously. In the case of multifocal IOL, the visual acuity showed a maximum at 0 D, then decreased and increased again, and showed a second peak at -4 D, and then decreased again. At defocus 0 D, the visual acuity was better in the monofocal IOL, with 0.097 (0.155) logMAR than in the multifocal IOL, with 0.097

(0.222) logMAR ( $P = 0.040$ , Wilcoxon signed rank test). At defocus -4 D, the visual acuity was better in the multifocal IOL, with 0.301 (0.320) logMAR than in the monofocal IOL, with  $0.728 \pm 0.260$  logMAR ( $P = 0.040$ , Wilcoxon signed rank test; Supplementary Table).

Table 2 shows satisfaction with distant vision, halo around a light, satisfaction with near vision, and NPA in monofocal and multifocal IOLs. For satisfaction with distant vision, the monofocal lens was better than multifocal IOL ( $P < 0.01$ , Wilcoxon signed rank test). The halo around a light was more prominent



**Figure 6.** A waiting room photographed with the intraocular lens (IOL) simulator and scientific camera. Through the multifocal IOL, the waiting room was blurry, and the halo around the ceiling light was prominent compared to the monofocal IOL. (A) Monofocal IOL, (B) multifocal IOL.

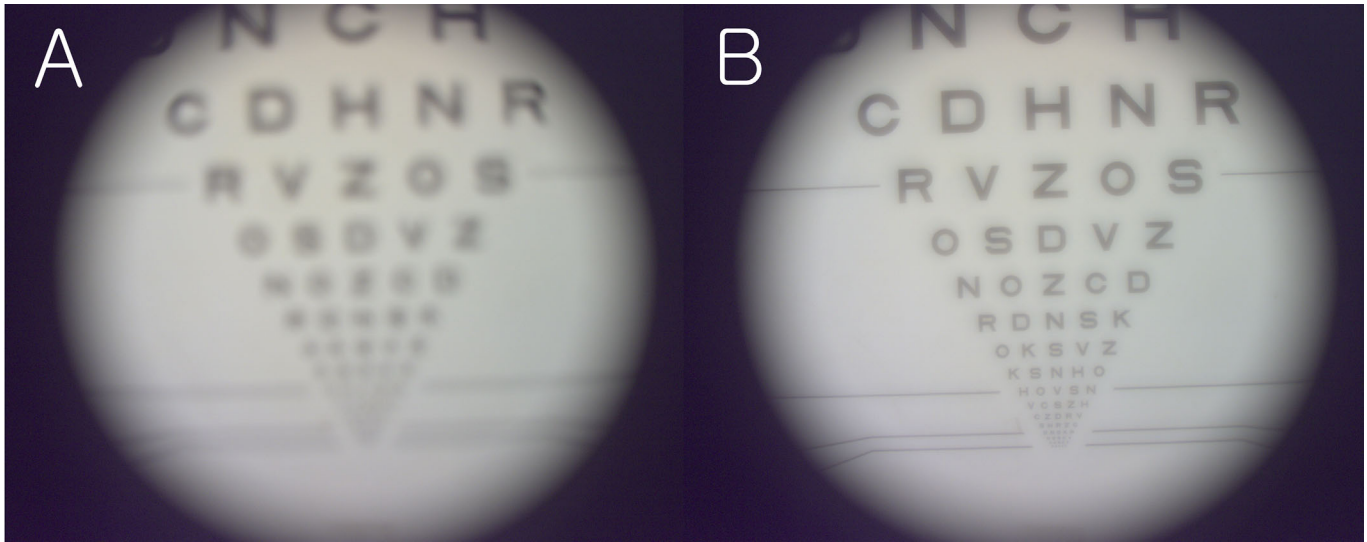


**Figure 7.** A distant building photographed with intraocular lens (IOL) simulator and scientific camera. Through multifocal IOL, the distant scenery in the daytime was blurry compared to monofocal IOL. (A) Monofocal IOL, (B) multifocal IOL.

with the multifocal lens than monofocal IOL ( $P < 0.01$ , Wilcoxon signed rank test). Satisfaction with near vision was higher in multifocal IOLs than in monofocal IOLs ( $P < 0.001$ , paired  $t$ -test). The NPA was 24.0 cm for the multifocal IOL, which was shorter than that for the monofocal IOL ( $P < 0.001$ , paired  $t$ -test).

The results of the scientific camera test were as follows: through the multifocal IOL, the waiting room was blurry, and the halo around the ceiling light was prominent compared to the monofocal IOL

(Fig. 6). Through the multifocal IOL, the distant scenery in the daytime was blurry compared to the monofocal IOL (Fig. 7). Through the multifocal IOL, the characteristics on the near visual acuity chart at a distance of 25 cm were clear, but through the monofocal IOL, the characteristics were blurry (Fig. 8). Through the multifocal IOL, unlike the monofocal IOL, halos were prominent around the traffic lights and car taillights or headlights at night (Fig. 9).



**Figure 8.** A near visual acuity chart photographed with intraocular lens (IOL) simulator and scientific camera. Through the multifocal IOL, the characteristics on the near visual acuity chart at a distance of 25 cm were clear, but through the monofocal IOL, the characteristics were blurry. **(A)** Monofocal IOL, **(B)** multifocal IOL.



**Figure 9.** A road photographed with the intraocular lens (IOL) simulator and scientific camera at night. Photographs taken with the intraocular lens (IOL) simulator and scientific camera. Through the multifocal IOL, unlike the monofocal IOL, halos were prominent around the traffic lights and car taillights or headlights at night. **(A)** Monofocal IOL, **(B)** multifocal IOL.

## Discussion

Our IOL simulator is the first device to allow patients to experience how the world looks with multifocal IOLs before cataract surgery using a concave lens and IOL in a wet chamber. This experience before surgery will help patients to decide whether to have a monofocal IOL or a multifocal IOL. If the patient

decides on multifocal IOL, the experience of various multifocal IOLs before surgery will help patients to select the type of multifocal IOL. This is equivalent to walking around and seeing while wearing a trial lens frame with trial lenses when fitting new glasses to check whether they cause dizziness in patients.

Similar devices have previously been available that allow patients to experience multifocal IOLs. The Rassow telescope uses another lens to neutralize the



base power of the multifocal IOL,<sup>23,24</sup> which is similar to our device. However, because the Rassow telescope uses a convex lens instead of a concave lens, it is difficult for the patient to adapt to it because it changes the up, down, left, and right views. Because we use a concave lens instead of a convex lens, it does not change the view vertically or horizontally, so patients can experience the real world and walk around while wearing a trial lens frame with an IOL simulator, with no difficulty adapting. However, because convex lenses rather than concave lenses are used in optical systems, there are many off-the-shelf convex lenses with different focal lengths compared to concave lenses. We could use only off-the-shelf concave lenses with focal lengths of  $-100$ ,  $-75$ ,  $-50$ , and  $-25$  mm. In this study, we used a concave lens with diopter power of  $-10$  D (focal length,  $-100$  mm) and an IOL with diopter power of  $9$  D, so the distance between the concave lens and the IOL and was  $16$  mm. If we use a convex lens, we can use many off-the-shelf convex lenses with different focal lengths. If we combine the appropriate convex lens and IOL power, the distance between the IOL and the convex lens can be reduced as much as possible. Accordingly, the aberration can be further reduced, and the discomfort caused by the longer vertex distance will also be reduced.

VirtIOL (10Lens S.L. U, Barcelona, Spain) allows the patient's defocusing curve for IOLs to be obtained.<sup>21,23,25</sup> However, some caution should be exercised when evaluating the results given that in VirtIOL experiments, the monofocal IOL achieved relatively good results at distances,<sup>21</sup> which does not correspond to clinical experience. Additionally, as this device is immobile, it is impossible to see the real world, and the patient can only see a simple target. Another method using a tunable lens for simulation,<sup>26-33</sup> the SimVis (2EYEVISION, Madrid, Spain), simulates a multifocal IOL using a tunable lens but does not insert a real IOL into the device.<sup>26,28,29,31</sup> The tunable lens changes its power periodically; for example,  $0$  D and  $+3.25$  D. The subjects can see the world through the lens. At this time, the characteristics of specific multifocal IOLs were reflected by adjusting the power of the two diopters and the time proportion of the two diopters. However, the device does not test the real IOLs. There is a simulator using adaptive optics with wavefront sensor and deformable mirror.<sup>34-37</sup> However, these systems are complex and cannot be experienced as mobile devices, unlike our device.

In this study, the NPA was measured with full correction of the refractive error to measure the amplitude of accommodation. The amplitude of accommodation was calculated by the NPA. As a result, the

mean NPA was  $47.1$  cm, and the mean amplitude of the accommodation was  $2.1$  D. Therefore, we could include patients who had the same model of monofocal IOLs inserted during cataract surgery instead of patients with phakic eyes because the pseudophakic eye has no accommodation power. However, we excluded these patients because these inclusion criteria do not fit the purpose of this device experiencing monofocal or multifocal IOLs before cataract surgery. However, over the age of  $50$  years, there may have been some cataract changes in the crystalline lens, which may affect the results. Therefore, monofocal IOLs were selected as a control group for the same eye and compared with multifocal IOLs. It may be possible to repeat the same study in young subjects without cataract changes. Of course, for young subjects, the accommodation power of their crystalline lens should be minimized by cycloplegics during the test.

Patients who are scheduled for cataract surgery cannot fully experience the simulator due to poor vision caused by cataracts. Although this is a disadvantage, if the fellow eye has minimal cataracts and good visual acuity, the patients can experience it through the fellow eye. Alternatively, if the fellow eye has already undergone cataract surgery and a monofocal IOL has been inserted, they can experience a multifocal IOL through the fellow eye. Of course, simulation is impossible if both eyes have moderate to severe cataracts.

In this study, an automatic refraction test was performed, and the fully corrected distance visual acuity of the patients was measured. Without subjective refraction, the refractive errors might not be thoroughly corrected. Although patients who had at least one eye with cataracts of NOINC1 by LOCS III, cortical opacity, or PSCO that did not block the visual axis, and corrected visual acuity better than  $0.1$  logMAR were included in the study, the cataractous changes in the lens will vary from patient to patient. Although only patients over  $50$  years of age were included in the study, each patient will have a different amplitude of accommodation. These could affect the defocus curve, satisfaction with distance vision, halo, satisfaction with near vision, and NPA. Therefore, it would be ideal to use the IOL simulator with cycloplegia in clinical practice.

In this study, the low diopter ( $9$  D) of the IOL was used to minimize the distance ( $16$  mm) between the concave lens and the IOL. A commercially available biconcave lens was  $f = -100$  mm. Therefore, if a  $9.0$  D IOL is used, the distance between the biconcave lens and the IOL is only  $16$  mm. If the distance between the concave lens and the IOL is too long, it is difficult to attach it to the trial lens frame and use it successfully. If we use a higher diopter IOL, we should use a concave

lens with higher power, which increases the distortion of the peripheral field of view due to spherical aberration of the concave lens.

In this experiment, to maximize the field of view, the patient eye, 3.8 mm aperture, IOL, concave lens, and trial lens were placed in order. However, this arrangement was somewhat inconvenient for the patient to use because the distance between the trial lens frame and the patient eye was rather long. Therefore, after mounting it on the trial lens frame, the patient had to hold the frame in his or her hand (Supplementary Fig. S2). It would be better to fix the IOL simulator in front of the frame for ease of use. We are revising the device to make it easy to wear, similar to a virtual reality simulator or head mount, such as an indirect ophthalmoscope. In this study, patients experienced IOL simulators after full correction of refractive error using trial lenses and lens frames. However, if the patient's eye is almost emmetropic or if the patient owns fully corrected glasses, it may be easier to experience with only the IOL simulator.

The pupil size has a great influence on the optical function of the IOL, including multifocal IOL and extended depth of focus IOL.<sup>38</sup> This IOL simulator has a 3.8-mm pupil because the IOL was held between 2 lens adapters with a 3.8-mm aperture. We can easily change the pupil size by changing lens adapters with different aperture diameters. Therefore, we can investigate how the world appears to patients with multifocal IOLs according to different pupil sizes by changing the size of the aperture in the IOL simulator.

The measured defocus curve of patients who experienced the Tecnis bifocal (add 3.25 D) IOL through the IOL simulator in this study was similar to the results of the patients who inserted the Tecnis bifocal (add 3.25 D) IOL during cataract surgeries.<sup>39,40</sup> Compared to the monofocal IOL, the satisfaction with distant vision was slightly worse, more halos were felt, satisfaction with near vision was higher, and the NPA was shorter (24.0 cm) in the multifocal IOL. The results obtained by the scientific camera and IOL simulator were similar to the results described above of the patients in this study (satisfaction with distant vision, halo, and satisfaction with near vision). This was also similar to the results of a previous study by the authors using the mobile model eye.<sup>18</sup> In the mobile model eye study, the Tecnis monofocal IOL was used as the monofocal IOL, and the Restor (Alcon, Fort Worth, TX) and Tecnis bifocal IOL were used as the multifocal IOL. Unlike monofocal IOLs, with the multifocal IOL, distant buildings appear blurry, and the near visual acuity chart looks clear. Moderate halos were observed around traffic lights or car headlights and taillights at night with multifocal IOLs.<sup>18</sup>

It would be ideal for the patients to see a traffic light or the headlights and taillights of a car through the IOL simulator at night to check the halo around a light. However, outpatients could not be tested at night. When one of the researchers (author H.H.S.) observed the street at night through the simulator, halos were prominent around the stoplights, car taillights, or headlights, as shown in Figure 9. This type of experiment is planned for volunteers.

Some patients who have multifocal IOLs inserted during cataract surgery are unsatisfied with their distance or near vision after surgery. Some patients undergo IOL exchange because they cannot tolerate glare or halos due to multifocal IOL. In the case series in which the multifocal IOL was explanted, the causes of explantation were decreased contrast sensitivity in 18 eyes (36%), photic phenomenon in 17 eyes (34%), and incorrect IOL power in 10 eyes (20%).<sup>41</sup> IOL exchange itself causes damage to the eye, and, in severe cases, irreversible corneal edema may occur. If the patients had experienced enough multifocal IOLs with the IOL simulator before surgery, cases of explantation of the multifocal IOLs might be reduced.

Because both eyes can be tested at the same time with our IOL simulators, patients can experience a “mix and match”<sup>42</sup> in advance, which inserts different types of IOLs into both eyes. Patients can see how the world looks like when a monofocal IOL is inserted into one eye, and a multifocal IOL is inserted into the other eye. Patients can see how the world looks when a bifocal IOL is inserted into one eye and an extended depth of focal (EDOF) IOL in the other eye. This is a significant advantage of being able to test both eyes in parallel.

In conclusion, in this prospective clinical trial, the subjects could experience the functions of multifocal IOLs with an IOL simulator developed by us. The defocus curve, satisfaction with distant vision, halo, and satisfaction with near vision was similar to the clinical results of patients who underwent multifocal IOL insertion. Using this simulator, patients can experience multifocal IOL before cataract surgery and select an intraocular lens.

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