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Clinical outcomes of a novel presbyopia-correcting soft contact lens with a small aperture

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ABSTRACT

Purpose: To investigate the efficacy and safety of a newly developed pinhole soft contact lens (Eyelike Pinhole II; Koryo Eyetech Co. Ltd.) for presbyopia correction.

Methods: This prospective clinical study enrolled 29 patients with presbyopia between October 2018 and December 2018. All participants wore the Eyelike Pinhole II in the non-dominant eye for > 3 h/day for a period of 1 week. Binocular and monocular uncorrected near visual acuities, distance-corrected near visual acuity (DCNVA), uncorrected distance visual acuity, and corrected distance visual acuity (CDVA) were measured before and after the intervention. All visual acuities were measured in logarithm of the minimal angle of resolution (logMAR) units. In addition, binocular defocus curves were generated, and contrast sensitivity values were obtained under photopic and mesopic conditions before and after lens wear.

Results: The mean DCNVA of the treated eye and the mean binocular DCNVA improved from 0.34 ± 0.12 to 0.15 ± 0.14 (P < 0.001) and 0.31 ± 0.13 to 0.11 ± 0.10 (P < 0.001) logMAR, respectively, after pinhole contact lens wear. Although the mean CDVA of the treated eye deteriorated from −0.04 ± 0.05 to 0.02 ± 0.11 logMAR (P = 0.015), there was no significant change in the mean binocular CDVA (P = 0.79). The binocular defocus curve showed a significant improvement from −5.0 dioptres (D) to −1.0 D after pinhole contact lens wear.

Conclusions: The newly developed Eyelike Pinhole II soft contact lens showed safe and effective outcomes; thus, it could be a promising option for the treatment of presbyopia.

1. Introduction

Presbyopia is an age-dependent condition wherein the eye loses its ability to accommodate. It begins to develop between 40 and 45 years of age, with the eye progressively failing to focus on near objects [1,2]. Considering the increased life expectancy and a gradual increase in the elderly population, interest in presbyopia correction has been growing [3].

The most rudimentary and commonly used strategy for presbyopia correction is the prescription of spectacles with monofocal, bifocal, or progressive power lenses [2]. However, active social lives have increased the demand for various surgical and non-surgical solutions for overcoming the limitations of reading glasses. Surgical options for ameliorating the symptoms of presbyopia include conductive keratoplasty, corneal inlays, excimer laser multifocal ablation, intraocular lens (IOL)-based surgeries, and sclera-based surgeries [4]. For non-surgical correction, a number of presbyopic contact lenses has been developed [5]. Unlike surgical strategies, presbyopic contact lenses are relatively inexpensive and easy to access; moreover, they are removable, which facilitates the management of any complications. Contact lens options for the correction of presbyopia can be divided into three main categories: supplemental spectacle correction over contact lenses, monovision contact lenses, and multifocal contact lenses [1,5–9]. In addition, a recent study documented the usefulness of pinhole contact lenses for the correction of presbyopia [3].

The concept of small-aperture optics has been applied for the alleviation of presbyopia symptoms through enhancement of the depth of focus [10,11]. Light transmission through a small aperture blocks non-

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focused light from the periphery and consequently enhances the depth of field, sharpens vision, and minimises higher order aberrations (HOAs). However, small pupils can also affect visual performance because the total luminance reaching the retina is reduced. Intracorneal inlays based on this concept (Kamra® Inlay; CorneaGen, Seattle, Washington, USA) are commercially available and have been reported as effective and safe options for presbyopes [10,12–14]. Previous reports demonstrated better contrast sensitivity with pinhole corneal inlays than with multifocal IOLs [15]. Recently, a small-aperture posterior chamber IOL was introduced and has become commercially available in selective countries [10,16]. Pupil constriction using medication is also a currently developing strategy for presbyopia, although frequent use of mitotic drugs is related with severe adverse reactions such as headache, ciliary spasm, chronic nasal inflammation, and retinal detachment [10,17]. Thus, pinhole soft contact lenses are a good option for presbyopes and are widely used [3,10].

The Eyelike NoanPinhole (Koryo Eyetech Co. Ltd, Seoul, Republic of Korea), the first commercially available pinhole soft contact lens, was found to improve distance-corrected near visual acuity (DCNVA), defocus curve values, and visual function questionnaire scores, both clinically and statistically [3]. However, it was observed that contrast sensitivity under photopic and mesopic conditions deteriorated after wear of these lenses. Therefore, the Eyelike Pinhole II (Koryo Eyetech Co. Ltd.) has been developed with an additional light-transmitting ring in the mid-peripheral area of the lens. The aim of this prospective study was to evaluate the efficacy and safety of this novel presbyopia-correcting pinhole soft contact lens.

2. Materials and methods

2.1. Subjects

This prospective clinical study was approved by the Korea Ministry of Food and Drug Safety and the Institutional Review Board (IRB) of Yonsei University College of Medicine (Seoul, South Korea; IRB No. 1-2018-0059). It adhered to the International Conference on Harmonization (ICH) Guidelines, principles of Korean Good Clinical Practice (KGCP), and the tenets of the Declaration of Helsinki. Written informed consent was obtained from all participants after the nature and possible consequences of the study were thoroughly explained. A copy of the consent form was provided to all participants.

Twenty-nine patients with presbyopia who were aged > 40 years were recruited. The inclusion criteria for this study were as follows: astigmatism, < 1 dioptres (D); corrected distance visual acuity (CDVA), 0.3 logarithm of the minimum angle of resolution (logMAR) or better in each eye; spectacle add power, ≥ +0.75 D; and voluntary agreement for participation and follow-up evaluations. Patients who were unable to make a self-decision regarding participation; those who could not wear contact lenses because of their occupation or other activities; those with severe ocular surface disease, including Stevens–Johnson syndrome, graft-versus-host disease, and Sjogren syndrome; those with corneal epithelial pathologies such as recurrent corneal erosion or epithelial defects [with the exception of mild dry eye disease (DED)]; those with keratoconus; and those with any ocular disease that could affect the required examinations were excluded.

2.2. Study design

The Eyelike PINHOLE II was prescribed for the non-dominant eye of every participant. All participants were trained for appropriate wear of the contact lenses and advised to wear them for at least 3 h/day during 1 week. The lenses are manufactured from 2-hydroxyethyl methacrylate with an ultraviolet light-blocking function. The overall diameter is 13.8–14.5 mm, with a base curve radius of 8.3–8.9 mm. The pinhole is designed with a light-transmitting area having an innermost diameter of 1.66 mm and a surrounding light-blocking area with a 2.37-mm diameter. An additional light-transmitting ring with a diameter of 2.85 mm is inserted, and a light-blocking area of 4.98 mm is located outside this ring (Fig. 1).

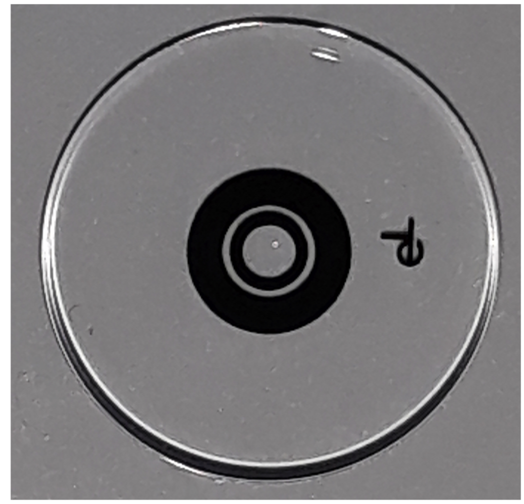

Fig. 1. Photograph of the Eyelike PINHOLE II (Koryo Eyetech, Seoul, Korea), a newly developed soft contact lens for presbyopia correction.

All participants underwent a detailed ophthalmological examination that included measurement of the logMAR uncorrected distance visual acuity (UDVA), CDVA, uncorrected near visual acuity (UNVA), and DCNVA; manifest refraction; slit-lamp examination (Haag-Streit, Köniz, Switzerland); intraocular pressure measurement (non-contact tonometer; NT-530, NCT Nidek Co., Ltd., Aichi, Japan); keratometry; and calculation of the Ocular Surface Disease Index (OSDI) score. Distance visual acuity was measured at 4 m while near visual acuity was measured at 40 cm. An ETDRS chart was used for both measurements. A binocular defocus curve was also generated as previously described [3]. For this purpose, all participants' eyes were defocused to a +3.00-D spherical value from a manifest refraction value. The binocular distance visual acuity was measured, and increments of −0.50 D were consecutively added binocularly until a value of −5.00 D was reached. The binocular visual acuity was measured after every increment. Contrast sensitivity testing was also performed using the Optec 6500 vision testing system (StereoOptical Co. Inc., Chicago, IL, USA) [3]. Binocular contrast sensitivity was measured at 1.5, 3, 6, 12, and 18 cycles per degree (cpd) under photopic and mesopic conditions with and without glare. All these examinations, including slit-lamp examination and intraocular pressure measurement for evaluating the safety of the lens, were repeated after 1 week of contact lens wear. Patients were additionally asked to complete a questionnaire regarding the following parameters at the follow-up visit: discomfort, visual symptoms, work performance, and overall satisfaction with the lens.

2.3. Statistical analysis

The sample size was calculated using the following formula with the results of a previous study [9]:

$$n= \frac{(z_{1-\alpha} + z_{1-\beta})^2\sigma^2}{((\mu_{post} - \mu_{pre}) - \delta)^2} = \approx 25.95$$

Here,

$\mu_{post} - \mu_{pre}$ is the true mean difference between the near visual acuities before and after contact lens wear (=–0.21).
σ: standard deviation (= 0.20)
δ: superiority margin (=–0.1 logMAR)
α: level of significance, 2.5% one-sided test (= 5% two-sided test)
β: type II error, 20%.

Table 1
Patient demographics.

Characteristics	N = 29
Age, years	49.11 ± 5.14 (42 to 63)
Sex	M:F = 2:27
Target eye for pinhole contact lens (non-dominant eye)	R:L = 8:21
Refractive error (D)	
Sphere	−1.35 ± 1.75 (−7.25 to 1.00)
Cylindrical	−0.57 ± 0.39 (−1.25 to 0)
SE	−1.69 ± 1.74 (−7.63 to 0.25)
Keratometry (D)	42.60 ± 2.32 (37.38 to 47.25)
logMAR UDVA	0.43 ± 0.49 (−0.08 to 0.17)
logMAR CDVA	−0.04 ± 0.05 (−0.18 to 0.05)
logMAR binocular CDVA	−0.05 ± 0.05 (−0.18 to 0.05)
logMAR UNVA	0.21 ± 0.21 (0.00 to 0.82)
logMAR DCNVA	0.34 ± 0.12 (0.10 to 0.70)
logMAR binocular DCNVA	0.31 ± 0.13 (0.10 to 0.70)

Results are expressed as mean ± standard deviation (range; min. to max.). CDVA, corrected-distance visual acuity; D, diopter; DCNVA, distance-corrected near visual acuity; logMAR, logarithm of the minimum angle of resolution; SE, spherical equivalent; UDVA, uncorrected distance visual acuity; UNVA, uncorrected near visual acuity.

The calculated sample size was 26, and 29 subjects were enrolled after considering a dropout rate of 10%. Values are expressed as mean ± standard deviation. After normality testing using the Shapiro–Wilk test, the paired *t*-test or Wilcoxon signed-rank test was used as appropriate for the comparison of baseline and post-intervention values. All statistical analyses were performed using SPSS statistics software (version 23; IBM Corporation, Armonk, NY, USA). A P-value of < 0.05 was considered statistically significant.

3. Results

A total of 29 individuals (two men and 27 women) aged 49.11 ± 5.14 years participated in this clinical study. The patient demographics are presented in Table 1. Twenty-one individuals showed right eye dominance and eight showed left eye dominance. The mean spherical equivalent (SE) refractive error was −1.69 ± 1.74 D.

3.1. Visual acuity

Baseline monocular and binocular visual acuity values are presented in Table 1. Visual acuities for the dominant and non-dominant eyes before and after contact lens wear in the non-dominant eye are presented in Table 2. DCNVA of the non-dominant eye significantly improved after contact lens wear (P < 0.001); however, CDVA significantly worsened (P = 0.001). There were no significant differences between baseline and post-intervention CDVA and DCNVA values for the dominant eye. With regard to binocular visual acuity, CDVA showed no significant change after contact lens wear (P = 1.000), whereas binocular DCNVA exhibited a significant improvement (P < 0.001).

3.2. Defocus curves

Defocus curves for mean binocular CDVA values before and after contact lens wear are shown in Fig. 2. The peaks of optimum distance visual acuity before and after contact lens wear were −0.05 ± 0.05 and −0.05 ± 0.04 logMAR, respectively; these findings corresponded to 0.00 D. There was no statistically significant difference at this vergence (P = 0.26). The defocus curves showed that the pinhole soft contact lens significantly improved the visual acuity for intermediate (lens power, −2.0 to −1.0 D; corresponding to 100–50 cm) and near (lens power, −3.0 to −2.5 D; corresponding to 40–33 cm) vision. Notably, improvements in visual acuity were observed over wide ranges of −5.0 to −1.5 D as well as +2.0 D and +3.0 D.

Table 2
Visual acuity of eyes before and after pinhole contact lens wear for presbyopia correction.

	Before pinhole lens wear	After pinhole lens wear	P-value
Target eyes (non-dominant eye)			
logMAR CDVA	−0.04 ± 0.05 (−0.18 to 0.05)	0.02 ± 0.11 (−0.08 to 0.3)	0.001[a]
logMAR DCNVA	0.34 ± 0.12 (0.10 to 0.70)	0.15 ± 0.14 (0 to 0.49)	< 0.001[a]
Dominant eyes			
logMAR CDVA	−0.05 ± 0.36 (−0.18 to 0.05)	−0.03 ± 0.05 (−0.08 to 0.15)	0.625
logMAR DCNVA	0.36 ± 0.16 (0.10 to 0.80)	0.34 ± 0.16 (0 to 0.70)	0.289
Binocular			
logMAR CDVA	−0.05 ± 0.05 (−0.18 to 0.05)	−0.05 ± 0.04 (−0.08 to 0)	1.000
logMAR DCNVA	0.31 ± 0.13 (0.10 to 0.70)	0.11 ± 0.10 (0 to 0.30)	< 0.001[a]

Results are expressed as mean ± standard deviation (range; min. to max.). CDVA, corrected-distance visual acuity; DCNVA, distance-corrected near visual acuity; logMAR, logarithm of the minimum angle of resolution; UDVA, uncorrected distance visual acuity.

[a] significant difference between baseline and post-intervention values; paired *t*-test or Wilcoxon signed-rank test.

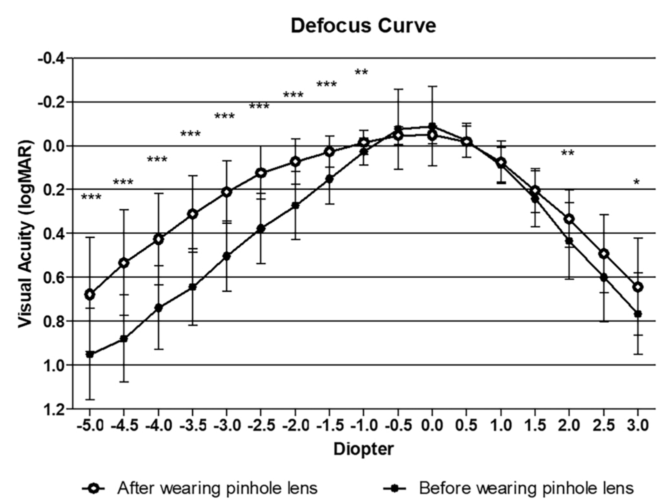

Fig. 2. Defocus curves generated before and after wear of a presbyopia-correcting pinhole contact lens [Eyelike PINHOLE II (Koryo Eyetech, Seoul, Korea)] all eyes were defocused to a +3.00-dioptre (D) spherical value from a manifest refraction value for defocus curve generation. The binocular visual acuity was measured, and increments of −0.50 D were consecutively added until a value of −5.00 D was reached. The binocular visual acuity was measured after every increment. *P < 0.05, **P < 0.01, ***P < 0.001 (significant differences between baseline and post-intervention values as per the paired *t*-test or Wilcoxon signed-rank test).

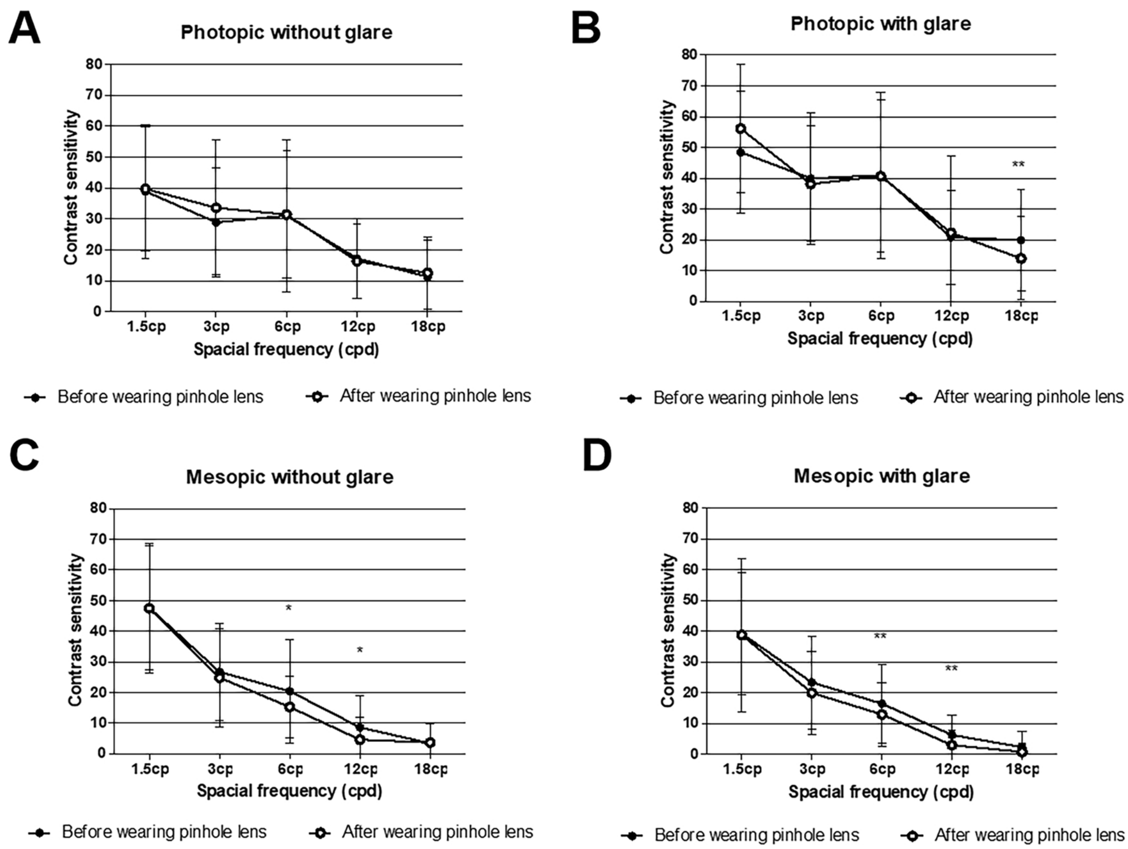

Fig. 3. Contrast sensitivity values before and after wear of a novel presbyopia-correcting pinhole contact lens [Eyelike PINHOLE II (Koryo Eyetech, Seoul, Korea)]. Contrast sensitivity was measured at 1.5, 3, 6, 12, and 18 cpd under photopic and mesopic conditions with and without glare. (A) photopic without glare. (B) photopic with glare. (C) mesopic without glare. (D) mesopic with glare. cpd, cycles per degree. *P < 0.05, **P < 0.01 (significant differences between baseline and post-intervention values as per the paired *t*-test or Wilcoxon signed-rank test).

3.3. Contrast sensitivity

Fig. 3 shows the contrast sensitivity values at 1.5, 3, 6, 12, and 18 cpd under photopic and mesopic conditions with and without glare. Under the photopic condition, there were no significant differences in all baseline and post-intervention values except those at 18 cpd with glare, which were better before contact lens wear. Under the mesopic condition, there were significant decreases in contrast sensitivity values at 6 and 12 cpd with or without glare. Overall, binocular contrast sensitivity, particularly that under the mesopic condition, deteriorated after wear of the presbyopia-correcting pinhole contact lens.

3.4. OSDI and questionnaire scores

Table 3 presents OSDI scores before and after pinhole contact lens wear. The score for the non-dominant eye significantly increased after contact lens wear (P < 0.05), whereas that for the dominant eye and the overall score for both eyes showed no significant changes.

Table 3
Ocular Surface Disease Index (OSDI) scores before and after pinhole contact lens wear for presbyopia correction.

	Before pinhole lens wear	After pinhole lens wear	P-value
Target eyes (non-dominant eye)	12.13 ± 11.38 (0 to 39)	20.99 ± 18.36 (0 to 63)	0.018[a]
Dominant eyes	11.53 ± 11.51 (0 to 39)	9.32 ± 10.29 (0 to 33)	0.061
Total eyes	12.00 ± 11.3 (0 to 39)	15.08 ± 12.08 (0 to 43)	0.225

Results are expressed as mean ± standard deviation (range; min. to max.).
[a] Significant difference between baseline and post-intervention scores; paired *t*-test or Wilcoxon signed-rank test.

Table 4
Summary of questionnaire results after wearing pinhole lens.

Characteristics	
Score of discomfort	4.66 ± 4.15 (0 to 15)
Score of visual symptom	3.59 ± 3.79 (0 to 12)
Score of work performance	
Near	8.45 ± 2.23 (2 to 10)
Intermediate	9.52 ± 0.83 (7 to 10)
Distance	9.00 ± 0.38 (3 to 10)

Tables 4 and 5 present the questionnaire findings and level of satisfaction after contact lens wear. Work performance scores at near, intermediate, and distance vision were 8.45 ± 2.25, 9.52 ± 0.83, and 9.00 ± 0.38, respectively, with a maximum of 10 points. The score for discomfort, including photophobia, pain, and dryness and foreign body sensation, was 4.66 ± 4.15, while that for visual symptoms, including glare, halo, diplopia, and fluctuation, was 3.59 ± 3.79, with a maximum of 16 points. Nineteen participants (66%) were satisfied with the overall outcomes of the contact lens, and 17 (59%) were more satisfied with the contact lens than with reading spectacles. Nineteen participants (66%) said they would recommend this lens to others.

Table 5
Satisfaction after wearing pinhole lens.

Characteristics		N = 29	
		n	%
Overall outcome	Very satisfied	1	3.45
	Satisfied	6	20.69
	A little satisfied	12	41.38
	Dissatisfied	8	27.59
	Very dissatisfied	2	6.90
Comparing with reading glasses	Very satisfied	1	3.45
	Satisfied	8	27.59
	A little satisfied	8	27.59
	Dissatisfied	9	31.03
	Very dissatisfied	3	10.34
Recommend this lens to others	Definitely	2	6.90
	Quite surely	6	20.69
	Maybe	11	37.93
	Less likely	8	27.59
	Never	2	6.90

4. Discussion

As life expectancy and the aged population continues to increase worldwide, the burden of presbyopia is gradually increasing [5]. There are various methods for alleviating presbyopia, such as excimer laser application in corneal refractive procedures, multifocal IOLs, and intracorneal inlays [2,4]. However, these strategies cannot fully resolve presbyopia [18,19]. Surgical strategies are relatively expensive and irreversible. Moreover, conventional correction of presbyopia using multifocal intraocular lens is limited by the use of separated light rays that enter the eye. A previous intracorneal inlay study showed that not all individuals exhibited enhanced task performance (such as reading) [10,11]. Therefore, a different approach is necessary for mitigating presbyopia. The present study attempted to correct presbyopia using the newly developed Eyelike PINHOLE II soft contact lens, which were worn in the non-dominant eye for 1 week. While DCNVA of the treated eye exhibited a significant improvement, the mean CDVA significantly worsened. Binocular DCNVA also exhibited a significant improvement, whereas binocular CDVA showed no apparent change. This implies that the lens enhances near visual acuity while hindering the impairment of binocular CDVA, thus preserving the individual's original distance vision in the absence of lens. These findings were consistent with those for previously evaluated pinhole contact lenses, which deteriorated the mean CDVA from 0.01 ± 0.02 to 0.1 ± 0.07 ($P < 0.006$) and enhanced the binocular DCNVA from 0.35 ± 0.14 to 0.16 ± 0.18 ($P < 0.001$) [3].

The defocus curves in this study also showed promising results. A previous study on presbyopia-correcting pinhole contact lenses found that the lenses significantly improved binocular visual acuity when spherical lens powers from −5.0 D to −2.0 D were added for defocus curve generation ($P < 0.05$) [3]. The defocus curves generated in the current study showed better results that the addition of spherical lens powers from −5.0 D to −1.0 D, showed a significant improvement ($P < 0.05$). Moreover, P-values were even lower than 0.001 at the spherical lens powers from −5.0 D to −1.5 D, whereas the previous study showed that P-values were lower than 0.001 at only −5.0 D and −4.0 D. These findings suggest that the pinhole lens allows the individual to perform daily tasks such as reading books or newspapers, texting on mobile phones, and working on the computer in a more convenient manner. In addition, visual acuity values before lens wear did not significantly exceed those after lens wear in any case. This indicated that the evaluated pinhole contact lens did not evidently worsen the vision quality.

A slight decrease in contrast sensitivity was observed after wear of the Eyelike PINHOLE II lens for 1 week. Although a significant decrease was only observed at 18 cpd (high spatial frequency) under the photopic condition with glare, the result was better than that for the previous lens design, which significantly worsened contrast sensitivity at 3, 12, and 18 cpd [3]. Under the mesopic condition with and without glare, a noticeable decrease in contrast sensitivity was observed. Although previous studies have also shown similar results ($P < 0.001$ at 1.5 and 3 cpd & $P = 0.026$ at 6 cpd with glare; $P = 0.007$ at 3 cpd without glare), the degree of decrease in contrast sensitivity was lower in the present study [3]. A difference of this magnitude is not expected to cause significant vision impairment at night, and it would be helpful to wear the lens at night as well.

In the present study, there was a significant increase in the OSDI score for the treated eyes, while score for the fellow eye did not show a considerable change. This indicates that the treated eye experienced some discomfort during contact lens wear. However, the questionnaire and survey scores contradicted this finding. The overall work performance score was high, indicating that the pinhole lens helped the patients in performing their daily activities. Moreover, the majority of participants were satisfied with the overall outcome, and 66% tended to recommend the lens to others. Although the scores for visual symptoms and discomfort were lower than the work performance scores, the overall satisfaction level was not affected. Thus, participants were willing to tolerate slight discomfort if they could perform their tasks effectively. Dry eye syndrome and ocular discomfort during contact lens wear, can be controlled by dry eye medications. Prior experience of wearing contact lenses may affect both overall satisfaction and the OSDI score, because participants with previous experience can adjust better than those with no prior experience. Therefore, individuals who wear contact lenses for the first time in advanced age may report lower satisfaction and exhibit a higher OSDI score.

Pinhole contact lenses are associated with some problems. First, when the eye blinks, the contact lens can be displaced, resulting in movement of the pinhole aperture from the centre of the pupil. This interrupts light entry into the retina [3,10]. Second, the amount of light entering the eye varies with the size of the pupil, and individuals with very large or very small pupils can experience ghost images under mesopic conditions [20]. It should be noted that the insufficient effectiveness noted by other study groups evaluating contact lenses with small apertures for presbyopia correction may be attributed to these issues [21,22]. However, it was reported that the pupil size did not significantly affect the clinical outcomes in patients who received Kamra® inlays [21,23]. A previous study investigated post-blink movement and greater total decentration for various soft contact lenses and reported values of 0.22 and 0.21 mm, respectively, which are not considered critical in actual clinical practice [24]. Further studies should assess the effects of the pupil size and lens movement or displacement. Despite these disadvantages, pinhole contact lenses are accessible, readily available, and relatively inexpensive, and they do not cause permanent eye changes that are observed with surgical treatment.

Even though, the questionnaire and survey findings were promising, an optimal balance between increased visual acuity and performance and decreased comfort is necessary. Moreover, long-term studies on the outcomes of the Eyelike PINHOLE II are necessary. A previous study of long-term monocular corneal inlay implantation showed a decrease in visual acuity that was not due to the inlay but due to normal age-related hyperopic changes [25]. Long-term studies can also help in elucidating any unknown disadvantages or benefits of the lens. In addition, the present study did not include a separated control group to fairly compare the efficacy of the lens. Future studies should include an appropriate control group in order to eliminate bias. Another study limitation is that the satisfaction survey and questionnaire for performance were administered only at the follow-up visit, because the study primarily focused on the outcomes after lens wear. Future studies should assess these parameters at baseline and after lens wear. Moreover, larger samples are necessary to reveal any possible complications that may not have been apparent or significantly noticeable in the present study. Finally, comparative analyses involving controls or other lens designs will further clarify the effectiveness of the Eyelike PINHOLE II for the correction of presbyopia [1,8].

In conclusion, the results of this study suggest that the newly developed Eyelike PINHOLE II soft contact lens holds promising potential for the treatment of presbyopia, although it may cause some discomfort. The safety and efficacy should be further investigated in studies with long-term follow-up periods and larger samples as well as studies involving comparisons with other multifocal contact lenses.

This work is original, has not been published, and is not being considered for publication elsewhere. This research was presented at the British Contact Lens Association (BCLA) clinical conference & exhibition held in Manchester in 2019. The authors have no financial or personal competing interests related to the research detailed here.

Declaration of Competing Interest

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