Clinical Efficacy of Pinhole Soft Contact Lenses for the Correction of Presbyopia

Park Si Yoon

Department of Medicine

The Graduate School, Yonsei University

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Directed by Professor Kim Eung Kweon

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This certifies that the Master's Thesis of Park Si Yoon is approved.

Thesis Supervisor : Kim Eung Kweon

Thesis Committee Member#1 : Kim Tae-im

Thesis Committee Member#2 : Jung Hosung

The Graduate School
Yonsei University

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ABSTRACT

Clinical Efficacy of Pinhole Soft Contact Lenses for the Correction of Presbyopia

Park Si Yoon

Department of Medicine
The Graduate School, Yonsei University

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I investigated the clinical efficacy of pinhole soft contact lenses for presbyopia correction. Twenty participants with presbyopia wore pinhole soft contact lenses in the non-dominant eye for 2 weeks. Manifest refraction, Goldmann binocular visual field tests, contrast sensitivity tests, and biomicroscopic examinations were performed along with evaluations of questionnaire responses and the binocular corrected distance visual acuity (CDVA), distance-corrected near visual acuity (DCNVA), distance-corrected intermediate visual acuity (DCIVA), and depth of focus, both before and after 2 weeks of lens wear. DCNVA at 33 and 40 cm and DCIVA at 50 and 70 cm showed significant improvements after pinhole lens wear (P-value: <0.001, <0.001, <0.001, and 0.046, respectively), with no changes in the binocular visual field and binocular

CDVA. Contrast sensitivities under photopic and mesopic conditions decreased at some frequencies; however, visual function questionnaire scores significantly improved (all P-values <0.001). These findings suggest that pinhole contact lenses effectively correct presbyopia.

Key words : presbyopia, pinhole contact lenses

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I. INTRODUCTION

Presbyopia is defined as age-dependent loss of accommodation caused by reduced crystalline lens flexibility. The symptoms of presbyopia gradually appear in the early forties[1-3] and result in a decline in the quality of life of affected individuals.[4] Given the longer life expectancy and progressive increase in the aged population, presbyopia is becoming a more challenging concern for eye care practitioners.[5] Several approaches for presbyopia correction have been extensively studied. Possible surgical procedures include monovision photorefractive keratoplasty, laser in situ keratomileusis (LASIK), presbyopic LASIK, lens-based procedures with cataract extraction and multifocal intraocular lens (IOL) or monovision IOL implantation, and intracorneal inlay insertion into corneal pockets. These procedures partially alleviate the discomfort caused by presbyopia, although some limitations remain unresolved.[6–10] Nonsurgical methods are generally attempted first and include the prescription of multifocal glasses and multifocal contact lenses.[11–13] Among the various methods, pinhole systems with the corneal inlay technique have been used on the basis of the concept that a small-diameter aperture can enhance the depth of focus and maintain acceptable visual acuity and contrast sensitivity.[9,10,14] After the commercially available corneal inlay with pinhole lens, KAMRA (Acufocus, Inc., Irvine, CA, USA), was introduced, it has been well reported that a pinhole system applied to the non-dominant eye can improve near and intermediate visual acuity while providing a continuous range of vision without a decrease in stereoacuity.[15,16] A pinhole system built within a contact lens, which can avoid surgery-related complications such as permanent decentration of the inlay and corneal opacity,[17] was evaluated by Garcia-Lazaro and his colleagues in a cohort of individuals with presbyopia.[18] The authors assessed the effects of different contact lens-based artificial pupil designs with varying aperture sizes on visual function and reported acceptable distance visual acuity and superior intermediate vision with the pinhole system having a central aperture of 1.6 mm. Unlike corneal inlays, pinhole contact lenses are removable and have the ability to rectify refractive errors. In the present study, I investigated the efficacy of the first commercially available pinhole soft contact lens (Eyelike NoanPinhole, Koryo Eyetech, Seoul, Korea) for the correction of presbyopia by evaluating near and far visual acuities, the depth of focus, contrast sensitivities, and the binocular visual field.

II. MATERIALS AND METHODS

1. Ethics

This prospective comparative study was performed in Severance Hospital, Yonsei University College of Medicine, Seoul, Korea from May 2015 to March 2016. It adhered to the principles of the Declaration of Helsinki, was approved by the Institutional Review Board of Yonsei University College of Medicine(1–2015-0015), and is registered at ClinicalTrials. gov(identification number : NCT02612584). Informed consent was obtained from all participants after the nature and possible consequences of the study were explained.

2. Subjects

Individuals with presbyopia aged 45–65 years were recruited for this study. The exclusion criteria for the study were as follows: a history of previous ocular surgery or trauma; the presence of corneal abnormalities (corneal guttata, recurrent corneal erosion, corneal dystrophy, etc.), chronic or severe dry eye, fundus abnormalities, glaucoma, uveitis, amblyopia, and/or other systemic diseases; and an extremely small or large pupil size (<1.0 mm under photopic conditions or >5.00 mm under mesopic conditions) in the non-dominant eye.

3. Eye Dominance

Ocular dominance testing was performed to determine the more suitable eye for pinhole contact lens application. Two different methods described in previous studies on small-aperture corneal inlay surgery were used.19 For determination of the motor dominant eye, the participants were asked to make a small circle with their fingers extended while looking at a distant target through the circle. Then, they were asked to close each eye sequentially, gaze at a distant target, and identify the eye being used for gazing at the target; the identified eye was designated as the motor dominant eye. The sensory dominant eye was determined by a blur test, which involved the placement of a + 1.50 D spectacle trial lens in front of the eye when the subject’s vision blurred. The eye that was more tolerant to the plus-power blur was defined as the sensory non-dominant eye. When these two dominance tests showed different results, the sensory non-dominant eye was selected for pinhole contact lens application.

4. Pinhole Soft Contact Lens

The Eyelike NoanPinhole (Koryo Eyetech), the first commercially available pinhole soft contact lens, was prescribed for the non-dominant eye according to the refractive error, with a target of emmetropia.

If necessary, a non-pinhole soft contact lens was prescribed for distance vision in the dominant eye. The participants were advised to wear the lenses for more than three consecutive hours per day, for more than 2 weeks. The pinhole and clear soft contact lenses were manufactured from 2-hydroxyethyl methacrylate (92.2%), with two base curves (8.60 and 8.90 mm) and two diameters (14.00 and 14.50 mm). The pinhole pattern was located in the center of the lens and was generated by a cast molding process. Diagnostic lens fitting with lenses having an 8.6-mm base curve and a 14.00-mm diameter was implemented for each participant. When significant deviation was noted, the base curve or radius was modified such that the pinhole lens fit in the center of the eye. The pinhole was designed with a 1.66-mm inner diameter for the central aperture and a 4.98-mm outer diameter (Figure 1).

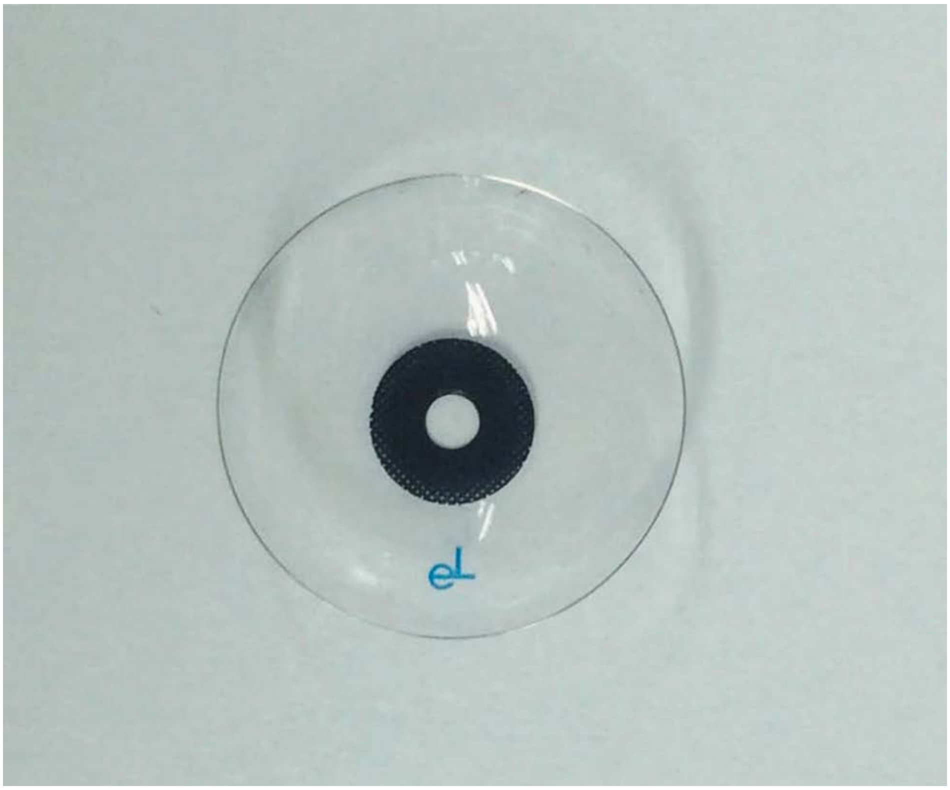

Figure 1. Photograph of the Eyelike Noan Pinhole (Koryo Eyetech, Seoul, Korea) soft contact lens.

5. Measurements

All subjects underwent a complete ophthalmological examination, including corneal fluorescein staining (NEI grading scale: 0–15), manifest refraction, and measurement of the corneal curvature with a Pentacam® Scheimpflug camera (Oculus, Wetzlar, Germany). The uncorrected distance visual acuity (UCDVA); corrected distance visual acuity (CDVA); distance-corrected near visual acuity (DCNVA) and distance-corrected intermediate visual acuity (DCIVA) at 33, 40, 50, and 70 cm; binocular CDVA, binocular DCNVA at 33 cm, and defocus curve were also recorded. In addition, all participants underwent binocular contrast sensitivity testing under photopic and mesopic conditions as well as binocular field testing, and they were asked to complete a questionnaire about visual symptoms and spectacle-dependence for near vision (Table 1). Ocular Surface Diseases Index (OSDI) scores were also determined. All these assessments were performed before and 2 weeks after the initiation of pinhole soft contact lens wear. For defocus curve measurement, the eyes were defocused to +3.00 D spherical from a manifest refraction value, and the binocular visual acuity was determined. Then, trial lenses with a negative spherical power were progressively added in increments of −0.50 D until a power of −5.00 D was reached, and the binocular visual acuity was measured with every increment. Defocus curves obtained before and after 2 weeks of pinhole lens wear were compared for each subject. Binocular contrast sensitivity was measured under photopic (target luminance, 85 candelas/square meter [cd/m2]) and mesopic (target luminance, 3 cd/m2) conditions, with and without glare, using the functional acuity contrast test of the Optec 6500 view-in test system (Stereo Optical Co, Inc, Chicago, IL, USA) at stimulus spatial frequencies ranging from 1.5 to 18 cycles/degree (cpd).

Goldmann perimetry (INAMI, Tokyo, Japan) was used to measure the binocular visual field. The participants were asked to watch a white Goldmann III4e target (4 mm2, 10 dB) that moved around from the meridian at 15-degree intervals up to 90 degrees. The degree at which The main target was not visible during binocular viewing in each meridian was recorded. The mean binocular visual field in each meridian before and after pinhole lens wear and the total change after pinhole lens wear were evaluated for each participant.

Table 1. Questionnaire regarding sense of discomfort, visual symptoms, and ability to perform tasks.

	Never	Sometimes	Half of the time	Almost Always	Always
1. Do you feel a sense of discomfort before or after wearing lenses?					
Photosensitivity					
Ocular pain and discomfort					
Dryness					
Foreign body sensation					
Glare					
2. Do you feel any visual symptom as follows, before or after wearing lenses?					
Halo					
Diplopia					
Fluctuation of visual acuity					
			Cannot perform	Quite difficult	Perform easily
Near distance tasks					
3. Do you have difficulty performing the following tasks?					
Reading medication instructions					
Reading newspapers					
Cleaning nails					
Using mobile phone					
Reading books or magazines					
Intermediate distance tasks					
Finding items in the kitchen					
Working with computer					
Looking in bathroom mirror					
Looking at calendar on the wall					
Looking at photo on the table					
Far distance tasks					
Reading road signs					
Recognizing people across the room					
Looking at clock on the wall					
Estimating the distance between cars					
Reading home address					

Never = 0, Sometimes = 1, Half of the time = 2, Almost always = 3, Always = 4, Cannot perform = 0, Quite difficult = 1, Perform easily = 2

6. Statistical Analysis

The data are presented as means ± standard deviations. All visual acuity measurements were converted to logarithm of the minimal angle of resolution (logMAR) values for data analyses. Paired-sample t-tests were used to compare measurements obtained before and after pinhole contact lens wear by using a statistical software package (SPSS version 20; SPSS Inc., Chicago, IL, USA). In accordance with a previous report on pinhole-aperture contact lenses for presbyopia correction,18 we found that a sample size of 19 individuals would yield an 80% chance (α = 0.05) of detecting a minimum visual acuity change of 0.14 logMAR after pinhole lens wear. A P-value of <0.05 was considered statistically significant.

III. RESULTS

In total, 20 individuals with presbyopia (14 women, six men) were recruited for this study. The patients' demographic characteristics are shown in Table 2. The mean spherical equivalent (SE) refractive error was 0.91 ± 1.72 D (range: −5.88 to +1.75 D). Twelve subjects exhibited myopia (mean SE refractive error: −1.86 ± 1.54 D, range: −5.87 to −0.50 D), four exhibited emmetropia, and four exhibited hyperopia (mean SE refractive error: +1.03 ± 0.48 D, range: +0.75 to +1.75 D).

Table 2. Patient demographics.

Age (years)		56.52 ± 4.96 (46–65)
Non-dominant eye		9: OD/11: OS
Target eye for pinhole contact		
SPH		−0.65 ± 1.71 (−5.75 - +2.00)
CYL		−0.40 ± 0.66 (−1.75 - +1.50)
SE		−0.91 ± 1.72 (−5.88 - +1.75)
Visual acuity of enrolled eye		
UCDVA		0.29 ± 0.37 (0–1.6)
BCDVA		0.01 ± 0.02 (0–0.05)
Binocular CDVA		0.002 ± 0.01 (0–0.05)
DCNVA (logMAR)	33 cm	0.43 ± 0.19 (0.19–1.0)
	40 cm	0.38 ± 0.17 (0.19–0.7)
DCIVA (logMAR)	50 cm	0.29 ± 0.13 (0.1–0.7)
	70 cm	0.25 ± 0.16 (0.1–0.8)
Binocular DCNVA at 33 cm		0.35 ± 0.14 (0.19–0.7)
Corneal staining score (NEI score)		0.37 ± 0.59 (0–2)
OSDI		18.27 ± 10.92 (0–43.18)
Target D (diopter)		0.30 ± 0.45 (−0.75 - +0.75)

OD: right eye, OS: Left eye, SPH = spherical power of manifest refraction, CYL = cylinder power of manifest refraction, SE = spherical equivalent of manifest refraction, UCDVA = Uncorrected distance visual acuity, BCDVA = Best corrected distance visual acuity, binocular CDVA = binocular corrected distance visual acuity, DCNVA = distance corrected near visual acuity, DCIVA = distance corrected intermediate visual acuity, NEI = National Eye Institute, OSDI = Ocular surface diseases index

1. Visual Acuity

The results of visual acuity testing before and after pinhole contact lens wear are shown in Table 3. The monocular DCNVA at 33, 40, 50 ($P < 0.001$ for all), and 70 ($P = 0.046$) cm showed significant improvements after pinhole soft contact lens wear in the nondominant eye. The binocular DCNVA at 33 cm also showed a significant improvement after 2 weeks of lens wear ($P < 0.001$). While binocular CDVA remained unchanged after pinhole lens wear ($P = 0.096$), monocular CDVA showed a significant decrease ($P = 0.006$). Defocus Curve Figure 2 shows the defocus curve for the mean CDVA values before and after 2 weeks of pinhole lens wear. The defocus curve provided one peak of maximum vision that corresponded to 0.00 D. The mean CDVA at 0.00 D was significantly better before pinhole lens wear. However, comparison of defocus curves based on a range of visual acuity values above 0.3 logMAR revealed a significantly wider range after pinhole soft contact lens wear (before: −1.50 D to +1.00 D, equivalent to 67 cm to 2m; after: −2.50 D to +1.00 D, equivalent to 40 cm to 2 m; $P = 0.03$). Notably, pinhole lens wear resulted in a significantly improved outcome for near vision, particularly at lens powers of −2.50 and −3.00 D (optically equivalent to 40 cm and 33 cm; $P = 0.004$ and 0.017, respectively).

Table 3. Visual acuity of enrolled eye with and without wearing pinhole contact lenses.

		Before wearing pinhole lens	After wearing pinhole lens	P value
CDVA (logMAR)		0.01 ± 0.02 (0–0.05)	0.1 ± 0.07 (0–0.22)	0.006
Binocular CDVA (logMAR)		0.002 ± 0.01 (0–0.05)	0.02 ± 0.04 (0–0.15)	0.096
DCNVA	33 cm	0.43 ± 0.19 (0.19–1.0)	0.18 ± 0.18 (0–0.7)	<0.001
logMAR)	40 cm	0.38 ± 0.17 (0.19–0.7)	0.11 ± 0.09 (0–0.22)	<0.001
DCIVA	50 cm	0.29 ± 0.13 (0.1–0.7)	0.12 ± 0.09 (0–0.22)	<0.001
logMAR)	70 cm	0.25 ± 0.16 (0.1–0.8)	0.14 ± 0.11 (0–0.3)	0.046
Binocular DCNVA at 33 cm logMAR)		0.35 ± 0.14 (0.19–0.7)	0.16 ± 0.18 (0–0.7)	<0.001
Corneal staining score (NEI score)		0.35 ± 0.59 (0–2)	0.60 ± 0.59 (0–2)	0.056

CDVA = Corrected distance visual acuity, binocular CDVA = binocular corrected distance visual acuity, DCNVA = distance corrected near visual acuity, DCIVA = distance corrected intermediate visual acuity, NEI = National Eye Institute

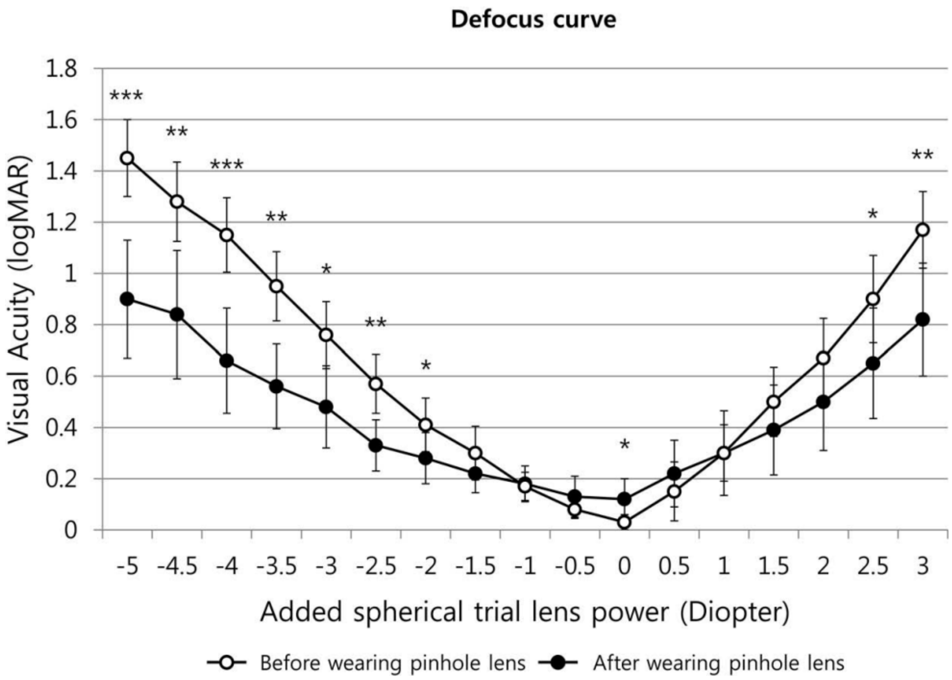

Figure 2. Defocus curves before and after 2 weeks of pinhole soft contact lens wear for the correction of presbyopia.

2. Contrast Sensitivity

There was no significant difference in the results of the binocular contrast sensitivity test at all spatial frequencies under photopic conditions without glare before and after pinhole lens wear. On the other hand, binocular contrast sensitivity under photopic conditions with glare showed a statistically significant decrease at 3, 12, and 18 cpd ($P = 0.005$, 0.021, and 0.029, respectively) after 2 weeks of pinhole lens wear. Under mesopic conditions, binocular contrast sensitivity showed a significant decrease at 3 cpd ($P = 0.007$) in the absence of glare and at 1.5, 3, and 6 cpd ($P < 0.001$, $P < 0.001$, and $P = 0.026$, respectively) in the presence of glare. Thus, pinhole soft contact lens wear resulted in an overall decrease in binocular contrast sensitivity, particularly under mesopic conditions (Figure 3).

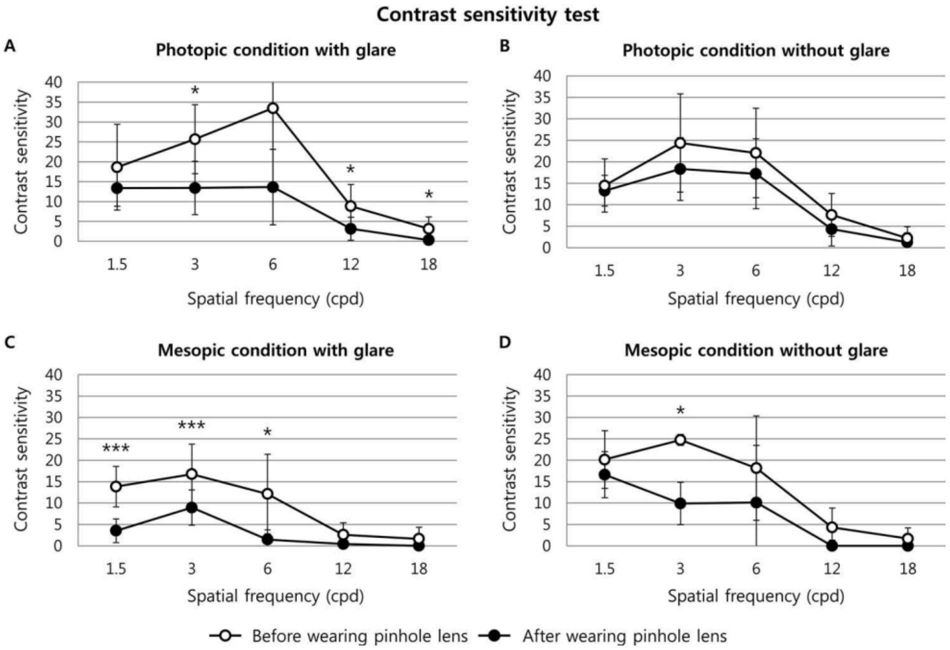

Figure 3.Contrast sensitivity values before and after 2 weeks of pinhole soft contact lens wear for the correction of presbyopia.

3. Binocular Visual Field Test

Figure 4 shows the mean degrees at which the target was no longer visible during binocular viewing in each meridian. The mean binocular visual field was the smallest in the superior meridian, both before (50.42 degrees) and after (49.17 degrees) pinhole lens wear. Moreover, pinhole lens wear resulted in no significant changes in the visual field in any of the meridians (P = 0.434).

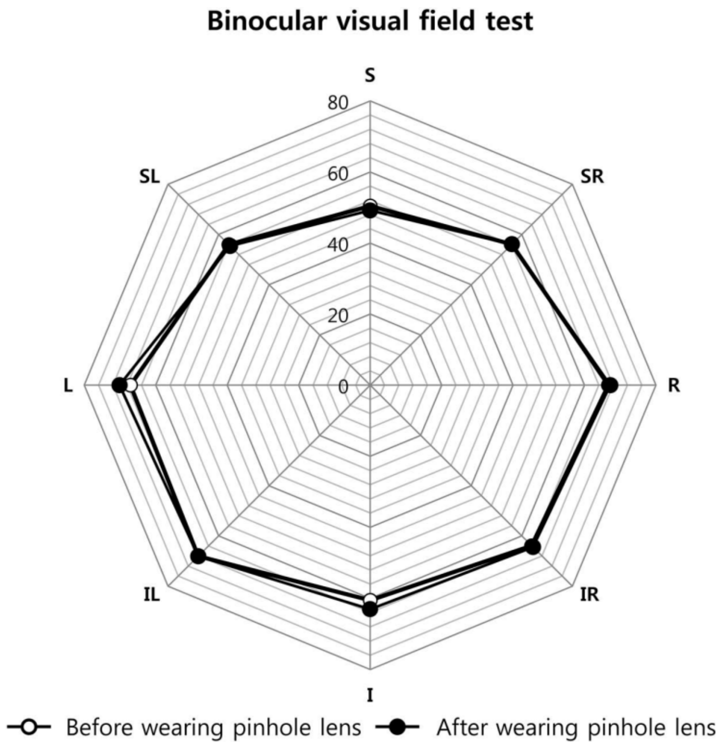

Figure 4. Binocular visual field values obtained by Goldmann perimetry before and after 2 weeks of pinhole soft contact lens wear for the correction of presbyopia Comparison of field size of binocular view with and without pinhole contact lenses.

4. Corneal Staining and Questionnaire Scores

There were no significant changes in corneal fluorescein staining (NEI score) at 2 weeks after the initiation of pinhole soft contact lens wear ($P = 0.056$). With regard to the OSDI score, there was no significant change after pinhole lens wear. Whereas questionnaire scores for discomfort (photosensitivity, ocular pain and discomfort, dryness, and foreign body sensation) were not meaningfully affected ($P = 0.728$), those for visual symptoms (glare, halo, diplopia, and fluctuation in visual acuity) showed significant decreases after pinhole lens wear ($P < 0.001$). Nevertheless, the subjects reported that their work performance under near, intermediate, and distance vision was significantly improved after pinhole lens wear ($P < 0.001$; Table 4).

IV. DISCUSSION

With a worldwide increase in the average lifespan and participation of seniors in society, the management of presbyopia has become an emerging clinical challenge. In the present study, I analyzed the clinical efficacy of pinhole soft contact lenses for the correction of presbyopia and found significant improvements in most visual parameters after pinhole lens wear for 2 weeks.

The pinhole system has been used as monovision therapy for the correction of presbyopia via an increase in the depth of focus and improvement in near and intermediate vision. The depth of focus, defined as the distance in front of and beyond the targeted object that appears to be in focus, can be enhanced by a decrease in the aperture size.[1] Although the depth of focus increases with a decrease in the size of the pinhole aperture, there is an accompanying decrease in retinal illuminance. Previous studies used computer-based modelling and determined 1.6 mmto be the most appropriate aperture size for presbyopia correction.[1,9] The pinhole soft contact lens assessed in the present study was also designed with a central aperture measuring 1.6mm, similar to the KAMRA inlay lens.

In the present study, eyes with an increased depth of focus associated with the pinhole aperture exhibited improved near vision performance without a significant decline in the binocular distance vision. Similar findings have been reported for corneal inlay pinhole systems[9,10,20,21] and artificially designed pinhole contact lenses in previous studies.[18] However, contrast sensitivity and visual symptom scores were significantly affected in a negative manner, and further studies are required to determine solutions for these limitations.

Another possible problem associated with the use of pinhole contact lenses is aperture displacement on blinking, which can interfere with the light pathway during retinal image formation. The resulting light deviations can cause glare, halo, and visual acuity fluctuation, particularly in individuals with excessive lens movement. In the present study, I could not assess the frequency or severity of lens decentration during the entire trial period, and the decreased visual symptom scores after pinhole lens wear (Table 4) could be attributed to decentration or excessive lens movement. This aspect also needs to be addressed in future studies.

The pupil size of the patient is yet another concern. The spherical aberration and depth of focus can change according to the pupil size.[22,23] In particular, individuals with pupils measuring less than 1 mm or more than 5 mm can experience ghost images under mesopic conditions or exhibit anisocoria.[24] However, previous studies have reported that the pupil size does not seem to influence the resultant visual acuity after KAMRA inlay implantation or pinhole contact lens wear.[18,25] In the present study, I excluded individuals with pupils measuring less than 1 mm or more than 5 mm; therefore, the influence of the pupil size on the visual acuity of subjects was probably negligible. Further studies should assess the effects of the pupil size by testing pinhole contact lenses in participants with various pupil sizes.

Contrast sensitivity tests measure the performance of spatial vision; notably, diminished contrast sensitivity may result in decreased vision quality despite normal visual acuity.[26] In the present study, contrast sensitivity, particularly that under mesopic conditions, exhibited a significant decrease after pinhole contact lens wear, similar to the finding in a previous study.[1] Accordingly, I recommend the use of pinhole contact lenses during daytime activities only.

The visual field is another factor that can be adversely affected by a pinhole system, considering the dim light on the peripheral retina.[27] Goldmann perimetry in the present study revealed no apparent changes in the binocular visual field after pinhole contact lens wear. This finding indicates the usefulness of pinhole soft contact lenses for presbyopia correction.

This study has some limitations. First, I did not measure stereoacuity. Lazaro et al. reported that stereoacuity was more negatively affected by pinhole contact lenses than by multifocal lenses.[1] Therefore, further studies should determine whether stereoacuity is impaired to the extent that it affects the individual's daily activities. Second, I did not evaluate the actual duration of lens wear in terms of the daily number of hours or the performance of the lenses after neuroadaptation. The long-term efficacy of pinhole soft contact lenses should be addressed in future studies. Third, a control group was not included in our study. The efficacy and acceptance of these lenses can be demonstrated more clearly if appropriate control groups such as a multifocal contact lens group or a spectacle-corrected group are included. Further studies should also address this point.

In conclusion, the present study demonstrated that pinhole soft contact lenses can significantly improve near and intermediate vision without affecting the binocular visual acuity, binocular visual field, and cornea. Although the pinhole can decrease contrast sensitivity under mesopic conditions by blocking light, pinhole contact lens wear in the non-dominant eye can improve the individual’s work performance under near, intermediate, and distance vision. Thus, pinhole soft contact lenses can be considered safe and effective for the correction of presbyopia. Further studies should address all the aforementioned limitations.

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ABSTRACT (IN KOREAN)

노안 교정 핀홀 (Pinhole) 콘택트 렌즈의 임상적 유용성

< 지도교수 김 응 권 >

연세대학교 대학원 의학과

박 시 윤

노안 교정을 위한 핀홀 콘택트 렌즈의 임상 효능을 조사하였다. 노안을 가진 20명의 대상자를 대상으로 자각적 굴절검사 시행 후 비 주시안에 2주동안 핀홀 콘택트 렌즈를 처방하여 착용하게 하였다. 모든 대상자에게 착용 전과 착용 2후의 자각적 굴절력 검사, 골드만 양안 시야검사, 대비감도검사, 생체 현미경 검사 및 설문지 검사를 시행하였으며, 양안 원거리 및 근거리, 중간거리의 나안 및 보정시력, 초점 심도 커브를 측정하였다.

렌즈 착용 후 33 및 40 cm 에서의 근거리 보정시력 및 50 및 70 cm 에서의 중간거리 보정시력은 현저한 개선을 보였으며 (P-value: <0.001, <0.001, <0.001, 0.046), 양안 시력 및 양안 시야 검사상의 변화는 보이지 않았다. 명소시 및 박명시 상태에서 일부 주파수의 대비감도 감소는 보였으나 시각 기능 설문 점수는 유의미한 개선을 보였다(P-values <0.001). 이러한 결과로 보았을 때 핀홀 콘택트 렌즈는 노안교정에 효과적일 것으로 사료된다.

핵심되는 말 : 노안, 핀홀 콘택트 렌즈