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REVIEW/UPDATE

Applications of the pinhole effect in clinical vision science

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The pinhole effect is commonly used to discriminate uncorrected refractive error from ocular diseases. A small aperture limits the width of light beams entering the eye, thus increasing the depth of focus. The pinhole effect has also been used in spectacles, contact lenses, corneal inlays, and intraocular lenses (IOLs) to improve reading by compensating for loss of accommodative function. Pinhole spectacles improve near visual acuity, but reduce reading speed, increase interblink interval, and decrease tear break-up time. For contact lenses and IOLs, pinhole devices are usually used in the nondominant eye, which allow compensation of various refractive errors and decrease spectacle dependence. Pinhole corneal inlays are implanted during laser in situ keratomileusis or as a separate procedure. Pinhole IOLs are gaining popularity, particularly as they do not bring a risk of a local inflammatory reaction as corneal inlays do. Disadvantages of using the pinhole effect include high susceptibility to decentration, decrease in retinal luminance levels, and difficulties in performing fundus examinations or surgery in eyes with implanted devices. There are also concerns regarding perceptive issues with different retinal illuminances in the 2 eyes (the Pulfrich effect).

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The number of users of intraocular lens (IOL) and contact multifocal lens has been expanding because of the growing popularity of these devices for the correction of presbyopia.[1] Several modern multifocal designs are based on the principle of simultaneous image formation, in which multiple foci are formed by different powered areas within the pupil.[2,3] This approach can lead to visual adverse effects, such as disability glare or halos, especially when the pupil size increases in low-illumination conditions. These difficulties can be overcome by using the pinhole effect in which a small aperture limits the width of light beams entering the light, thus increasing the depth of focus (DoF).[4,5] Small openings such as pinholes and stopped-down camera apertures create sharper images by blocking out-of-focus rays rather than focusing them with lenses.

Ideally, an eye images every point of any object on a corresponding spot on the retina. If the eye is not corrected properly, each point will form a blurred retinal image instead.[6,7] A pinhole, say of 1-mm diameter, placed close to the eye will reduce the width of the bundle of rays entering the eye from each object point and reduce the area of retinal blur, thus improving vision.[6–11] Diffraction starts to seriously adversely affect image quality as pupil size decreases, and there may be no benefit in smaller pupil sizes such as 0.75 mm and 0.5 mm.[6] There is also a decrease in the retinal illumination that may affect vision adversely in low-illumination environments.[12] The decrease in illumination mentioned above can be overcome by increasing the task illuminance with types of focal lighting.[13] For various combinations of pupil sizes and field angles, pinholes reduce the amount of light reaching the retina with attenuation of image brightness.[14,15] This does not have to be a significant problem if higher lighting levels can be provided. Pinhole IOLs and corneal inlays are most of the time implanted monocularly to obtain acceptable near vision while the other eye gives good distance vision.[16] An alternative to a pinhole is to increase the level of spherical aberration in a corrective device to allow a proportion of the image-forming light to be in reasonable focus for a particular object distance. Moreover, it has been claimed that decreasing the pupil size provides better accuracy, predictability, and patient satisfaction than inducing spherical aberration.[17]

Pinhole occluders can improve visual acuity (VA) over a range of distances by reducing retinal blur presented by narrowing the beam of light entering the eye, cutting off peripheral aberration, and increasing DoF.[15,18–20] Spectacles, contact lenses, corneal inlays, and IOLs using the pinhole effect are commercially available.[2,21,22] This article presents an evaluation of the use of the pinhole effect in ophthalmology and optometry.

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METHODS

PubMed and Scopus were the main resources used to search the medical literature. An extensive look-up was performed to identify relevant articles concerning the use of pinholes in ophthalmology and optometry as on September 1, 2022. The following keywords were used in various combinations: *pinhole and occluder*, *test*, *principle*, *glasses*, *corneal inlay*, *contact lens*, *intraocular lens*, *IOL*, and *presbyopia*. Of the studies retrieved by this method, we reviewed all publications in English and abstracts of non-English publications. Studies were critically reviewed to create an overview and guidance for further search. No attempts to discover unpublished data were made. The search strategy is presented in Appendix 1 (available at http://links.lww.com/JRS/B8). Although several review articles have been published in a similar topic recently, these considered only contact lenses and IOLs.[11,23–26]

APPLICATIONS IN CLINICAL VISION SCIENCE

The search revealed 445 articles, of which 142 were included in the final analysis. Clinical studies using the pinhole principle are presented in Table 1 and discussed in the following subsections.

Pinhole Test

The pinhole occluder can be used as a part of a trial frame set or as a separate occluder with a handle (Figure 1).[56] The pinhole occluder, which is an opaque disc with a small hole, is used to detect whether poor VA is due to a refractive error.[57] If so, the pinhole will improve VA, whereas worse VA suggests macular diseases or lens opacities, and no change indicates amblyopia. The World Health Organization recommends the pinhole test for the Rapid Assessment of Avoidable Blindness survey to distinguish between refractive errors and conditions not correctable with eyeglasses in adults.[58] The pinhole test has also been shown useful in estimating the potential improvement over spherocylindrical correction with hybrid contact lenses in keratoconus and other corneal diseases.[27]

Although the pinhole test is used often in clinical practice, it has not been described extensively.[59,60] Kumar et al. found that the improvement in the pinhole test is correlated with the magnitude of spherical equivalent refraction (Spearman $\rho = 0.68$, $P < .001$) and concluded that the pinhole occlusion is a valid gauge of refractive error in Rapid Assessment of Avoidable Blindness surveys.[29] Melki et al. suggested that the pinhole test is a simple and reliable method for estimating visual outcomes after uneventful cataract surgery.[61] Lowenstein et al. noted that the pinhole test reduced the rate of patients with false-positive results in uncorrected VA screening, who would have unnecessarily undergone a complete ophthalmological examination.[59] In another study, the pinhole test was considered as a simple predictor of improvement with hybrid contact lenses (rigid center surrounded by a soft lens skirt).[27] The improvement in VA with the pinhole test was correlated positively with VA with a hybrid contact lens in patients with keratoconus and other corneal diseases and was better than with spherocylindrical correction.[27] Finally, the pinhole test may be used to identify a poor refraction, for example, if the spectacle-corrected VA is 6/7.5 and the pinhole improves this to 6/6, perhaps astigmatism may have been missed.

Chronic glaucoma is the second leading cause of blindness after cataract globally, and single studies have assessed the utility of pinhole VA testing for glaucoma screening.[62] Although glaucoma was not considered as a priority for Vision 2020, an appropriate technique for glaucoma detection is desirable. Cook et al. investigated 6 techniques for glaucoma screening in low-resource settings: pinhole VA, counting fingers confrontation visual screening, frequency doubling technology C-20-1 visual field, air-puff tonometry, pupil light response, and lens-free ophthalmoscope of the disc.[31] Testing the pinhole VA using a cutoff point of 6/18 in 1 or both eyes had both the highest sensitivity and specificity; only lens-free direct ophthalmology with a cutoff point of 0.7 for the vertical cup:disc ratio combined with testing for an afferent pupil defect had similar values for detection. However, a follow-up study did not confirm the value of the pinhole test with 6/18 VA in a rural African setting—trained general nurses referring glaucoma suspects did not lead to increased glaucoma service delivery.[30] This was because of the lack of perception of the importance of screening for eye conditions, as well as severe workload by the primary health center. To date, glaucoma screening cannot be considered cost-effective.[63]

The pinhole test has also been criticized for imprecise estimation of postrefractive VA.[64,65] This might be unreasonable criticism given the main point that is to determine that there is an uncorrected error, or inadequate correction, on poor vision. The pinhole test is used mainly in adults and older children as it might be difficult to perform in younger children and in the elderly or mentally impaired.[28,66] Moreover, in patients with low visual acuities, it might not be a sufficient predictor of VA.[28,66] Although it has been pointed out that training of a refractionist might not take much longer than for a clinical evaluation of refraction, the problem in under-resourced settings might be the lack of trained refractionists to provide a clinical evaluation.[29,57,64] In conclusion, it is imperative to emphasize that pinhole VA cannot be considered a dependable or highly accurate predictor of corrected distance VA (CDVA).[67] One to 2.0 mm, but not smaller (0.5 to 0.75 mm), pinholes might provide VA 20/40 or better for small refractive errors; for greater refractive errors, the VA strongly decreases.[6]

Pinhole Spectacles

Pinhole spectacles consist of a standard spectacle frame containing perforated plastic instead of a lens.[15] Multiple-pinhole spectacles are more commonly used than single-pinhole spectacles: They might consist of an array of more than 100 pinholes separated horizontally and vertically by approximately 3 mm (Figure 2). For one manufacturer, the aperture is smaller in the front than in the rear (0.9 mm vs 1.2 mm), but different manufacturers might have different arrangements.[11] Multiple pinholes make it easier to find a hole centered on the pupils than single pinholes. Pinhole spectacles increase the DoF and compensate for defocus, thus enabling patients with presbyopia to read. Although the use of single-pinhole spectacles has been evaluated, they

Table 1. Clinical studies presenting the applications of the pinhole principle and reporting outcomes of 10 or more patients

Study	Design	Results
Pinhole test		
Kanclerz et al., 2022[27]	29 eyes of 19 patients with advanced keratoconus improvement in the pinhole test and with hybrid contact lenses	Results of the pinhole test were strongly correlated with hybrid lens VA (r = 0.81). The pinhole can be considered as a simple predictor of improvement with hybrid contact lenses
Chen et al., 2021[28]	1672 children (age 6.6 ± 0.4 y) UDVA vs CDVA vs pinhole VA	Pinhole does not increase the screening accuracy of detecting decreased CDVA
Kumar et al., 2019[29]	204 eyes of 104 individuals (age 63 ± 7.8 y) Pinhole VA vs CDVA	Improvement on pinhole testing was correlated with the magnitude of spherical equivalent refraction (Spearman ρ = 0.68, P < .001)
Dean et al., 2012[30]	294 people screened for glaucoma with a threshold of VA lower than 6/18 in 1 or both eyes	Only 2 of 294 people were screened by ophthalmologists. About a quarter of patients who were offered surgery refused
Cook et al., 2009[31]	105 eyes screened for glaucoma Pinhole VA vs counting fingers confrontation visual field screening vs frequency doubling technology C-20-1 visual field screening vs air-puff tonometry vs pupil light response vs direct ophthalmoscopy	Testing the pinhole VA with a cutoff point of 6/18 in 1 or both eyes had a sensitivity and specificity greater than 90% and an accuracy greater than 90% for case detection of cataract or glaucoma
Pinhole spectacles		
Park et al., 2019[32]	32 patients with presbyopia (age 52 ± 5 y) wearing and not wearing pinhole spectacles for 1 wk	Pinhole spectacles improve visual acuity and accommodation-related parameters. The low legibility, increased interblink interval, and shortened break-up time of pinhole spectacles resulted in ocular discomfort and fatigue
Kim et al., 2017[33]	36 health participants (age 33 ± 7 y) with mean SE −2.7 ± 2.3 D wearing single- or multiple-pinhole spectacles	Both single and multiple-pinhole spectacles improved VA and DoF. Both types reduced visual field, contrast sensitivity, stereopsis, and reading speed and increased ocular discomfort
Kim et al., 2014[34]	48 eyes of 48 patients (age 36 ± 7 y) with a mean SE −2.4 ± 3.3 D	Wearing pinhole spectacles improved UDVA and UNVA, increased DoF and subjective accommodative amplitude, but also increased pupil size, reduced contrast sensitivity, and reduced stereopsis
Pinhole corneal inlay		
Moshirfar et al., 2018[35]	50 eyes undergoing KAMRA implantation in the nondominant eye (age 52 ± 4)	86% of patients had UNVA of 20/32 or better; 88% UDVA of 20/25 or better at 36 mo. Longitudinal corneal topography revealed a gradual pattern of corneal steepening over the body of the inlay and flattening over the aperture, correlating with a hyperopic shift
Lin et al., 2017[36]	60 patients undergoing KAMRA implantation	No significant change in stereoacuity after implantation
Vilupuru et al., 2015[37]	Results of 78 patients randomized to receive Cystalens, AcrySof IQ ReSTOR +3.0 D, or TECNIS +4D Multifocal vs results of 507 patients receiving a KAMRA inlay	KAMRA inlay patients had improved intermediate and near vision with minimal to no change to distance vision and better contrast sensitivity in the inlay eye, compared with the multifocal IOLs, and better binocular contrast sensitivity than all 3 IOL. The multifocal IOLs were superior in near vision at their respective optimum near focus points, but worse in intermediate vision compared with both KAMRA inlay and Crystalens AO
Tomita et al., 2013[38]	223 patients (mean age 54 ± 5 y) with previous LASIK underwent KAMRA implantation because of presbyopia into the nondominant eye into a pocket underneath the flap	UDVA in the operated eye decreased 1 line from 20/16 preoperatively to 20/20 6 mo postoperatively while the mean UNVA improved 4 lines from J8 to J2
Dexl et al., 2012[39]	24 patients with presbyopia (45-60 y) undergoing KAMRA implantation	Decrease in reading distance, improvement in near VA, with no change in reading speed
Seyeddain et al., 2012[40]	32 patients with emmetropia undergoing flap creation and Acufocus inlay implantation in the nondominant eye because of presbyopia	Mean UNVA improved from J6 preoperatively to J1 at 3 y while mean uncorrected intermediate VA improved from 20/40 to 20/25
Yilmaz et al., 2011[41]	39 patients with emmetropia undergoing flap creation or relift and KAMRA inlay implantation in the nondominant eye	Improvement in UNVA to a mean J1—all patients had an improvement of 2 or more lines
Seyeddain et al., 2010[42]	32 patients with emmetropic presbyopia with AcuFocus Corneal Inlay 7000 (KAMRA) implanted in the nondominant eye	Mean binocular UNVA improved from J6 preoperatively to J1 after 24 mo

(continued on next page)

Table 1. Continued

Study	Design	Results
Yilmaz et al., 2008[43]	39 eyes emmetropic or emmetropic after LASIK (patient age 52 ± 4 y); KAMRA inserted into the nondominant eye	After 1 y, mean UNVA improved from preoperative J6 to J1. All eyes had UNVA of J3 or better and 85% had J1 or better
Pinhole contact lens		
Jun et al., 2020[44]	29 patients with presbyopia wore a pinhole contact lens (Eyelike Pinhole II) in the nondominant eye for 1 wk	Mean monocular and binocular distance-corrected near VA improved significantly with the contact lens wear
Park et al., 2019[45]	20 patients with presbyopia wore a pinhole contact lens (Eyelike Noan Pinhole) in the nondominant eye for 2 wk	With distance correction, near VA, intermediate VA, and visual function questionnaire scores improved with the lens
García-Lázaro et al., 2013[46]	22 patients with emmetropic presbyopia randomized to receive a pinhole or PureVision multifocal (Baush & Lomb) contact lens in 1 eye	Both lenses provided good binocular VA and intermediate vision. Near vision was better with PureVision, but not satisfactory for either lens
García-Lázaro et al., 2012[47]	22 patients with emmetropic presbyopia wore 1.6-mm, 2.5-mm, and 3.5-mm apertures and a 1.6-mm central aperture in a 4.0-mm–diameter opaque zone (clear outside) contact lens in the nondominant eye. Results were compared with the binocular distance correction	All lenses provided functional intermediate vision, but poor near acuity and stereoacuity; they decreased distance binocular contrast sensitivity
Pinhole IOL		
Langer et al., 2021[48]	17 eyes of 17 patients with highly irregular cornea undergoing IC-8 Apthera implantation	The IC-8 Apthera IOL was well-suited for patients with lens exchange in highly irregular corneas
Ang 2020[49]	10 patients undergoing bilateral IC-8 Apthera implantation (target −0.5 to −0.75 D) vs 10 patients undergoing IC-8 Apthera implantation into the nondominant eye, and a monofocal IOL into the dominant eye targeting emmetropia	Contralateral and bilateral IC-8 Apthera IOLs provided good visual acuity across all distances
Shajari et al., 2020[50]	17 eyes of 17 patients with highly irregular cornea undergoing IC-8 Apthera implantation	Corrected distance VA improved from 0.37 ± 0.09 preoperatively to 0.19 ± 0.06 logMAR 3 mo postoperatively. Postoperative UDVA, uncorrected intermediate VA, and UNVA improved significantly in 100%, 88%, and 88% of cases, respectively
Son et al., 2019[16]	13 patients received Lentis LS-313 MF20 IOL in the dominant eye (target plano) and IC-8 Apthera IOL in the nondominant eye (target −0.5 D)	At 5 mo postoperatively, the mean binocular uncorrected distance, intermediate, and near vision were −0.04 ± 0.11 logMAR, 0.00 ± 0.10 logMAR, and 0.11 ± 0.08 logMAR, respectively. This approach caused minimal photic phenomena
Hooshmand et al., 2019[51]	126 patients: In the dominant eye, monofocal IOL with plano target; in the nondominant eye, IC-8 Apthera IOL with −0.75 D target	Over 90% of the patients with no preexisting ocular pathology had UDVA, intermediate VA, and near VA 6/12 or better. By the final follow-up at 29 ± 20 wk, over 50% of patients reported complete spectacle independence
Ang et al., 2018[52]	11 eyes of 10 patients (age 65 ± 6 y) with corneal astigmatism of 0.75 to 2.0 D underwent cataract surgery with unilateral or bilateral IC-8 Apthera implantation	The IC-8 Apthera IOL improved vision in patients with corneal astigmatism. All patients had 20/30 or better postoperatively
Dick et al., 2018[53]	6 patients with bilateral IC-8 Apthera implantation vs 11 patients with IC-8 Apthera implantation in the nondominant eye (target −0.5 to −0.75 D)	Bilateral implantation resulted in better intermediate and near VA, but monocular implantation gave higher overall satisfaction and less halo problems
Dick et al., 2017[54]	105 patients (age 68 ± 8 y) Aspheric monofocal IOL into the dominant eye (emmetropia), and 4 to 6 wk later, IC-8 Apthera IOL (target −0.5 to −0.75 D) in the nondominant eye	99%, 95%, and 79% of patients achieved 20/32 or better binocular UDVA, intermediate VA, and near VA, respectively. 96% were satisfied with the procedure
Trindade et al., 2017[12]	24 eyes of 21 patients (age 67.5 ± 8.4 y) with irregular astigmatism due to keratoconus, post–radial keratotomy, post–penetrating keratoplasty, and traumatic corneal laceration received the Xtrafocus IOL	Median corrected distance VA improved from 20/200 preoperatively (range 20/800 to 20/60) to 20/50 postoperatively (range 20/200 to 20/20)
Grabner et al., 2015[55]	12 patients with monocular implantation of IC-8 Apthera IOL (age 60.5 ± 7.5 y)	100% of eyes maintained 20/40 or better visual acuity over a range of +0.50 D to −1.5 D of added defocus

J = Jaeger; RCT = randomized controlled trial; SE = spherical equivalent

allow even less incident light rays to enter the eye.[33] Theoretically, there should not be any difference for small pupils for any object point, but there may be diplopia once the pupil size becomes larger than the pinhole separation.

The use of pinhole spectacles to increase the DoF in presbyopia has been examined clinically. Kim et al. found the uncorrected distance (UDVA) and uncorrected near VA (UNVA) to improve from logMAR 0.44 ± 0.46 and 0.26

Figure 1. The pinhole occluder typically used in a trial frame set is an opaque disc with a single hole at its center

Figure 2. Single-pinhole (*A*) and multiple-pinhole (*B*) spectacles . Reproduced with permission from Kim et al.[33]

± 0.40 to 0.19 ± 0.25 and 0.14 ± 0.22, respectively.[34] The DoF, evaluated by adding spherical lenses that maintained VA of 20/25 or better at a 4-meter distance chart, increased from 2.6 ± 1.7 to 3.9 ± 1.7 D. However, visual field parameters of test time, visual field index, mean deviation, and pattern standard deviation deteriorated with the pinhole spectacles, as well as the contrast sensitivities at 3 cycles per degree (cpd), 6 cpd, 12 cpd, and 18 pd.[34,68] Stereopsis deteriorated after wearing the pinhole spectacles, and the pupil size increased markedly to a mesopic size (from 3.6 ± 0.5to 6.2 ± 0.6 mm). For this reason, visual quality is decreased in patients using pinhole spectacles under dim illumination, and particular attention is needed when wearing them in these conditions. In another study on healthy participants with and without refractive errors, single-pinhole spectacles reduced visual field sensitivities: The mean deviations of the visual field for the single-pinhole and multiple-pinhole spectacles were −21.72 ± 3.21 dB and −5.60 ± 2.40 dB, respectively, which were significantly lower than the baseline of +0.36 ± 1.24 dB.[33] The pupil size was greater with single-pinhole than with multiple-pinhole spectacles (5.9 ± 0.4 mm and 5.3 ± 0.5 mm, respectively). The reading speed was lower with single-pinhole than with multiple-pinhole spectacles, with no benefit on distance and near VA. Park et al. analyzed the use of multiple-pinhole spectacles in 32 patients with presbyopia (age 52 ± 5 years) for 1 week.[32] The pinhole spectacles increased subjective monocular accommodation from 4.4 ± 0.8 to 5.2 ± 1.1 D, increased the DoF from 1.4 ± 0.4 to 2.0 ± 0.3 D, and increased the amplitude to fusional convergence from 13 ± 7 to 22 ± 10 prism diopters. However, reading speed decreased, interblink interval increased, tear break-up time shortened, and subjective ophthalmic symptoms worsened. While using pinhole spectacles, individuals are unable to scan an entire sentence because of their limited field of view, but can read only a few words at a time. To comprehend the contents of a book, they must read each word successively without blinking. As a consequence of continuous staring, tear break-up time is shortened.[32]

Pinhole spectacles have been marketed by several companies with claims that they permanently cure a wide range of vision deficiencies and refractive errors.[69] They have also been advertised as helping to “relax the eye muscles,” “exercise the eye,” and “decrease eye strain.” Wearing pinhole spectacles creates a cosmetic issue.[6] Owing to a lack of any evidence, this type of claim is no longer allowed to be made in the United States under the terms of a legal settlement with the Federal Trade Commission.[69] Potential benefits were obvious as the retail price of such a piece of plastic with multiple pinholes ranged from $19.95 to $49.95.[69] In conclusion, pinhole spectacles might be marketed to the ignorant as a cheap way of obtaining clear vision without purchasing proper spectacles.[70]

Pinhole Corneal Inlays

Keratophakia was developed approximately 50 years ago to alter the power of the cornea by inserting an artificial lens or a lens-shaped piece of donated cornea between its layers.[71,72] However, the first report of implanting a pinhole corneal inlay dates back only to 1995.[73] In this case, a small-diameter hefilcon A hydrogen corneal inlay with a 2-mm–diameter aperture and a 30 to 60-μm thickness was implanted. Four of 5 patients with presbyopia had an improvement in UNVA from J5-J6 to J1-J2. However, 2 patients had a loss of 2 lines of distance VA and required explantation of the inlay.

Current pinhole corneal inlays are small rings made of polyvinylidene fluoride, which has high biocompatibility.[74,75] The KAMRA inlay (Acufocus, Inc.) is incorporated with carbon to make it opaque and has a diameter of 3.8 mm and a

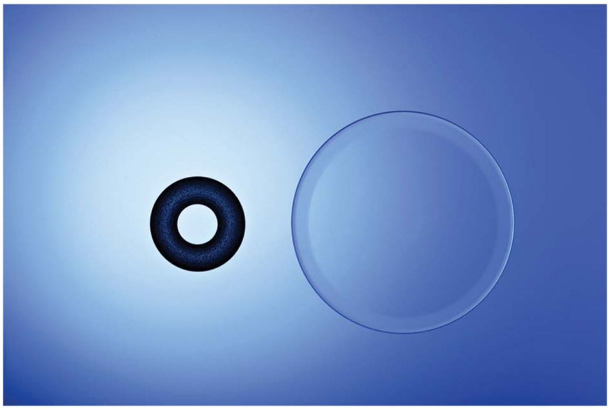

Figure 3. A KAMRA inlay alongside a 14-mm–diameter soft contact lens. Reproduced with permission from Naroo and Bilkhu.[77]

1.6-mm central aperture with a 1600 random-hole pattern to facilitate nutrient flow within the cornea and is formed into a 7.5-mm spherical radius to adjust to the mean radius of curvature of the anterior cornea (Figure 3).[76] The outer diameter of 3.8 mm, which is much smaller than the size typically created during laser in situ keratomileusis (LASIK), allows maintenance of the peripheral field of vision. The inlay does not require power calculation and does not affect CDVA. The first version of the inlay, the ACI 7000 (Acufocus, Inc.), was 10-μm thick while the currently used KAMRA pinhole inlay is 5-μm thick.[40,77] The inlay is inserted after creation of a corneal flap with a mechanical microkeratome or femtosecond laser into the nondominant eye.[78] The inlay is positioned based on the presurgical position of the first Purkinje reflex. The procedure can be performed during LASIK in patients with ametropia, but has been reported in patients with emmetropia.[41,43] It can be used for patients with a crystalline lens or after cataract surgery.[76] In patients having undergone LASIK and presenting with presbyopia, it is possible to create a pocket 80 μm below the previous flap with a femtosecond laser to implant the inlay.[38] Early studies reported good UNVA outcomes in patients having undergone radial keratotomy or after phakic IOL surgery.[79] The procedure does not induce permanent changes in corneal hysteresis or corneal resistance factor.[80]

In one clinical study, the near VA in patients with presbyopia improved from a mean J6 to a mean J1.[43] Yilmaz et al. found the mean UNVA was 20/20 after KAMRA implantation, and 96% of patients could read J3 or better; after 52 ± 3 months, 4 of 39 inlays were removed (because of the inlay creating a buttonhole, a thin overlying flap, or dysphotopsia).[41] Vilupuru et al. compared outcomes of KAMRA implantation and multifocal or accommodating IOL implantation.[37] Patients receiving the KAMRA inlay had better contrast sensitivity than patients receiving multifocal IOLs (Crystalens, AcrySof IQ ReSTOR +3.0 D, or TECNIS +4D Multifocal), but multifocal IOLs were superior to the KAMRA inlay regarding near VA. The KAMRA inlay in the nondominant eye does not worsen stereoacuity, in contrast with monovision induced by a contact lens or LASIK.[36,37,81–83] Overall satisfaction was reported high at 89%.[82] Improvement in intermediate and near vision was much better in bright light than in dim light.[84] Dexl et al. found KAMRA implantation to decrease reading distance, to improve binocular reading acuity, but did not increase reading speed.[39]

In a follow-up of 36 months, the inlay causes the anterior cornea to steepen over the inlay, but flatten over the aperture; this hyperopic shift in refraction should be taken into account when planning the refractive outcome or in subsequent procedures such as cataract extraction.[35,85] In a case series by Amigó et al., 4 of 5 cases manifested a hyperopic shift while 1 case manifested a myopic shift more than 6 to 19 months postoperatively.[86] Decentration of the inlay may increase transverse chromatic aberration and lead to monocular diplopia, blur, and lateral spread of light rays.[87,88] Importantly, the inlay can be removed or repositioned without affecting corneal topography or aberrometry; such a procedure may be required because of night glare, photophobia, starburst, blurry vision, and halos.[89–91] Complications include depigmentation of the inlay (AcuFocus ACU-10R160), development of interface haze or corneal fibrosis, infectious keratitis, and damage of the inlay after cosmetic eyelid laser treatment.[92–96] Complications of LASIK such as epithelial ingrowth occur also with KAMRA implantation.[78]

Corneal inlays such as the KAMRA device were welcomed optimistically.[97] However, subsequent longitudinal investigations demonstrated a decline in postoperative VA and increased risk of complications such as corneal haze.[98] The pathway underlying corneal haze formation remains unclear; microscopic examinations have found thin, acellular fibrous membranes overlaying the pores of the corneal inlay.[99] Moreover, chronic inflammatory cells were found on the surface of the inlays.[100] In future, targeted therapeutics might reduce the risk of corneal haze. However, the frequency of repeated surgical interventions and long-term complications has stalled the use of synthetic corneal inlays in the U.S.[97] Human allograft materials may reduce foreign-body response, but a pinhole allograft corneal inlay is not available yet.

Pinhole Contact Lenses

After the development of pinhole corneal inlays, the concept of treating presbyopia with a pinhole contact lens emerged (Figure 4). García-Lázaro et al. analyzed 4 custom-made 14-mm–diameter pinhole contact lens designs: 3.5-mm, 2.5-mm, and 1.6-mm apertures in an 8-mm opaque zone and a 1.6-mm aperture in a 4.0-mm opaque zone.[47] After fitting the pinhole contact lens on the nondominant eye, the mean binocular UDVA and CDVA were poorer than in patients without a pinhole contact lens, near VA was not affected, and there was significant improvement in intermediate VA.[47] There was no difference at any distance between different aperture sizes. In another study by García-Lázaro et al., the distance VA with a 1.6-mm aperture in an 8.0-mm diameter opaque contact lens was slightly worse than with a PureVision Multifocal IOL (Bausch & Lomb, Inc.), but the near vision was not

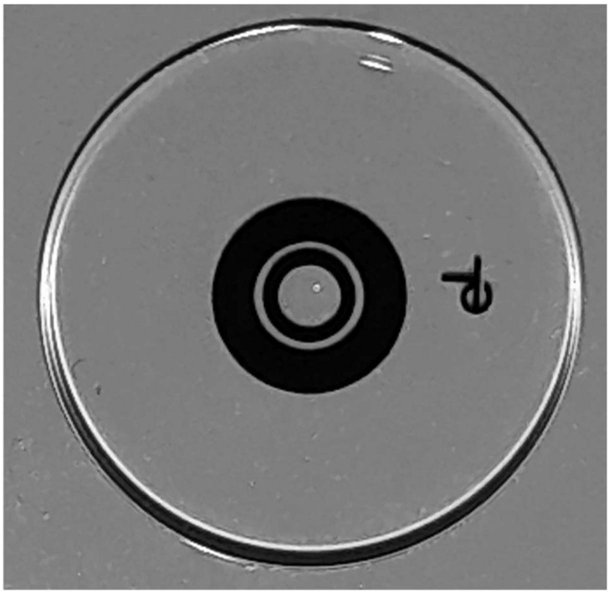

Figure 4. Pinhole contact lens. Photograph of the Eyelike PINHOLE II (Koryo Eyetech), a recently developed soft contact lens for presbyopia correction. Reproduced with permission from Jun et al.[44]

satisfactory with either lens (logMAR 0.4 ± 0.2 and 0.3 ± 0.1, respectively).[46] In 2019, Park et al. used the first commercially available pinhole soft contact lens (Eyelike Noan-Pinhole, Koryo Eyetech) with a 1.66-mm aperture and a 4.98-mm–wide opaque zone.[45] The lens is manufactured from 2-hydroxyethyl methacrylate (92.2%) with 2 diameters (14.0 mm and 14.5 mm) and 2 base curves (8.60 mm and 8.90 mm). After 2 weeks of wearing these contact lenses in the nondominant eye, for presbyopes, the VA at 33 cm, 40 cm, 50 cm, and 70 cm improved significantly from logMAR 0.43 ± 0.19 to 0.18 ± 0.18, 0.38 ± 0.17 to 0.11 ± 0.09, 0.29 ± 0.13 to 0.12 ± 0.09, and 0.25 ± 0.16 to 0.14 ± 0.11, respectively.[45] Moreover, visual function questionnaire scores improved significantly. With distance correction, Jun et al. found the distance VA of the treated eye deteriorated (from logMAR −0.04 ± 0.05 to 0.02 ± 0.11) while the mean monocular near VA and mean binocular near VA improved from 0.34 ± 0.12 to 0.15 ± 0.14 and 0.31 ± 0.13 to 0.11 ± 0.10 logMAR, respectively, after pinhole contact lens wear.[44]

The use of pinhole contact lenses has been questioned because of potential problems with the centration of the lens. Unlike corneal inlays, a pinhole contact lens may move on the eye upon blinking or eye movements.[101,102] Another potential problem with soft contact lenses is an excursion lag with eye movement and lens uplift with blink, which can be greater than 0.5 mm depending on a range of factors including lens material and design, blink time, corneal morphology, and post–lens tear film.[103]

Pinhole IOLs

Capsular Bag IOLs Pinhole IOLs show similar through-focus curves as small-aperture corneal inlays.[104] The former can be used in patients with keratoconus for whom corneal inlays are not recommended.[105] The IC-8 Apthera is a small-aperture single-piece hydrophobic IOL with an annular mask embedded in the IOL material (Figure 5, A). The IOL has attained the Conformite Europeenne (CE) mark and is available in Australia, Europe, and Asia, and in 2022, it received Food and Drug Administration approval in the U.S. It has a biconvex aspheric 6.0-mm–diameter optic and 360-degree square posterior edge and is available in power from +10 to +30 D in 0.5-D steps. The small-aperture IOL is intended for implantation in the capsular bag and has modified C haptics and an overall diameter of 12.5 mm. As centration is critical for this IOL, the lens should not be implanted if appropriate intraocular support of the lens is not possible. The embedded annular mask is made of polyvinylidene difluoride, has an outer diameter of 3.23 mm and a central aperture of 1.36 mm in diameter, and contains 3200 microperforations arranged in a pseudorandom fashion to aid in folding of the IOL. Usually, a monofocal IOL targeting plano refraction is implanted into the dominant eye while the IC-8 Apthera IOL is implanted into the nondominant eye targeting −0.5 to −0.75 D. However, combined approaches have also been described; that is, Son et al. reported excellent distance intermediate and near VA with minimal photic phenomena after implantation of a multifocal refractive IOL (Lentis Mplus LS-

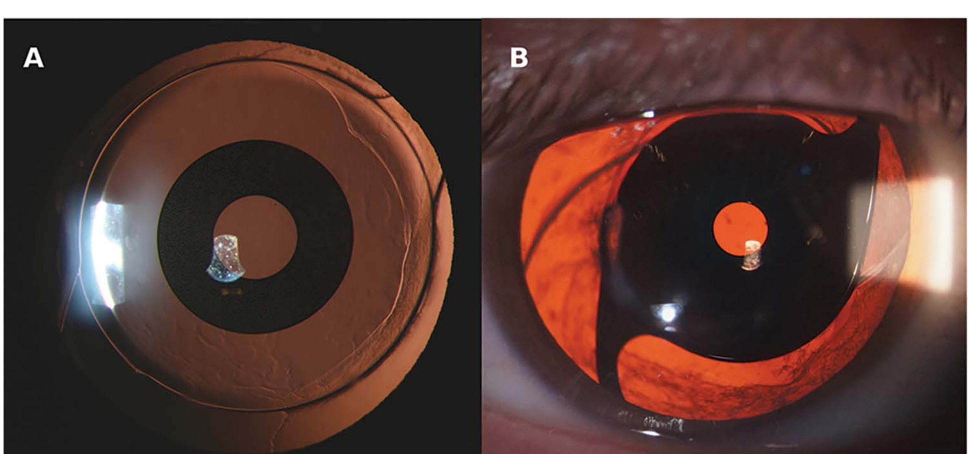

Figure 5. *A*: Acufocus IC-8 Apthera IOL. *B*: Slitlamp photograph of the perfect position with slight nasal decentration of the Xtrafocus supplementary implant. Courtesy of Dr. Claudio Trinidade.

313) into the dominant eye and an IC-8 Apthera IOL into the nondominant eye.[16] Ang reported excellent satisfaction after bilateral IC-8 Apthera implantation; the first eye received targeted −0.5 to −0.75 D while the second was plano.[49] In another study, patients receiving bilateral IC-8 Apthera implantation had better intermediate and near VA than those receiving IC-8 Apthera implantation into the nondominant eye, but monocular implantation resulted in higher overall satisfaction scores and lower halo scores.[53]

Implantation of the IC-8 Apthera IOL is well-suited for patients with lens exchange for highly irregular corneas, for example, with keratoconus, with corneal scars, and after keratoplasty and radial keratotomy.[48,50,106] Not only does this approach improve UDVA, intermediate VA, and near VA but it also has a high safety index and satisfaction rate.[50] Patients having undergone corneal refractive surgery might benefit from implantation of the IC-8 Apthera IOL into the nondominant eye if there are difficulties in IOL power calculation and for high postoperative corneal aberrations.[107] Patients with aniridia may benefit from IC-8 Apthera implantation in addressing iris tissue defects and related symptoms, particularly in combination with the partial aniridia ring (Type 96G, Morcher GmbH).[108] Implantation of the IC-8 Apthera IOL after previous unilateral Intracor (intracorneal ring placement for presbyopia) treatment may improve VA at far and intermediate distances.[109]

Iris-Claw IOL The pinhole diaphragm IOL (Ophtec BV) is an iris-claw–haptic, rigid, 1-piece black polycarbonate IOL with an 8.5-mm overall length including the haptics, the optic having a diameter of 3.0 to 4.0 mm, with a central hole of 2.0 to 4.0 mm. The IOL is custom-made based on the surgeon's preference and has no optical power; however, it does not have a CE mark.[110] A single case reported successful treatment of subjective complaints associated with corneal irregularities in keratoconus after several surgical interventions.

Supplementary IOL The Xtrafocus pinhole intraocular implant (Morcher GmbH) is made of foldable hydrophobic acrylic and can be implanted through a 2.2-mm corneal incision (Figure 5, B). The initial version of the device had a closed-loop design with 3 haptics, but was replaced by a 2-haptic open-loop design to allow easier implantation. The implant received a CE mark in July 2016 and has been released to the European market. The device has a 6.0-mm black opaque diaphragm with a central 1.3-mm opening. It is implanted into the ciliary sulcus and has a 14-degree angulation to prevent injury to the uveal tissue. Trindade et al. treated pseudophakic eyes of patients with high levels of aberration due to keratoconus, post–radial keratotomy, post–penetrating keratoplasty, and traumatic corneal laceration.[12,37] The median CDVA improved from 20/200 preoperatively (range 20/800 to 20/60) to 20/50 postoperatively (range 20/200 to 20/20). Manifest refraction was unaffected while a subjective visual performance questionnaire revealed improvement at all tested distances. No major complication occurred.[12,37] Another indication for the Xtrafocus implantation includes pupillary defect after trauma.[111,112] As with other pinhole device inlays/IOLs, the device eliminates fluctuation in residual refraction after radial keratotomy and increased the DoF in a patient with pseudophakia.[113] Capsular bag placement might provide better centration of the IOL than sulcus placement, but no cases of decentration of the Xtrafocus implant have been reported.

Pharmacological Pupil Constriction

Pilocarpine is a miotic agent whose action is based both on partial or full agonism of the muscarinic M3 receptor. It has been used to increase DoF in different concentrations, different forms, and also as a combination with other drugs.[114] It can induce ciliary muscle contraction, which increases accommodation. Vuity (pilocarpine hydrochloride ophthalmic solution) 1.25% is a prescription eyedrop used to treat age-related blurry near vision (presbyopia) in adults.[114] Therefore, miotics have also been used to treat residual ametropia after cataract surgery or in patients with considerable higher-order aberrations.[115,116] As the utility of miotic eyedrops has been covered in several other review articles, this issue has not been discussed here in depth.[117,118]

Pinhole Pupilloplasty

A more invasive option described by Narang et al. is pinhole pupilloplasty.[119] In this technique, a 10-0 needle is passed through the paracentesis and iris tissue near the pupillary margin and is then introduced into a 26-gauge needle on the opposite quadrant through the distal iris leaflet. A modified Siepser slipknot, the 4-throw technique, is used to maintain a self-locking self-retaining knot.[120] The procedure might be repeated in other quadrants to achieve a pupil of desired configuration and to decrease the pinhole size. The pupil at the conclusion of the surgery should be of approximately 1.5-mm diameter and centered on the Purkinje 1 images formed from the light source of the surgical microscope.[121,122] The procedure has successfully reduced higher-order aberrations in keratoconus after keratoplasty or after radial keratotomy.[123,124] Problems with this technique are the pupil size being too small or too large and decentration relative to the patient's visual axis.[125]

Other Applications of the Pinhole Effect

One use of the pinhole effect is in interferometers and similar instruments in which 2 spots of light are imaged at the pupil and then interfere to create interference fringes on the retina. One instrument was the Lotmar interferometer (or Haag-Streit Visometer) for the use in Haag-Streit–type slitlamps, another was the Rodenstock retinometer (Rodenstock GmbH) which again was a slitlamp attachment, and a current hand-held device is the Lambda 100 retinometer (Heine Optotechnik GmbH).[126] Using a coherent source of light, 2 beams are directed through an area of the lens where the opacity is the least dense and interference fringes are formed on the retina.[127] The fringes can be oriented in different meridians, and the spatial frequency corresponding to the VA can be varied.[128] By this means, the VA after cataract surgery can be predicted.

The pinhole principle was used in a slightly different form as the Potential Acuity Meter, in which a Snellen VA chart was projected through a small 0.15-mm aperture and mounted on a slitlamp.[129] The device was able to correctly predict the VA after cataract surgery in 95% of cases, by avoiding blockage or scattering of light that would occur because of cataract. As for the interferometers described above, the light is focused at the pupil (Maxwellian view).[130] The entrance point is altered to find somewhere at which the lens is reasonably clear to predict VA after cataract surgery. A conventional pinhole can be used similarly by asking the patients to move their head to get the best clarity. All the aforementioned applications were much commonly used in the past when cataract surgery was delayed a lot longer than occurs now.

Finally, the Scheiner disc effect is that in which light entering into the eye is restricted to 2 small regions on opposite sides of the pupil. This is used to determine refraction in a considerable variety of refraction instruments. This can be extended to Hartmann-Shack aberrometers and laser ray-tracing instruments that are effectively multiple-pinhole devices, the former for light leaving the eye and the second for light entering the eye.

DISADVANTAGES

Contact lenses, corneal inlays, and IOLs using the pinhole principle are available commercially.[3,21,131] However, pinhole occluders reduce the light reaching the retina, cause blur due to diffraction, and limit the visual field.[15,132] In cases of a physiologically large pupil, the benefits of small-aperture implants may be less prominent.[104]

Another potential problem associated with the use of pinhole corneal inlays and IOLs is imaging of the eye fundus through the pinhole. With the KAMRA inlay, it has been reported that it is possible to perform color fundus imaging, ultra-widefield fundus imaging (Optos 200Tx, Optos plc), spectral-domain optical coherence tomography, and photocoagulation of retinal breaks, but visualization of the details behind the inlay was hindered.[133,134] There are reports of performing vitrectomy through KAMRA inlays.[135–137] As it might be difficult to visualize the fundus through a surgical contact lens, several manual rotations of the eye with surgical tools during vitrectomy are required, and a wide-angle viewing system for vitrectomy having a larger distance from the cornea has been recommended.[135–137] With the Morcher Xtrafocus implant, it was not possible to conduct binocular indirect ophthalmoscopy with a 20 D lens, but it was possible with a small panretinal lens, similarly as ultra-widefield scanning laser ophthalmoscopy is feasible.[12] A potential problem might be the accentuation of a previous floater brought about by Xtrafocus. Vitrectomy with Xtrafocus has not been reported, but because of floater accentuation, the device was explanted in a single report.[138] For the IC-8 Apthera IOL, it is possible to perform nonmydriatic fundus photography and a 24-2 automated threshold visual field examination.[139] The XtraFocus IOL is transparent to infrared light; using infrared equipment such as an optical coherence tomography, scanning laser ophthalmoscopy, or an infrared slitlamp, it is possible to visualize structures behind the IOL. The IC-8 Apthera IOL is not transparent to infrared light. Although difficult, it is also possible to perform indirect ophthalmoscopy with these devices implanted. A single study found that after IC-8 Apthera implantation, it is possible to perform vitrectomy for floaters with a widefield fundus visualization system (Resight, Carl Zeiss Meditec AG).[139]

If a neutral-density filter (a filter that reduces or modifies the intensity of all wavelengths) is placed in front of 1 eye, interocular differences in retinal illuminance result in distortion in spatial perception.[140,141] A lateral motion of an object in the field of view is interpreted by the brain as having a depth component, known as the Pulfrich effect, due to a delayed timing in the eye with the filter.[140] The effect increases as the pinhole size decreases.[12,140] Although ray-tracing techniques have shown that different stop designs and positions of placing the pinhole in relation to the corneal and lens may produce similar axial imagery, off-axis, the vignetting effects associated with the distance between the stop and the iris aperture result in different magnitudes.[142] In most cases, this effect might be noticeable, but is not troublesome.

CONCLUSION

The pinhole effect is commonly used to discriminate uncorrected refractive error from ocular diseases, particularly in low-resource settings. The pinhole effect has been successfully applied in contact lenses, corneal inlays, and IOLs. Disadvantages of using the pinhole effect include high susceptibility to decentration, decrease in retinal luminance levels, and difficulties in performing fundus examinations or surgery in eyes with implanted devices. There are also concerns regarding perceptive issues when coping with different retinal illuminances in the 2 eyes, for example, the Pulfrich effect. As the number of presbyopes worldwide is increasing, the use of the pinhole effect will increase.

WHAT WAS KNOWN

- The pinhole effect is used to discriminate uncorrected refractive error from ocular diseases.
- The pinhole effect is also used in spectacles, contact lenses, corneal inlays, and IOLs to compensate for the loss of accommodative function.

WHAT THIS PAPER ADDS

- Disadvantages include high susceptibility to decentration, decrease in retinal luminance levels, and difficulties in fundus viewing.
- There are also concerns regarding perceptive issues with different retinal illuminances in the 2 eyes.

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