Efficacy and Safety of Hole Implantable Collamer Lens in Comparison with Original Implantable Collamer Lens in Patients with Moderate to High Myopia

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Background: *Laser in situ Keratomileusis (LASIK) is the most commonly performed and widely accepted corneal refractive procedure. The Visian Implantable Collamer lens (ICL, STAAR Surgical), a posterior chamber phakic intraocular lens, has been reported to be very effective in correction of moderate to high myopia in patients who are unable to proceed with LASIK surgery due either high correction or thin cornea. A modified implantable collamer lens (ICL) with a central hole (diameter 0.36 mm), "Hole ICL", was created to improve aqueous humor circulation: not only does it make the ICL implantation feasible without prior Laser peripheral iridotomy, but it also helps to reduce the incidence of cataract formation after ICL implantation because of its resultant improvement in aqueous humor circulation behind the ICL.*
Objective: *To evaluate the efficacy and safety of the new "Hole ICL" in comparison with conventional ICL 3 months after implantation.*
Material and Method: *This study was a non-inferiority trial in which both ICL models, the conventional ICL (Group A) and the new Hole ICL (Group B), were studied. Patients were divided into 2 groups, each containing 60 eyes: the conventional ICL group, requiring laser peripheral iridotomy, and the new Hole ICL group. The uncorrected distance visual acuity (UDVA) log MAR and the intraocular pressure (IOP) were recorded preoperatively, and then 1 day, 1 week, 1 month and 3 months postoperatively. Spherical aberration was measured preoperatively and 3 months postoperatively.*
Results: *The mean age in the conventional ICL group was 29.75±6.17 years (range 21-45 years), and 28.75±5.27 years (range 21-39 years) in the Hole ICL group. There was no pupillary block in either group. The UCVA log MAR in both groups showed statistically significant improvement 3 months postoperatively compared with preoperative log MAR, but there was no statistically significant difference between the log MARs of the two groups 3 months postoperatively. There was no significant change in preoperative IOP and IOP 1 day, 1 week, 1 month and 3 months postoperatively in either group, there was no difference between postoperative IOP in the two groups, and there was also no statistical significance between the spherical aberration changes in the 2 groups 3 months postoperatively.*
Conclusion: *The two groups had similar clinical effectiveness in terms of unaided visual acuity, best corrected visual acuity, intraocular pressure and spherical aberration induction. The new Hole-ICL group (Group B) needed no preoperative laser peripheral iridotomies or intraoperative iridectomy.*

Keywords: *Phakic intraocular lens, Implantable collamer lens, Hole implantable collamer lens*

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Since its introduction in the 1990s[1,2], laser in situ keratomileusis (LASIK) has become the most commonly performed and widely accepted corneal refractive procedure. Some patients with moderate to high myopia or thin corneas are faced with some restrictions in its use because of the possible risk of developing keratectasia; moreover, a large amount of laser ablation may lead to deterioration in superior intrinsic corneal optical performance. The Visian Implantable Collamer Lens (ICL, STAAR Surgical) has been reported to be effective in the correction of moderate to high myopia[3-12]. This surgical procedure may have advantages over laser in situ keratomileusis (LASIK) because it is not only highly predictable but also largely reversible. Recently, toric ICLs have also been shown to be effective in the correction of high

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myopic astigmatism[13,14]. Because LASIK requires more laser ablation in highly myopic eyes, resulting in more surgically induced higher-order aberrations (HOAs), especially spherical aberration[15-17], ICL implantation has been demonstrated to be better in terms of lower risk of ectasia, dry eye and HOA induction, which can compromise the contrast sensitivity (CS) function. ICL implantation is also considered to induce fewer HOAs than wave front-guided (WFG) LASIK[14]; however, in order to prevent the occurrence of pupillary block, this surgical technique requires costly preoperative laser peripheral iridotomy, which frequently involves some pain and can sometimes be accompanied by intraocular hemorrhage if done intraoperatively. Moreover, there is also a possible risk of cataract formation, presumably resulting from direct contact between the ICL and the crystalline lens, or from malnutrition attributable to poor circulation of the aqueous humor behind the ICL. The new ICL with central artificial hole (Hole ICL) was developed in order to rectify such disadvantages[18-20]. The modulation transfer function (MTF) of an ICL at 1.0 mm central hole in the optic region was found to be similar to that of an unperforated ICL in a previous study; furthermore, the in vitro optical performance of an ICL with 0.36-mm central hole at various IOL powers fulfills the International Organization for Standardization (ISO) criteria for modulation transfer function[18]. Another study demonstrated that Hole ICL implantation was good in all measures of safety, efficacy, predictability, and stability[21]. Nevertheless, the differences in intraocular pressure (IOP) after surgery and higher-order aberrations (HOAs), especially spherical aberration, between the unperforated ICL and the Hole ICL, have not been elucidated so far. The objectives of the current studywere to compare levels of: 1) efficacy in the prevention of IOP elevation; 2) visual performance; and 3) HOAs, especially spherical aberration, after conventional ICL implantation with those of Hole ICL implantation which has the benefit of not requiring preoperative peripheral iridotomy or intraoperative iridectomy.

Material and Method

This study was approved by the ethics committee of Rajvithi Hospital (No. 209/2558). This non-inferiority trial examined 120 eyes of 64 patients who underwent posterior chamber phakic ICL with 0.36-mm central artificial hole (Hole ICL) and conventional ICL, STAAR Surgical) for the correction of moderate (-6.0 to -9.5) to high (-10.0 and over) myopia in patients who were unable to proceed with laser vision correction. Patients were required to be in the 20-45 years age range, with no pathologic ocular diseases, and with endothelium cell count of over 2,000/mm^2. Using an envelope technique, eligible patients were randomly allocated, using RAND function in Microsoft Excel, to receive conventional ICL implantation as the control group (60 eyes), called Group A, and Hole ICL implantation as the study group (60 eyes), called Group B. The patients were masked to the types of ICLs implanted in their eyes. Eyes with keratoconus were excluded from the study using the keratoconus screening of Galileii (Zimmer).

Calculation of ICL power and size was performed by the manufacturer (STARR Surgical) using a modified vertex formula in both types of ICL. The size of the ICL was also chosen by the manufacturer on the basis of the horizontal corneal diameter and anterior chamber depth measured with caliper, IOL Master (Carl Zeiss) and Galileii (Zimmer).

With regard to surgical procedures, in the conventional ICL implantation group (Group A), the patients underwent 2 positions of preoperative peripheral iridotomies with a neodymium-Yttrium-aluminum-garnet laser. In the Hole ICL implantation group (Group B), the patients did not undergo preoperative laser peripheral iridotomies or intraoperative iridectomy. All surgery was performed by the same surgeon (PN) in Rajavithi Hospital using sutureless clear cornea incision. The surgeon was equally experienced with both types of ICL because they have similar platform structures. On the day of surgery, the patients were given dilating and antibiotic agents. After topical anesthesia of 0.5% tetracaine hydrochloride (Alcon Laboratories, Inc), a model V4 ICL (Hole ICL or conventional ICL) (STAAR Surgical) was implanted through a 3-mm temporal clear corneal incision with the use of injector cartridge (STAAR Surgical) after placement of viscoelastic device (Provisc, Alcon Laboratories, Inc) into the anterior chamber. The ICL was placed in the posterior chamber behind the iris plane, positioning the toric marker in the case of toric model, and the viscosurgical device was completely removed by washing out the anterior chamber with balanced salt solution. All surgeries were uneventful, and no intraoperative complication was observed. A combination of antibiotic and steroidal medications (Tobradex, Alcon Laboratories Inc) was administered topically 4 times a day after surgery for 2 weeks.

All patients underwent full preoperative

ophthalmologic examination including uncorrected distance (UDVA) and corrected (CDVA) distance visual acuities (Log MAR charts), refractive status, slit-lamp evaluation, tonometry and fundoscopy. We assessed wave front aberration preoperatively and 3 months after surgery, and intraocular pressure (IOP) was measured before and 1 day, 1 week, 1 month and 3 months after surgery. Ocular HOAs, especially spherical aberration (Z4-0), for 5-mm pupil were measured by Hartmann-Shack aberrometry (LADAR aberrometer, Alcon Laboratories, Inc) which converts the data points into wave front values using Zernike terms up to the 4th order. The root mean square of the fourth-order coefficient was taken to represent spherical-like aberrations. The value of the device in the assessment of ICL patients in both groups has been reported. Pupillary block was monitored with slit-lamp examination during the study period, and IOP was also measured by non-contact tonometry (NT-530P, Nidek). Patients' intraocular pressure(IOP)were evaluated postoperatively at 1 day, 1week, 1 month and 3 months at Rajavithi Hospital. All examinations were performed by 2 experienced ophthalmologists (PP and SC) who were masked to the treatment. Data analysis was performed by one of the authors (SC) once data collection was completed. The author was not involved in the care of the trial patients at any point during the period of analysis and did not know which of the groups was Hole or conventional ICL. At 3 months follow-up, UDVA, CDVA, monitoring of pupillary block, intraocular pressure (IOP) and manifest refraction followed by aberrometry with pupil dilation using LADAR Wave wave front sensing aberrometer (Alcon Laboratories, Inc) were recorded in both groups.

Three months after surgery, postoperative outcomes were evaluated, including analysis of UDVA and the difference between the expected and the obtained outcomes in spherical equivalent (SE), and also the difference between the expected and the obtained optical quality. The UDVA and CDVA were expressed in Log MAR notation. Also at three months follow-up, intraocular pressure (IOP) and pupillary block were monitored. Any patients who did not complete the follow-up examination after three months were also excluded.

The objective optical quality of all surgical eyes was evaluated analyzing (5.0-mm pupil diameters) the root mean square (RMS) of spherical aberration Z (4,0). Spherical aberration changes between preoperative and postoperative state were recorded for both groups.

Statistical analysis was performed using SPSS for Window Software (version 17.0, SPSS, Inc). The sample size calculation was taken from n4 studies' program for a non-inferiority trial with continuous outcome. In a previous study,the standard deviation and mean difference of log MAR UDVA between 2 groups were 0.22 and 0.2 respectively[21]. Non-inferiority margin = 0.1. Ratio between 2 groups = 1.00. Alpha = 0.05. Beta (β) = 0.20. The sample size was 60 eyes in each group.

Normality of all data samples was evaluated using the Kolmogorov-Smirnov test. Paired t-test was performed for comparisons of preoperative and postoperative examinations and expected versus obtained data. The Student t-test or Mann-Whitney test were used to compare the continuous variables between groups. For all statistical tests, the same level of significance was used ($p<0.05$).

Results

There were 60 eyes in the Conventional ICL group and the same number in the Hole ICL group. The patient age at the time of surgery was 29.75±6.17 years (range 21 to 45 years) in the conventional ICL group, and 28.75±5.27 years (range 21 to 39 years) in the Hole ICL group. The preoperative manifest spherical equivalent was -9.17±2.58 D (range -16.4 to -5.3 D) in the conventional ICL group and -9.50±3.21 D (range -18.9 to -3.6 D) in the Hole ICL group. Preoperative Uncorrected Distance Visual (UDVA) acuity was logMAR 2.0±0.0 in the conventional ICL and 1.98±0.12 in the Hole ICL group. The preoperative demographics of the study population are summarized in Table 1. There were no significant differences between the 2 groups in terms of Manifest sphere (p = 0.534), Manifest axis (p = 0.460), Manifest spherical equivalent (p = 0.274), Spherical aberration (p = 0.541), logarithm of the minimal angle of resolution (log MAR uncorrected distance visual acuity [UDVA]) (p = 0.343), or log MAR best spectacle-corrected distance visual acuity (CDVA) (p = 0.303). Manifest cylinder and intraocular pressure (IOP) were statistically significantly different p-value = 0.024 and 0.015 respectively, but there was no clinically significant difference.

All surgeries were done by PN and were uneventful, and no cataract formation, pigment dispersion glaucoma, significant intraocular pressure rise (including pupillary block), or any other vision-threatening complications were observed at any time during the observation period. Neither contact nor high vaulting in excess of 1.25 mm between the ICL and the

Table 1. Demographic characteristics of subjects with corresponding 2-tail *p*-values to compare between-groups parameters

	Implantable collamer lenses	Hole implantable collamer lenses	*p*-value
	n = 32 cases	n = 32 cases	
Age (years)	29.75±6.17 (21 to 45)	28.75±5.27 (21 to 39)	0.488
Gender (% female)	24 (75.0%)	22 (68.8%)	0.578
	n = 60 eyes	n = 60 eyes	
Manifest sphere (D)	-9.17±2.58 (-15.8 to -3.3)	-8.84±3.23 (-18.5 to -3.3)	0.534
Manifest cylinder (D)	-1.79±1.16 (-4.5 to 0.0)	-1.32±1.07 (-5.0 to 0.0)	0.024*
Manifest axis (°)	104.55±75.38 (0.0 to 180.0)	114.40±75.41 (0.0 to 180.0)	0.460
Manifest spherical equivalent (D)	-10.06±2.38 (-16.4 to -5.3)	-9.50±3.21 (-18.9 to -3.6)	0.274
Intraocular pressure (mmHg)	14.94±2.62, (7.8 to 21.7)	13.83±2.30 (8.7 to 18.0)	0.015*
Spherical aberration (mm)	-0.17±0.32, (-0.8 to 1.5)	-0.21±0.33 (-0.8 to 0.9)	0.541
LogMARUDVA	2.00±0.00, (2.0 to 2.0)	1.98±0.12 (2.0 to 1.1)	0.343
LogMARCDVA	-0.03±0.10, (-0.2 to 0.3)	-0.05±0.08 (-0.2 to 0.2)	0.303

Values are presented as n (%), mean ± SD, (minimum to maximum), *p*-value from student t-test. * Significant at $p<0.05$. UDVA = uncorrected distance visual acuity, CDVA = corrected distance visual acuity

crystalline lens was observed through the study period.

There were significant differences between preoperative and postoperative uncorrected distance visual acuity (UDVA) in both groups ($p<0.05$ in both groups), but there were no significant differences between the postoperative UDVA ($p = 0.206$) in the two groups, as summarized in Table 2. Also no statistically significant between-group differences were found in CDVA ($p = 0.568$) or expected versus obtained refractive state. In terms of efficacy outcomes, the UCVA was 0.3 logMAR or better in all eyes, and 0.1 logMAR or better in 83.3% of eyes in the ICL group and 86.7% of those in the Hole ICL group 3 months after surgery, as shown in Fig. 1.

With regard to visual quality outcomes, there were no significant differences between postoperative spherical aberration in the 2 groups ($p = 0.815$), as shown in Table 2.

In terms of safety outcomes, CDVA was 100% for all eyes in both groups for 0.3 logMAR or better at 1 day, 1 week, 1 month and 3 months after surgery. There were no statistically significant between-group differences in CDVA 3 months after surgery as shown in Table 2. There was no statistically significant difference in the two groups in terms of refractive outcomes in manifest sphere ($p = 0.459$), manifest cylinder ($p = 0.724$) or manifest spherical equivalent ($p = 0.462$), as shown in Table 2. There were no significant

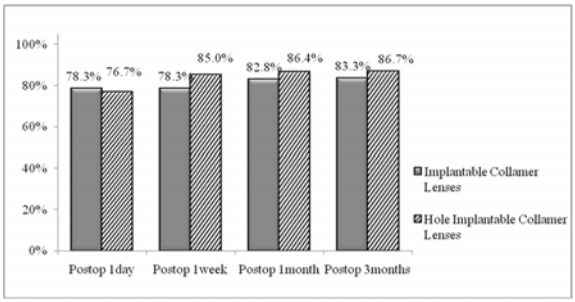

Fig. 1 Comparison of percentage of uncorrected distance visual acuity 1 day, 1 week, 1 month and 3 months after surgery in achieving 0.1 logMAR in conventional ICL and new Hole ICL as 0.1 logMAR is equivalent to 20/20 in snellen chart.

differences between preoperative and postoperative intraocular pressure (IOP) in the two groups ($p = 0.125$ in the ICL group and $p = 0.403$ in the Hole ICL group), but there were statisticallysignificant between-group differences between postoperative IOP ($p = 0.002$); however, this difference was not clinically significant (mean difference 95% CI -1.48 [-2.39 to -0.56]), as shown in Table 2. The IOP in both groups was quite stable throughout the study period at 1 day, 1 week, 1 month and 3 months after surgery, as shown in Fig. 3. No pupillary block was observed in slit-lamp examination of the Hole ICL group at any time during the study period.

Table 2. Postoperative outcomes at 3 months in terms of manifest refraction outcome, uncorrected distance visual acuity, corrected distance visual acuity, intraocular pressure and spherical aberration 3 months after implantable collamer lens implantation. Corresponding 2-tail *p*-values to compare between-groups differences are shown for each parameter

	Implantable collamer lenses (n = 60 eyes)	Hole implantable collamer lenses (n = 60 eyes)	Mean difference (95% CI)	*p*-value
Manifest sphere (D)	0.28±0.46	0.34±0.40	0.06 (-0.10 to 0.21)	0.459
Manifest cylinder (D)	-0.53±0.44	-0.55±0.46	-0.02 (-0.19 to 0.13)	0.724
Manifest axis (°)	76.58±77.88	72.67±78.39	-3.92 (-32.17 to 24.33)	0.784
Manifest spherical equivalent (D)	0.02±0.41	0.07±0.34	0.05 (-0.09 to 0.19)	0.462
Intraocular pressure (mmHg)	14.73±2.33	13.26±2.72	-1.48 (-2.39 to -0.56)	0.002*
Spherical aberration (mm)	-0.30±0.25	-0.29±0.26	0.01 (-0.08 to 0.10)	0.815
LogMARUDVA	-0.01±0.10	-0.03±0.10	-0.02 (-0.06 to 0.01)	0.206
LogMARCDVA	-0.10±0.06	-0.10±0.07	-0.01 (-0.03 to 0.02)	0.568

Values are presented as mean ± SD, Mean difference (95% confidence interval (lower to upper)). The *p*-value from student t-test. * Significant at $p<0.05$.
UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity

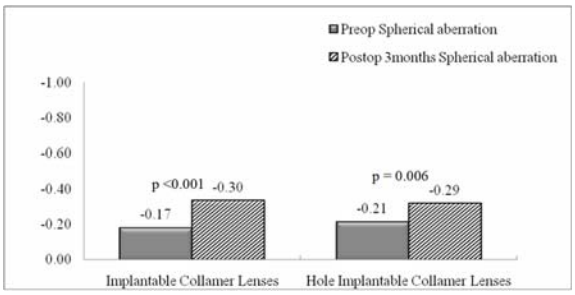

Fig. 2 Comparison of spherical aberration in microns and *p*-values between preoperative and 3 months post-operatively of conventional implantable collamer lens (ICL) and the new hole implantable collamer lens.

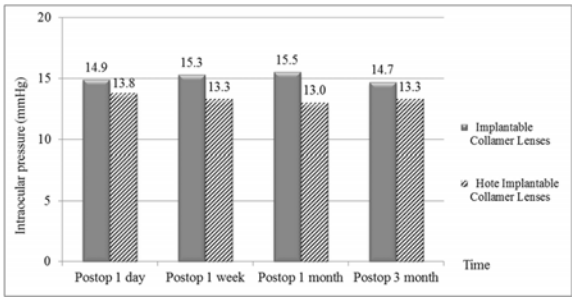

Fig. 3 Comparison of intraocular pressure in mmHg 1 day, 1 week, 1 month and 3 months after surgery and r-value 3 months after surgery for conventional implantable collamer lens and new hole implantable collamer lens.

Discussion

Despite its proven efficacy, conventional ICL still requires preoperative laser peripheral iridotomies or intraoperative iridectomy, which increases costs and surgical risk. Many studies have already demonstrated that Hole ICL implantation performed well in all measures of safety, efficacy, predictability and stability for correction of moderate to high myopia with or without astigmatism, and that no significant IOP rise (including pupillary block) occurred throughout the study periods, even without preoperative laser peripheral iridotomies or intraoperative peripheral iridectomy, suggesting that it could be a viable new surgical option for the treatment of such eyes[21]. An optical system with a central hole has already been used for some astronomical telescopes, providing excellent optical quality[22,23]. A recently study has demonstrated that conventional ICL implantation induced significantly fewer ocular higher order aberrations (HOAs), especially spherical aberration, than did Wave front-guided LASIK in the treatment of high myopia[24]. However, there are still concerns about the optical performance and postoperative IOP of the new ICL with a central artificial hole.

This non-inferiority trial aimed to demonstrate that Hole ICL is just as good as conventional ICL in terms of refractive outcomes, as we did not expect to see a great improvement in the results from the already established conventional ICL. The present study has corroborated the effectiveness of both Hole ICL and

conventional ICL in correcting moderate to high myopia. The two ICLs yielded similarly effective refractive results at 1 day, 1 week, 1 month and 3 months postoperatively, which is statistically significant in terms of preoperative refractive state (p<0.0001), but no statistically significant difference was found between groups (p = 0.122), as shown in Table 1 and Fig. 1. In our study, all eyes (100%) achieved 0.3 logMAR or better UDVA in both groups, 83.3% in group A and 86.7% in group B achieved 0.1 logMAR UDVA, as shown in Fig. 1. Analysis of the difference between the expected and the obtained refraction showed no statistically significant difference.

In the terms of optical performance, the MTF of Hole ICL has been reported to be similar to that of conventional ICL. The study addressed concerns that the hole may cause deterioration in the optical quality of the ICL. The optical performance of ICL with 0.36-mm central hole at various IOL powers fulfills the ISO criterion for MTF[20]. The present study has demonstrated that visual quality in HOA, especially in terms of spherical aberration, was not statistically significantly different in the two groups either before, or 3 months after, surgery (p = 0.402 preoperative, p = 0.524 postoperative) as demonstrated in Table 2 and Fig. 2, thus confirming that the central hole does not cause deterioration in optical quality as previously feared.

With regard to pupillary block and IOP, our study demonstrated that there was no pupillary block in the HoleICL group. IOP in the Hole ICL group was statistically significantly lower but without clinical significance 3 month after surgery (p = 0.002) (mean difference 95% CI -1.48 [-2.39 to -0.56]) as shown in Table 2. Also there was no rise in IOP in either group at any point in the study from day 1 to 3 months after surgery, as seen in Fig. 3, implying that Hole ICL is equivalent in efficacy and safety to conventional ICL. Complications with intraoperative hemorrhage from surgical peripheral iridectomy may induce raised IOP during or after surgery; hence, we believe that Hole ICL implantation has many advantages over conventional ICL implantation in the management of preoperative pain, intraoperative hemorrhage, and raised IOP. Although IOP did not rise after surgery, this does not necessarily indicate that pupillary block will not occur, but many authors have found no pupillary block in Hole ICL at any point of their studies[21,25]. However, pupillary block needs to be observed in a long-term study to establish whether or not the 0.36 mm central hole in HoleICL can perform as well as a smaller hole in peripheral iridotomy.

No cataract formation was found during the study period. Although we gain improvements in visual performance after ICL implantation, the possibility of increased risk of significant cataract development should be borne in mind. The US Food and Drug Administration (FDA) Trial demonstrated that the incidence of anterior subcapsular cataracts with conventional ICL was 2.7%[10]. Fugisawa et al reported that the insertion of an ICL causes a change in the dynamics of the intraocular aqueous humor[18]. Shimizu et al also stated that, as a result of improvement in the circulation of the aqueous humor to the anterior surface of the crystal line lens through the central hole, Hole ICL may also reduce the risk of cataract formation[21]. Kawamorita et al demonstrated that flow velocity of 0.25 mm in front of the center of the crystalline lens was 0.474x10-2 for the eye without ICL, 1.52x10-1 mm/sec for the Hole ICL, and 1.21x10-5 mm/sec for conventional ICL[25]. All previous studies have suggested that the Hole ICL may have more benefits than the conventional ICL in terms of less pupillary block and lower risk of cataract formation.

In conclusion, this non-inferiority clinical trial comparing Hole ICL and conventional ICL will help determine whether this new model, Hole ICL, has equal or better visual outcomes and visual performance compared to conventional ICL in the correction of moderate to high myopia in a clinical setting, together with its additional advantage of not requiring preoperative laser peripheral iridotomies or intraoperative peripheral iridectomy. Hole ICL also may reduce the risk of cataract formation due to the attendant better aqueous circulation from the central hole. The authors believe that the newly developed Hole ICL implantation is promising as a next generation surgical option for the correction of such eyes.

What is already known on this topic?

Correction of moderate to high myopia, with or without astigmatism, has been reported to be effective with posterior chamber phakic IOL (ICL). Conventional ICL has been reported to induce fewer higher order aberrations (HOAs) than Wavefront guided LASIK.

What this study adds?

The new HoleICL appears to be equivalent in safety, stability, effectiveness and predictability to conventional ICL, does not require potentially painful preoperative laser iridotomies or avoids the potential risk of hemorrhage which can result in from

intraoperative iridectomy.

Potential conflicts of interest

None.

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การศึกษาเปรียบเทียบประสิทธิภาพและความปลอดภัยของเลนส์แก้วตาเทียมที่แก้สายตาแบบมีรูตรงกลางเมื่อเปรียบเทียบกับเลนส์แก้วตาเทียมที่แก้สายตาแบบไม่มีรูในผู้ป่วยสายตาสั้นปานกลางถึงสั้นมากที่ไม่สามารถทำเลสิกได้

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ภูมิหลัง: *เลนส์เสริมที่แก้สายตาสั้นชนิดที่ใส่หลังม่านตา implantable collamer lens (ICL) ชนิดที่มีรูตรงกลาง (ขนาดของรู 0.36 mm) ที่เรียกว่า Hole ICL ได้รับการสร้างสรรค์ขึ้นมาเพื่อให้น้ำในช่องหน้าม่านตาสามารถไหลผ่านไปได้ ซึ่งนอกจากทำให้ผู้ป่วยที่เข้ารับการผ่าตัดไม่ต้องผ่านกระบวนการที่ต้องทำการเจาะม่านตาด้วยแสงเลเซอร์ก่อนการผ่าตัดหรือต้องทำการตัดม่านตาให้เป็นรู ระหว่างการผ่าตัดแล้วยังช่วยให้ลดโอกาสเกิดต้อกระจกภายหลังการใส่เลนส์เสริมชนิดนี้เนื่องจากระบบการไหลเวียนของน้ำในช่องหน้าม่านตาดีขึ้นด้วย*

วัตถุประสงค์: *การศึกษานี้มุ่งหวังเพื่อประเมินประสิทธิภาพและความปลอดภัยของเลนส์เสริม 2 กลุ่ม คือเลนส์เสริมรุ่นเดิมที่ไม่มีรูตรงกลาง (กลุ่ม A) และเลนส์เสริม ICL ชนิดใหม่ที่มีรูตรงกลาง (กลุ่ม B) ที่ระยะเวลา 3 เดือน หลังการผ่าตัด*

วัสดุและวิธีการ: *ทำการศึกษาแบบ non-inferiority trial โดยการผ่าตัดใส่เลนส์เสริม ICL ทั้ง 2 แบบ แบบดั้งเดิมที่ไม่มีรูตรงกลาง (กลุ่ม A) ที่ต้องทำการยิงเลเซอร์ม่านตาก่อนผ่าตัดและแบบใหม่ที่มีรูตรงกลาง (กลุ่ม B) โดยมีจำนวน 60 ตา ในแต่ละกลุ่มทำการวัดระดับการมองเห็นด้วยตาเปล่า (UDVA) และระดับความดันลูกตาก่อนและหลังผ่าตัด 1 วัน 1 อาทิตย์ 1 เดือน และ 3 เดือน หลังผ่าตัด วัดค่าความเพี้ยนการรวมแสง (spherical aberration) ก่อนและหลังผ่าตัด 3 เดือน*

ผลการศึกษา: *จากการศึกษา 120 ตา กลุ่มละ 60 ตา อายุเฉลี่ยในกลุ่ม ICL แบบดั้งเดิมอยู่ที่ 29.75±6.17 ปี (อายุตั้งแต่ 21-45 ปี) อายุเฉลี่ย ICL แบบที่มีรูตรงกลางอยู่ที่ 28.75±5.27 ปี (อายุตั้งแต่ 21-39 ปี) ระดับการมองเห็นด้วยตาเปล่า (UDVA) และระดับการมองเห็นแบบที่แก้ที่ดีที่สุด (CDVA) ทั้ง 2 กลุ่มไม่มีความแตกต่างกันทางสถิติ ความดันลูกตา (IOP) ไม่ได้มีการเปลี่ยนแปลงหรือมีความดันตาที่สูงตลอดการศึกษา ทั้งก่อนการผ่าตัดและที่ 1 วัน 1 อาทิตย์ 1 เดือน และ 3 เดือน หลังผ่าตัดทั้ง 2 กลุ่มและไม่มีความแตกต่างกันทางสถิติของความดันตาที่ 3 เดือน หลังผ่าตัด ในการเปรียบเทียบระหว่างกลุ่ม การวัดความเปลี่ยนแปลงความเพี้ยนของการรวมแสงแบบ spherical aberration ก่อนการผ่าตัดและที่ 3 เดือน หลังผ่าตัด ไม่พบความแตกต่างกันทางสถิติระหว่าง 2 กลุ่ม*

สรุป: *เลนส์เสริม ICL ทั้ง 2 กลุ่มมีประสิทธิภาพในการรักษาเท่ากันทั้งในแง่การมองเห็นด้วยตาเปล่า การมองเห็นแบบที่แก้ได้ดีที่สุด การควบคุมความดันตาและการเปลี่ยนแปลงของความเพี้ยนของการรวมแสง เลนส์เสริม ICL แบบมีรูตรงกลางไม่ต้องยิงเลเซอร์ม่านตาก่อนผ่าตัดหรือต้องทำการเจาะม่านตาขณะผ่าตัด*