Original Article

Safety and efficacy of implantable phakic contact lens versus implantable collamer lens in myopia correction

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ABSTRACT

Background: Phakic intraocular lenses (pIOLs) have proven to be excellent substitutes for excimer laser keratorefractive surgery in certain situations. We aimed to assess the efficacy and safety of two pIOLs, the implantable collamer lens (ICL V4c) versus the implantable phakic contact lens (IPCL V2), for myopic correction.

Methods: In this prospective randomized clinical trial, we allocated eligible eyes with myopia > - 6 diopters into IPCL or ICL implantation groups, each including 100 eyes of 100 individuals. Preoperative and postoperative assessments at 3, 6, and 12 months included measurements of the spherical equivalent (SE), uncorrected distance visual acuity (UCDVA), best-corrected distance visual acuity (BCDVA), intraocular pressure (IOP), maximum keratometry (K1), minimum keratometry (K2), mean keratometry (Kmean), anterior chamber depth (ACD), anterior chamber angle (ACA), and endothelial cell density (ECD).

Results: The groups had comparable demographic characteristics and baseline visual and anatomical values (all $P > 0.05$). The UCDVA, BCDVA, and SE of the two groups were comparable at baseline and at all postoperative follow-up examinations (all $P > 0.05$). Both groups experienced significant improvements in UCDVA, BCDVA, and SE at three months postoperatively (all $P = 0.001$), and measurements remained stable for up to 12 months. Keratometry readings were comparable between the groups over the follow-up period and remained unchanged at all visits (all $P > 0.05$). The ACA in the ICL group was significantly decreased at three months postoperatively ($P = 0.001$) and then widened significantly at 6 and 12 months (both $P = 0.001$). In the IPCL group, the postoperative ACA was significantly decreased at three months ($P = 0.001$) and was comparable to that in the ICL group ($P > 0.01$). However, at the 6- and 12-month postoperative visits, the ACA was significantly narrower in the IPCL group than in the ICL group (both $P = 0.001$). The ACD in both groups was decreased at three months postoperatively (both $P = 0.001$) and remained stable until the end of the study. The ECD remained comparable between the groups at all postoperative visits (all $P > 0.05$). We did not observe a significant ECD reduction in either group at any postoperative follow-up visit (all $P > 0.05$). We encountered no serious complications in either group.

Conclusions: ICL and IPCL had comparable safety and efficacy outcomes in terms of anterior chamber morphometrics, visual and refractive results, and corneal parameters. Further multicenter randomized clinical trials with longer follow-up periods, larger sample sizes, and measurement of additional anterior chamber and corneal morphometrics, vault, and other vision parameters are needed to verify these findings.

KEYWORDS

myopias, phakic intraocular lens, visual acuities, ocular refraction, keratorefractive surgical procedure, corneal endothelial cell damage, anterior chambers, intraocular pressures

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How to cite this article: Amer I, Ziada HA, Elgazzar AF, Abdella WS, Abdelgbar AA, Goda I, Amer RS, Abdel-Rahman Osman HO, Mohamed SA, Mansour MN, Alsadawy Hassan M, El Gabbar AGA, Hamed MA. Safety and efficacy of implantable phakic contact lens versus implantable collamer lens in myopia correction. Med Hypothesis Discov Innov Ophthalmol. 2023 Winter; 12(4): 160-167. https://doi.org/10.51329/mehdiophthal1482

Received: 14 December 2023; Accepted: 28 January 2024

INTRODUCTION

Phakic intraocular lenses (pIOLs) have proven to be excellent substitutes for excimer laser keratorefractive surgeries in certain situations [1-3]. They offer several benefits over keratorefractive surgeries, such as applicability to individuals with high myopia and relatively fewer induced higher-order aberrations. In addition, pIOLs provide better magnifying power for retinal images and increased contrast sensitivity than laser in situ keratomileusis, regardless of whether the myopia is low or high [1-3]. Other benefits include preserving accommodation, which is a definite benefit over refractive lens exchange, and the ability to correct refractive errors when keratorefractive procedures are not recommended [4].

The implantable collamer lens (ICL) is a posterior chamber pIOL that is effective in correcting high myopia. This device improves visual parameters and eliminates myopic regression [5]. However, because an intraocular procedure is required, the technique is associated with potential complications such as cataract formation, endothelial cell loss, endophthalmitis, retinal detachment, and anterior segment injury [5, 6]. One drawback of this pIOL is the financial burden it poses, particularly in developing countries [5, 7].

An alternative pIOL, the implantable phakic contact lens (IPCL), has been developed to address these issues [5]. The IPCL offers a noticeable financial benefit, as its price is significantly lower than that of the ICL. Moreover, the IPCL can correct higher degrees of myopia—up to - 30 diopters (D)—compared to the maximum correction of - 18 D provided by the ICL [7]. However, peripheral iridectomy is necessary before or during surgery because the IPCL model V1 lacks a central opening. Inadequate iridectomy can lead to pupillary block glaucoma and increased intraocular pressure (IOP) [8]. In addition, visually significant cataracts have been observed during a one-year follow-up after IPCL [9]. The likely cause of anterior subcapsular cataract formation is fibrous metaplasia of the lens epithelium resulting from low vaulting, as confirmed on anterior segment optical coherence tomography (OCT) [9]. To address these drawbacks, an updated version of the IPCL (IPCL V2), which includes an artificial central hole measuring 350 μm, has recently been made available. With this modification, a peripheral iridectomy is no longer necessary, and cataract and pupillary blockage glaucoma may occur less frequently [10, 11].

The purpose of the present trial was to examine the safety and efficacy of IPCL V2 versus ICL V4c during a one-year follow-up.

METHODS

This prospective randomized clinical trial compared the visual, anatomical, and refractive outcomes in patients with myopia who were randomly allocated to receive either IPCL or ICL implantation. The Institutional Review Board of Al-Azhar University approved this study. Written informed consent was obtained from all patients. All procedures were performed in compliance with the principles of the Declaration of Helsinki and its revisions. Our study was registered at ClinicalTrials. gov (trial registration number: NCT06058780).

The inclusion criteria were as follows: age > 18 years, stable refraction for at least 12 months, myopia > - 6 D, refractive astigmatism within 3 D, a central anterior chamber depth (ACD) > 2.7 mm (distance between the corneal endothelium and the anterior lens capsule [5]), an endothelial cell count of ≥ 2000 cells/mm^2, and no history of intraocular surgery or any other ocular or systemic diseases. Lactating and pregnant women were excluded from the study.

Patient recruitment began in September 2020. We recruited all eligible patients who underwent pIOL implantation for the treatment of myopia. Patients were randomly allocated to one of two groups: the *ICL group* comprised 100 eyes of 100 individuals who underwent ICL implantation (ICL Model V4c; STAAR Surgical Co., Nidau, Switzerland), and the *IPCL group* comprised 100 eyes of 100 individuals who underwent IPCL implantation (IPCL V2 model; Care Group, Baroda, India) (Figure 1). Computer-generated random numbers were used for simple randomization of the participants into two groups. Allocation concealment was observed using a sealed envelopes approach [12]. For statistical reasons, only one eye of each individual was considered.

Preoperative assessments, such as measurements of visual acuity, IOP, and other imaging parameters, were performed by a single trained technician who was blinded to study group allocation. Initially, biometry (ZEISS IOLMaster 500; Carl Zeiss Meditec AG, Jena, Germany) was used to calculate IOL power. The Pentacam Scheimpflug imaging system (Pentacam® HR; Oculus, Wetzlar, Germany) was used to measure the maximum keratometry (K1), minimum keratometry (K2), mean keratometry (Kmean) [13], and anterior chamber angle (ACA) [14].

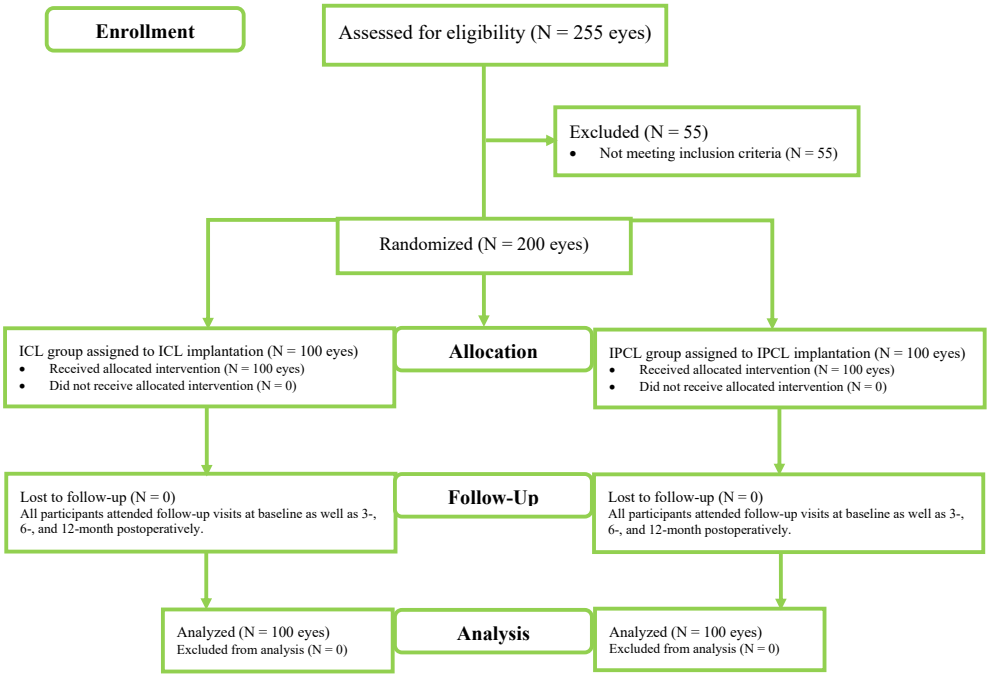

Figure 1. CONSORT-style flow diagram shows patient allocation into ICL or IPCL group. Abbreviations: N, number of eyes. Note: The implantable collamer lens (ICL) group comprised 100 eyes of 100 individuals who underwent ICL implantation (ICL Model V4c; STAAR Surgical Co., Nidau, Switzerland), and the implantable phakic contact lens (IPCL) group comprised 100 eyes of 100 individuals who underwent IPCL implantation (IPCL V2 model; Care Group, Baroda, India).

A skilled surgeon performed all surgical procedures and took the necessary measures for pIOL implantation. Internal ACD was measured using OCT (Cirrus-OCT; Carl Zeiss Meditec, Dublin, CA, USA) and was verified using IOLMaster ACD while considering the thickness of the cornea. IOL power was calculated according to the manufacturer's instructions. ICL power was computed using the updated vertex formula [15]. IPCL power was determined using the online IPCL calculator [7]. ACD was used to determine the pIOL size.

Uncorrected distance visual acuity (UCDVA) was recorded in decimal notation using a Snellen chart (Auto Chart Projector CP 670; Nidek Co., Ltd., Gamagori, Japan). An automated refractometer (Topcon KR-800 Auto Refractometer; Topcon Corp., Tokyo, Japan) was used to evaluate refraction. Employing the trial frame, refraction was then subjectively refined, and the best-corrected distance visual acuity (BCDVA) was recorded in decimal notation using a Snellen chart. The spherical equivalent (SE) was calculated in D using the spherical component of the refined subjective refraction plus one-half the cylindrical component [16]. IOP was measured using an air puff tonometer (CT-80; Topcon Corp.). Detailed dilated and undilated slit-lamp biomicroscopic examinations (Haag-Streit Photo-Slit Lamp BX 900; Haag-Streit AG, Koeniz, Switzerland) were performed. Endothelial cell density (ECD) was measured using a specular microscope (CEM 530; Nidek Co.).

The surgical procedure for the ICL group was as follows. A 3-mm incision was made in the temporal cornea after local anesthetic (Oxybuprocaine Hcl 0.4%; Benox® ; EIPICO, Egyptian International Pharmaceutical Industries Co., Cairo, Egypt) and mydriatic (Cyclophrine® 0.2% cyclopentolate; Kahira Pharmaceuticals, Cairo, Egypt) eye drops were applied. A viscoelastic substance was intracamerally injected. An ICL V4c model with a central hole was inserted using an injector cartridge (STAAR Surgical Co.). On the ciliary sulcus, the four ICL footplates were positioned along a 180° axis. The intracameral viscoelastic substance was washed out using a balanced salt solution [5, 17, 18].

The surgical procedure for the IPCL group was as follows. Before the operation, local anesthetic (Oxybuprocaine Hcl 0.4%; Benox®; EIPICO) and mydriatic (Cyclophrine® 0.2% cyclopentolate; Kahira Pharmaceuticals) eye drops were applied. Following the intracameral injection of viscoelastic material, a 3-mm precise corneal incision was created to implant the IPCL into the anterior chamber. Once the footplates were tucked behind the iris, the viscoelastic material was completely removed using a balanced salt solution [5, 7].

Postoperative care and follow-up schedules were identical for all the included eyes. During the first two weeks, tobramycin 0.3% and dexamethasone 0.1% (Tobradex®; Alcon Laboratories, Fort Worth, TX, USA) and moxifloxacin 0.5% (Vigamox®; Alcon Laboratories) eye drops were administered three times daily. Patients were

assessed on the first day, the first week, and every two months up to one year postoperatively. We recorded the baseline and postoperative values for UCDVA, BCDVA, SE, IOP, keratometry readings, ACA, ACD, and ECD at 3, 6, and 12 months to compare outcomes of the study groups.

Statistical analyses were performed by a statistician who was blinded to group allocation. SPSS Statistics for Windows (version 26.0; IBM Corp., Armonk, NY, USA) was used for the analysis. The Kolmogorov – Smirnov test was used to determine the normality of data distribution. Qualitative data for each group, presented as frequencies and percentages, were compared using the chi-square test. Because our data were not normally distributed, we present continuous data in terms of the median (second quartile [Q2], third quartile [Q3]). Follow-up comparisons within each group were performed using the Friedman test with notation as ^{a}P-value. Pairwise comparisons between two follow-ups were performed using the Wilcoxon matched-pairs signed rank test with notation as ^{b}P-value. The two groups were compared using the Mann – Whitney U test with notation as ^{c}P-value. Statistical significance was defined as a P-value < 0.05.

RESULTS

We allocated 200 eyes with myopia to one of two groups that had comparable demographic characteristics, whereby the median (Q2, Q3) ages for the ICL and IPCL groups were 22 (20, 25) and 22 (17.3, 29.8) years ($P = 0.530$), respectively. The groups had identical male (n = 54, 54% in each group) to female (n = 46, 46% in each group) ratios ($P > 0.99$).

We observed no statistically significant differences in keratometry readings between the two groups at the end of follow-up (all $P > 0.05$). The median (Q2, Q3) K1, K2, and Kmean were 43.6 (42.5, 44.3), 45.3 (43.3, 46.0), and 44.1 (42.0, 46.0) D, respectively, at baseline in both groups and were similar at all follow-up visits.

The UCDVA, BCDVA, and SE of the two groups were comparable at baseline and at all postoperative follow-up visits (all $P > 0.05$) (Table 1). However, in both groups, the median (Q2, Q3) UCDVA, BCDVA, and SE were

Table 1. Comparisons of UCDVA, BCDVA, and SE between groups during follow-up

Variables	ICL group (n = 100)	^{b}P-value	IPCL group (n = 100)	^{b}P-value	^{c}P-value
UCDVA (decimal), Median (Q2, Q3)					
Baseline	0.05 (0.05, 0.1)	-	0.04 (0.05, 0.1)	-	0.14
3-month post-operative	0.5 (0.4, 0.7)	**0.001**	0.5 (0.4, 0.7)	**0.001**	0.93
6-month post-operative	0.5 (0.4, 0.7)	**0.001**	0.5 (0.4, 0.7)	**0.001**	0.12
One year post-operative	0.5 (0.4, 0.7)	**0.001**	0.5 (0.4, 0.7)	**0.001**	0.98
^{a}P-value	**0.001**		**0.001**		
BCDVA (decimal), Median (Q2, Q3)					
Baseline	0.3 (0.2, 0.6)	-	0.2 (0.2, 0.6)	-	0.2
3-month post-operative	0.6 (0.4, 0.6)	**0.001**	0.6 (0.4, 0.6)	**0.001**	> 0.99
6-month post-operative	0.6 (0.4, 0.6)	**0.001**	0.6 (0.4, 0.6)	**0.001**	> 0.99
One year post-operative	0.6 (0.4, 0.6)	**0.001**	0.6 (0.4, 0.6)	**0.001**	> 0.99
^{a}P-value	**0.001**		**0.001**		
SE (D), Median (Q2, Q3)					
Baseline	- 14 (- 18, - 11)	-	- 14.5 (- 19, - 10.5)	-	0.3
3-month post-operative	- 0.5 (- 75, - 0.25)	**0.001**	- 0.5 (- 75, - 0.25)	**0.001**	> 0.99
6-month post-operative	- 0.5 (- 75, - 0.25)	**0.001**	- 0.5 (- 75, - 0.25)	**0.001**	> 0.99
One year post-operative	- 0.5 (- 75, - 0.25)	**0.001**	- 0.5 (- 75, - 0.25)	**0.001**	> 0.99
^{a}P-value	**0.001**		**0.001**		

Abbreviations: UCDVA, uncorrected distance visual acuity; BCDVA, best-corrected distance visual acuity; SE, spherical equivalent; n, number of eyes; Q2, the second quartile; Q3, the third quartile; D, diopters. Note: P-values < 0.05 are shown in bold; Follow-up comparisons within each group were performed using the Friedman test with notation as ^{a}P-value; Pairwise comparisons between two follow-ups were performed using the Wilcoxon matched-pairs signed rank test with notation as ^{b}P-value; The two groups were compared using the Mann – Whitney U test with notation as ^{c}P-value; The implantable collamer lens (ICL) group comprised 100 eyes of 100 individuals who underwent ICL implantation (ICL Model V4c; STAAR Surgical Co., Nidau, Switzerland); The implantable phakic contact lens (IPCL) group comprised 100 eyes of 100 individuals who underwent IPCL implantation (IPCL V2 model; Care Group, Baroda, India); The SE was calculated in D using the spherical component of the refined subjective refraction plus one-half the cylindrical component [16].

Table 2. Comparisons of IOP, ACA, ACD, and ECD between groups during follow-up

Variables	ICL group (n = 100)	[b] *P*-value	IPCL group (n = 100)	[b] *P*-value	[c] *P*-value
IOP (mmHg), Median (Q2, Q3)					
Baseline	14.0 (12.0, 16.0)	-	14.0 (12.0, 16.0)	-	> 0.99
3-month post-operative	12.7 (10.7, 14.7)	**0.001**	16.0 (13.5, 18.0)	**0.001**	**0.001**
6-month post-operative	12.6 (10.6, 14.6)	**0.001**	15.7 (13.5, 18.0)	**0.001**	**0.001**
One year post-operative	12.6 (10.6, 14.6)	**0.001**	15.7 (13.5, 18.0)	**0.001**	**0.001**
[a] ***P*-value**	**0.001**		**0.001**		
ACA (degree), Median (Q2, Q3)					
Baseline	37.0 (34.6, 37.3)	-	36.9 (34.6, 37.3)	-	0.8
3-month post-operative	26.4 (24.5, 30.1)	**0.001**	26.5 (24.5, 30.0)	**0.001**	0.9
6-month post-operative	30.2 (29.3, 30.7)	**0.001**	26.0 (24.0, 30.0)	**0.001**	**0.001**
One year post-operative	32.2 (30.0, 33.0)	**0.001**	26.5 (24.3, 30.1)	**0.001**	**0.001**
[a] ***P*-value**	**0.001**		**0.001**		
ACD (mm), Median (Q2, Q3)					
Baseline	3.5 (3.4, 3.8)	-	3.5 (3.4, 3.8)	-	> 0.99
3-month post-operative	3.0 (2.9, 3.3)	**0.001**	3.0 (2.8, 3.1)	**0.001**	**0.007**
6-month post-operative	3.2 (3.1,3.5)	**0.001**	3.0 (2.8, 3.1)	**0.001**	**0.001**
One year post-operative	3.1 (3.0, 3.4)	**0.001**	3.0 (2.8, 3.1)	**0.001**	**0.001**
[a] ***P*-value**	**0.001**		**0.001**		
ECD (cells/mm²), Median (Q2, Q3)					
Baseline	2710 (2519, 2927)	-	2764 (2568, 2972)	-	0.2
3-month post-operative	2747 (2519, 2916)	0.6	2770 (2568, 2927)	0.7	0.5
6-month post-operative	2764 (2568, 2972)	0.1	2785 (2564, 2962)	0.8	0.8
One year post-operative	2747 (2559, 2927)	> 0.99	2764 (2564, 2972)	0.9	0.64
[a] ***P*-value**	0.15		0.96		

Abbreviations: IOP, intraocular pressure; ACA, anterior chamber angle; ACD, anterior chamber depth; ECD, endothelial cell density; n, number of eyes; mmHg, millimeter of mercury; Q2, the second quartile; Q3, the third quartile; mm, millimeters; cells/mm², cells per square millimeters. Note: *P*-values < 0.05 are shown in bold; Follow-up comparisons within each group were performed using the Friedman test with notation as [a]*P*-value; Pairwise comparisons between two follow-ups were performed using the Wilcoxon matched-pairs signed rank test with notation as [b]*P*-value; The two groups were compared using the Mann – Whitney U test with notation as [c]*P*-value; The implantable collamer lens (ICL) group comprised 100 eyes of 100 individuals who underwent ICL implantation (ICL Model V4c; STAAR Surgical Co., Nidau, Switzerland); The implantable phakic contact lens (IPCL) group comprised 100 eyes of 100 individuals who underwent IPCL implantation (IPCL V2 model; Care Group, Baroda, India).

significantly improved three months postoperatively (all $P = 0.001$) and remained stable for up to 12 months (Table 1).

Both groups had comparable baseline IOP, ACA, ACD, and ECD values (all $P > 0.05$) (Table 2). No IOP elevation was observed in any of the eyes. However, despite comparable median (Q2, Q3) IOP levels at baseline ($P > 0.05$), eyes in the ICL group had significantly lower IOP values at all follow-up visits than those in the IPCL group (all $P = 0.001$) (Table 2); however, these values were within the clinically normal IOP range.

In the ICL group, the median (Q2, Q3) ACA significantly decreased from 37.0° (34.6°, 37.3°) at baseline to 26.4° (24.5°, 30.1°) at three months postoperatively ($P = 0.001$), and it then widened significantly to 30.2° (29.3°, 30.7°) and 32.2° (30.0°, 33.0°) at 6 and 12 months, respectively (both $P = 0.001$). In the IPCL group, the median (Q2, Q3) ACA decreased significantly from 36.9° (34.6°, 37.3°) at baseline to 26.5° (24.5°, 30.0°) at three months postoperatively ($P = 0.001$), which was comparable to that in the ICL group ($P > 0.01$). However, at the 6- and 12-month postoperative visits, the ACA was significantly narrower in the IPCL-implanted eyes than in the ICL-implanted eyes (both $P = 0.001$) (Table 2).

The median (Q2, Q3) ACD in the ICL group decreased significantly from 3.5 (3.4, 3.8) mm at baseline to 3.0 (2.9, 3.3) mm at three months postoperatively and remained stable until the end of the study. In the IPCL group, ACD decreased from 3.5 (3.4, 3.8) mm at baseline to 3.0 (2.8, 3.1) mm at the third month, which was significantly shallower than that of the ICL group ($P = 0.007$) (Table 2), and it remained stable until the end of the study.

The median (Q2, Q3) ECD remained comparable between the groups at all postoperative visits (all $P > 0.05$). We did not observe a significant ECD reduction in either group at any postoperative follow-up visit (all $P > 0.05$) (Table 2). We did not encounter any serious complications, such as cataract or elevated IOP, in either group at the one-year follow-up.

DISCUSSION

We compared the effectiveness of IPCL and ICL in correcting high myopia and observed comparable efficacy between the two pIOLs, as reported by Rateb et al. [5] and Sachdev et al. [7], with a similar postoperative follow-up period.

Our study demonstrated significant improvements in UCDVA and BCDVA in both study groups, without significant between-group differences. These results are comparable to those of a three-year follow-up trial of 526 eyes conducted by the US Food and Drug Administration, which reported a significant improvement in BCDVA in 94.7% of all studied patients [19]. Mahmoud et al. [20] observed a substantial enhancement in the BCDVA of eyes implanted with toric ICL and toric IPCL, with no differences between the two devices, which supports our results. Visual acuity, refraction, and keratometric reading stability were important outcomes. In our study, the median (Q2, Q3) BCDVA was stable at 0.6 (0.4, 0.6) decimal at all follow-up visits in both groups. Likewise, K1, K2, and Kmean remained stable at all follow-up visits without surgically induced astigmatism in either group, which is consistent with the results of Mahmoud et al. [20].

Cataract development and IOP elevation are the most common complications after pIOL implantation [21]. In our trial, we encountered no complications attributable to the use of the holed ICL and holed IPCL, which provide patent circulation for the aqueous humor and decrease the risk of cataract formation. The importance of using the holed IPCL and holed ICL is demonstrated by the findings of Sachdev et al. [22], who used a non-holed IPCL in the management of myopia and myopic astigmatism and reported a 2.9% rate of cataract development and a 2.23% rate of IOP elevation [22]. However, the presence of hole confers long-term safety in the use of ICLs [23].

ECD is an important metric for these operations [24]. In our study, the median (Q2, Q3) ECD remained comparable between the groups and there was no significant reduction in either group at any postoperative follow-up visit. These findings are similar to those of Yasa et al. [25] and Shimizu et al. [17]. Over a three-year postoperative period, Choi et al. [26] used a non-contact specular microscope to compare the ECD of eyes with ICLs (V4c and V5 with a central hole) with that of eyes that underwent excimer laser keratorefractive surgery. They observed no significant difference in ECD loss compared to the preoperative values between the two groups, with no significant ECD loss at any time point. Surprisingly, at the last visit, eyes with ICLs had a significantly higher proportion of hexagonal cells and a lower coefficient of variation in cell size than eyes that underwent excimer laser keratorefractive surgery [26]. The findings of the current and previous studies may indicate safety of pIOLs with regard to ECD. However, long-term studies are necessary to justify our reasoning.

Using linear regression analysis, Tan et al. [27] observed that SE and anterior chamber morphometrics such as ACD and ACA play a crucial role in the vault three months after ICL implantation [27]. Likewise, using logistic regression analysis, Yang et al. [28] observed that ACA, but not ACD, was an independent risk factor for an abnormal vault [28]. Therefore, we included these parameters in our pre- and postoperative assessments of the two groups and observed similar SEs that remained comparable at all postoperative visits. Both groups showed significant improvement in SE at three months postoperatively, and SE remained unchanged throughout the remainder of follow-up. ACA significantly decreased in the ICL group from 37.0° at baseline to 26.4° at the three-month postoperative visit, then widening to 30.2° and 32.2° at 6 and 12 months, respectively. In the IPCL group, the ACA decreased significantly from 36.9° at baseline to 26.5° at three months postoperatively and was comparable to that of the ICL group. However, at the 6- and 12-month postoperative visits, the ACA was significantly narrower in the IPCL group than in the ICL group. Similarly, the ACD in both groups decreased from 3.5 mm at baseline to 3.0 mm at three months postoperatively, and then remained virtually stable until the end of the study. Considering SE, ACD, and ACA as independent predictors of the vault [27, 28], the stability of these factors in our participants may imply the presence of a normal vault. However, further clinical trials that include vault measurements with anterior chamber morphometrics and refractive outcomes are needed to verify this reasoning.

In this randomized clinical trial, we posed the question of which of the two pIOLs is superior, and we observed comparable efficacy and safety of the two pIOLs despite the large difference in cost between the devices. However, differences may appear in future studies with larger sample sizes and longer follow-up periods. A limitation of our study was the small number of participants, which could explain the insignificant differences

between the two arms. Nonetheless, this restriction had little impact on the study's overall findings, given the minimal variations in outcome measures between the study groups. Another limitation is the short follow-up period; thus, we recommend further similar studies with at least 3 – 5 years of follow-up to confirm our preliminary findings and establish the true incidence of cataracts and decreased ECD in both groups.

CONCLUSIONS

ICL and IPCL had comparable safety and efficacy outcomes in terms of anterior chamber morphometrics, visual and refractive results, and corneal parameters. Further multicenter randomized clinical trials with longer follow-up periods, larger sample sizes, and measurement of additional anterior chamber and corneal morphometrics, vault, and other vision parameters, are needed to verify these preliminary findings.

ETHICAL DECLARATIONS

Ethical approval: The Institutional Review Board of Al-Azhar University approved this study. Written informed consent was obtained from all patients. All procedures were performed in compliance with the principles of the Declaration of Helsinki and its revisions. Our study was registered at ClinicalTrials. gov (trial registration number: NCT06058780).
Conflict of interest: None.

FUNDING

None.

ACKNOWLEDGMENTS

None.

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