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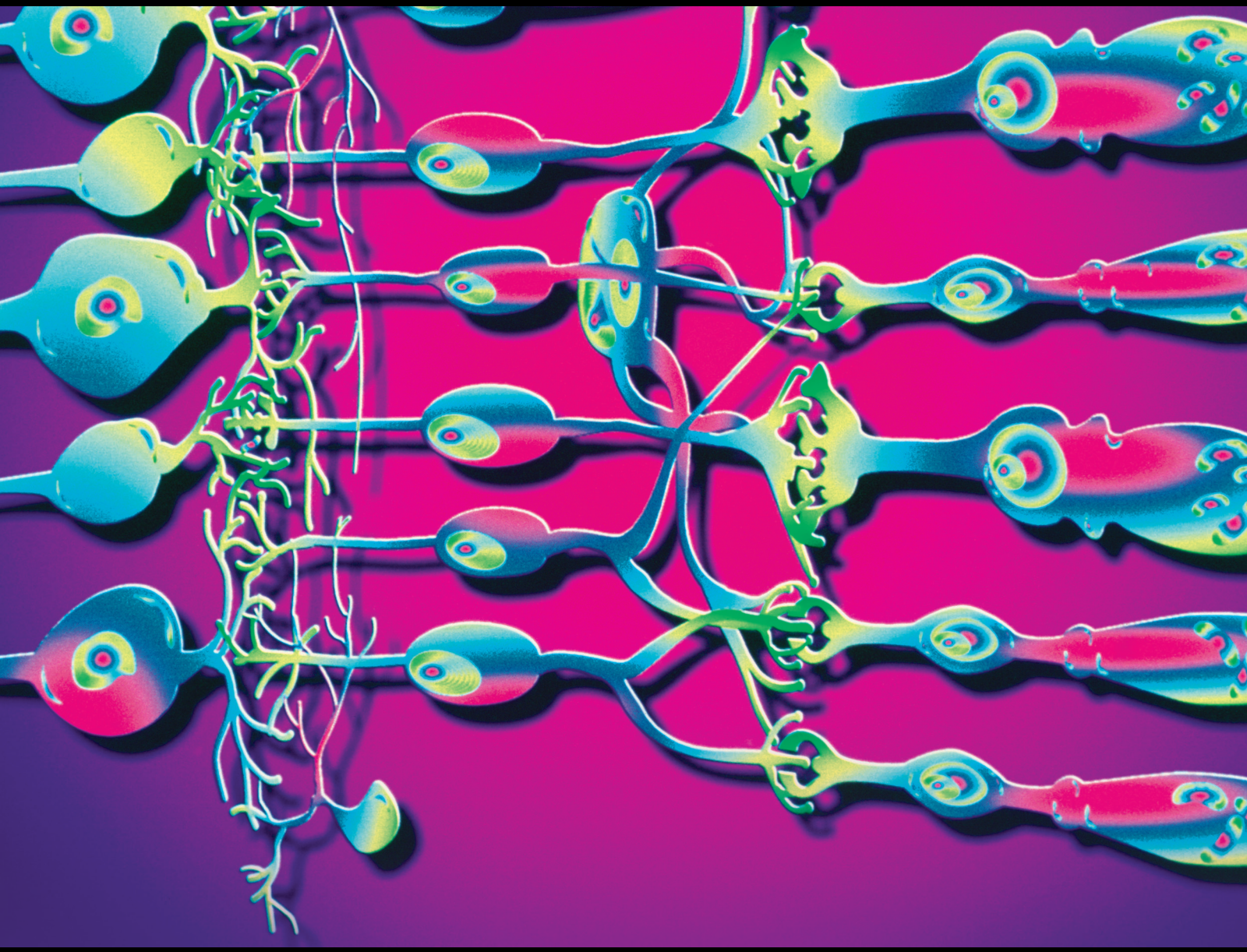

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Research Article

Longitudinal Changes of Axial Length and Associated Factors in Congenital Ectopia Lentis Patients

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Purpose. To investigate the longitudinal changes and associated factors of axial length (AL) in congenital ectopia lentis (CEL) patients. *Methods*. In this retrospective study, medical records of CEL patients were reviewed from January 2014 to December 2019 at the Zhongshan Ophthalmic (ZOC) in China. Patients were divided into the surgery group and the nonsurgery group. Data of refractive power, best-corrected visual acuity (BCVA), and intraocular pressure (IOP) as well as ocular biometrics including AL, corneal curvature, white-to-white (WTW), and central corneal thickness (CCT) were collected at baseline and each follow-up visit. Multiple linear regression was performed to assess the potential associated factors for axial length growth in congenital ectopia lentis patients. *Results*. Compared with the nonsurgery group, the change rate of AL among children aged 3 to 6 years old was slower in the surgery group (0.443 ± 0.340 mm/year vs. 0.278 ± 0.227 mm/year, $P < 0.05$). However, no statistically significant difference for the change rate of AL was detected between the surgery group and the nonsurgery group ($P > 0.05$) among patients aged 7 years or older. For the surgery group, the results of the linear regression model showed that a higher change rate of AL was associated with younger age (older age: $\beta = -0.009$, 95% CI: −0.014 to −0.003, and $P = 0.002$) and worse baseline BCVA (logMAR) ($\beta = 0.256$, 95% CI: 0.072 to 0.439, and $P = 0.007$). As for the nonsurgery group, younger baseline age (older age: $\beta = -0.027$, 95% CI: −0.048 to −0.007, and $P = 0.01$) and longer baseline AL ($\beta = 0.073$, 95% CI: 0.023 to 0.122, and $P = 0.006$) were associated with a higher change rate of AL. *Conclusions*. The AL change rate was clearly associated with age both in the surgery group and in the nonsurgery group. Intervention strategies such as surgery should be performed earlier for CEL that meets the surgical criteria. Worse baseline BCVA and longer baseline AL are associated factors that would affect the growth rate of AL in the surgery and nonsurgery group, respectively.

1. Introduction

Congenital ectopia lentis (CEL) is defined as the dislocation of the lens from its natural position [1] which usually occurs bilaterally and is often associated with inherited connective tissue disorder such as Marfan syndrome, Weill–Marchesani syndrome, homocystinuria, and Ehlers–Danlos syndrome [2]. Dislocation of the lens could cause high refractive error such as irregular astigmatism, high myopia, or high hyperopia, which usually leads to not only visual impairment but could also lead to diplopia and strabismus, especially during the critical period in ocular development [3].

The methods of CEL treatment could be generally classified into conservative treatment and operative treatment. It is generally considered that patients with mild EL and transparent crystalline lenses without serious complications can be conservatively treated, that is, observation with regular follow-up and wearing spectacles or contact lenses for refractive correction. Only when a dislocated lens seriously impairs vision and quality of life, should surgical intervention be adopted [4].

Previous studies reported that both visual deprivation and optical defocus can alter the ocular growth pattern due to the rapid elongation during the ocular growth period of childhood [5, 6]. Axial length (AL), which is generally considered to be one of the primary determinants of the refractive status, could be affected by different treatment methods in children with cataracts [7]. Our previous research has shown that the eyes with CEL had a longer AL compared with the normal eyes, and this difference was more significant in children younger than 12 years old [8]. However, the influence of different therapy methods and potential associated factors on the axial growth in CEL patients has not been reported.

In the study, we aimed to analyze and compare the longitudinal changes of AL in different treatment strategies and evaluate the potential associated factors that will affect the longitudinal changes of AL for CEL patients.

2. Methods

2.1. Subjects. In this retrospective study, CEL patients were recruited from January 2014 to December 2019 from the Zhongshan Ophthalmic Center. The inclusion criteria were as follows: (1) patients with detailed clinical data and biological parameters and (2) patients were followed up for 26 months on an average (range 1–3 years) and the interval between two follow-ups was more than 3 months. The exclusion criteria were as follows: (1) patients with incomplete data; (2) preexisting ocular diseases that may influence ocular development, such as congenital glaucoma, congenital cataracts, or other ocular diseases that can lead to defocus or deprivation; (3) patients with lens dislocation due to ocular trauma, tumor, or surgery. Surgery was considered if one or more of the following criteria [9, 10] was observed: (a) best-corrected visual acuity (BCVA) was less than 0.3; (b) complicated with severe cataract; (c) monocular diplopia; (d) progressive subluxation of the lens affecting the pupillary axis with or without elevation of intraocular pressure (IOP); and (e) with serious complications, such as secondary glaucoma, corneal endothelial decompensation, and/or retinal detachment.

Patients were divided into the 2 groups according to the baseline age: 3 to 6 years old (3–6 y) and 7 or more years old (≥7 y). In each age group, patients were further divided into the surgery group and the nonsurgery group based on their treatments. For the operative treatment group, the eye that underwent surgery was included for the study, and for the conservative treatment group, only the right eye was included for the study. For the nonsurgery group, the baseline age and baseline axial length were defined as the age of initial diagnosis of CEL. For the surgery group, age at the time of the surgery and the preoperative axial length were regarded as the baseline age and baseline axial length of statistical analysis, respectively. Subgroup analyses were carried out in accordance with the baseline age and baseline SE. Basic characteristics such as age, gender, medical history, and hospitalization time were extracted. Parameter and refractive data of ocular including anterior chamber depth (ACD), astigmatism, intraocular pressure (IOP), white-to-white corneal diameter (WTW), central corneal thickness (CCT), best-corrected visual acuity (BCVA), and spherical equivalent (SE) were also recorded.

The study followed the tenets of the Declaration of Helsinki and was approved by the Institutional Review Board of the Zhongshan Ophthalmic Center in Sun Yat-sen University (IRB-ZOC-SYSU), Guangzhou, China.

2.2. Surgical Technique. For patients that underwent surgery, the surgical criteria were consistent with previous studies [11, 12]. Surgery was performed by the same surgeon (Dr. DY Zheng), and patients underwent the same procedure of lens extraction and transscleral IOL fixation. In detail, two triangular scleral flaps were made at 4 and 10 o'clock posterior of the corneal limbus. A 3.0 mm clear corneal tunnel incision was made at 12 o'clock, and a continuous circular capsulorhexis (CCC) was performed. Lens extraction was performed with the capsule being held by the iris retractor, and the capsular bag was taken out after the phacoaspiration. Intraocular lens (IOL) transscleral fixation was then performed with the two IOL haptic sutured by using an 8-0 prolene suture at 2 mm posterior to the corneal limbus under the sclera flap. A 10-0 nylon suture was used to close the scleral flaps and the main corneal incision. Anterior vitrectomy was performed only in the eyes with severe vitreous prolapse.

2.3. Statistical Analysis. All the included data were extracted from medical records and checked by two independent investigators (JXH and ZKL). The data that follow the Gaussian distribution were analyzed by using Student's *t*-test, and the data that do not the follow Gaussian distribution were performed using the rank-sum test for between-group comparisons. P values less than 0.05 were considered statistically significant.

Univariate and multivariate linear regression analyses were conducted to assess potential correlation between baseline biometry variables and the AL change rate. All data analyses were performed using Stata 14.0 software (Stata Corp., College Station, TX, USA).

3. Results

In total, 148 eyes of 148 CEL patients were included in this study. Among them, 101 (68.2%) underwent surgery and 47 (31.8%) received conservative therapy. The demographic and clinical features of patients are presented in Table 1.

In this study, significant differences of baseline AL between the surgery group and the nonsurgery group were found in patients aged 3 to 6 years (24.73 ± 1.90 mm vs. 24.0 ± 2.19 mm, and $P < 0.05$). In patients aged 7 years or older, no difference of baseline AL was detected between the two groups (25.6 ± 2.45 mm for the surgery group vs. 25.6 ± 3.12 mm for the nonsurgery group and $P = 0.486$) (Table 2 and Figures 1 and 2). And there was a significantly worse baseline logMAR BCVA in the surgery group than in the non-surgery group (0.774 ± 0.362 vs. 0.471 ± 0.302, $P < 0.05$) for the 3 to 6 year age group, wwhile in the older

Table 1: The demographic characteristics of the included CEL patients.

	Total	Surgery group	Nonsurgery group	*P*
Median age (IQR)	6 (5–11)	7 (5–13)	6 (4–8)	0.035
Age group, *n* (%)				
3–6 years	75	48	27	0.002
≥7 years	73	53	20	
Total	148	101	47	
Male, *n* (%)	96 (64.9%)	67 (66.3%)	29 (61.7%)	0.292

Table 2: Baseline and the changing trend of ocular parameters in the surgery group and the nonsurgery group of CEL patients.

	3–6 years			≥7 years		
	Surgery group	Nonsurgery group	*P*	Surgery group	Nonsurgery group	*P*
Baseline						
AL (mm)	24.73 ± 1.90	24.0 ± 2.19	0.047	25.6 ± 2.45	25.6 ± 3.12	0.486
SE (D)	−5.27 ± 10.0	−7.37 ± 8.13	0.18	−3.94 ± 11.08	−11.0 ± 8.06	0.007*
BCVA (logMAR)	0.774 ± 0.362	0.471 ± 0.302	0.001*	0.498 ± 0.311	0.472 ± 0.212	0.367
IOP (mmHg)	14.04 ± 3.32	12.9 ± 2.58	0.075	13.7 ± 2.83	14.9 ± 3.35	0.09
Km	39.44 ± 6.43	41.1 ± 1.67	0.09	39.7 ± 8.78	41.1 ± 1.73	0.243
WTW (mm)	12.17 ± 0.57	12.14 ± 0.603	0.422	12.06 ± 0.486	12.1 ± 0.484	0.431
CCT	541.9 ± 46.0	544.4 ± 44.4	0.392	543.41 ± 45.1	545.4 ± 51.7	0.245
Change of AL (mm/year)	0.278 ± 0.227	0.443 ± 0.340	0.007*	0.121 ± 0.168	0.156 ± 0.123	0.201

AL = axial length; *D* = diopter; SE = spherical equivalent; BCVA = best-corrected visual acuity; IOP = intraocular pressure, *y*; Km = (*K*1 + *K*2)/2; WTW = white-to-white corneal diameter; CCT = central corneal thickness.

age group (7 years or older), no significant difference of the baseline BCVA differences was detected between the surgery group and the nonsurgery group (Table 2 and Figure 3). For patients aged 3 to 6 years old, the increase rate of AL was 0.278 ± 0.227 mm per year after surgery in the surgery group, which was lower than that in the nonsurgery group (0.278 ± 0.227 mm/y vs. 0.443 ± 0.340 mm/y and $P < 0.05$). However, no statistically significant differences of the AL growth rate were found between the surgery subgroup and the nonsurgery subgroup in the7 years or older group (Table 2 and Figures 4 and 5). No statistically significant difference was detected for corneal astigmatism, WTW, CCT, IOP, and SE between the surgery subgroup and the nonsurgery subgroup at the baseline in the two age groups (Table 2).

Multivariate linear regression showed that the AL growth rate was associated with older surgery age ($\beta = -0.009$, 95% CI: −0.014 to −0.003, and $P = 0.002$) and lower logMAR BCVA ($\beta = 0.256$, 95% CI: 0.072 to 0.439, and $P = 0.007$) in the surgery subgroup. For the nonsurgery subgroup, the AL change rate was associated with older age ($\beta = -0.027$, 95% CI: −0.048 to −0.007, and $P = 0.01$) and shorter AL ($\beta = 0.073$, 95% CI: 0.023 to 0.122, $P = 0.006$) (Table 3). Linear regression analysis also revealed that the AL change rate was significantly associated with surgical treatment after adjusted for age and sex in all patients aged 3 to 6 years old ($\beta = -0.16$, 95% CI: −0.30 to −0.02, $P = 0.022$).

4. Discussion

In the current study, we found that the average AL change rate in the surgery group was 0.28 ± 0.23 mm/year, which was slower than that in the nonsurgery group (0.44 ± 0.34 mm/year) for patients aged 3 to 6 years old. In the surgery group, age at surgery and baseline BCVA was significantly associated with axial elongation after IOL implantation for CEL patients. As for the nonsurgery group, the factors associated with axial length growth were the baseline age and baseline AL. For all patients aged 3 to 6 years old, the AL change rate was significantly associated with surgical treatment after adjusted for age and sex.

Few studies have investigated the influence of different treatment methods on axial elongation. In this study, our results show that the AL change rate in the surgery group was slower than that in the nonsurgery group for patients aged 3 to 6 years old. It was believed that surgical treatment had an obvious effect on curbing the AL elongation during the early period of eyeball development. One explanation is that surgical treatment can provide patients with a better visual quality, while conservative therapy cannot maintain a stable visual quality. It is well known that a stable visual quality is beneficial for normal eyeball development while depriving the eye of form vision will result in excessive axial elongation and myopia [5, 13–15]. Previous studies have drawn similar conclusions that in patients with CEL, the conservative treatment method such as wearing spectacles or contact lenses could lead to a high incidence of amblyopia [16], which often accompanies axial elongation.

Interestingly, no statistically significant differences were detected between the surgery group and the nonsurgery group for AL growth for the 7 years or older group. Our results were consistent with a previous study that reported that AL increased rapidly at younger age and then slowed and stabilized [17]. One possible reason is that the influence of lens dislocation on the development of AL may be stronger when the eye is undergoing the most rapid phase of

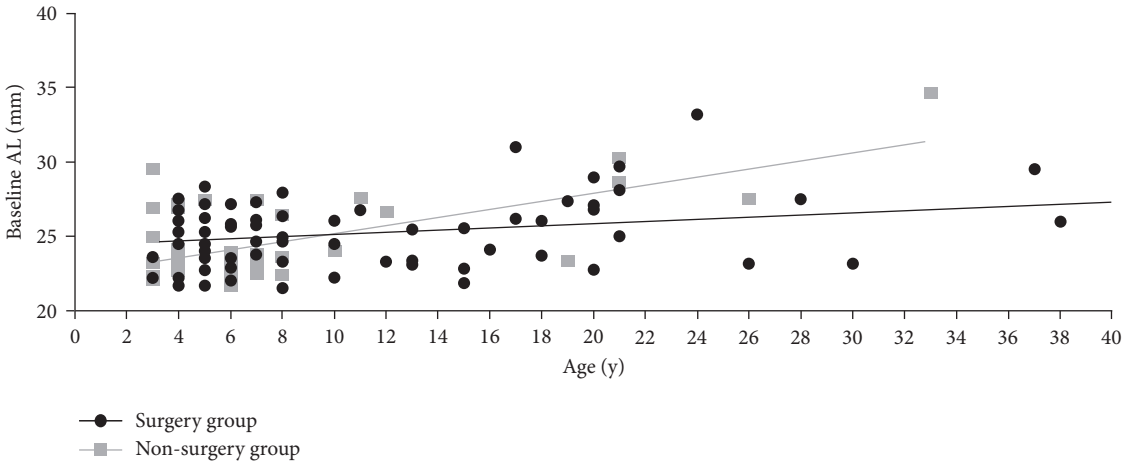

Figure 1: Distribution of axial length with age in the surgery group and the nonsurgery group of CEL patients.

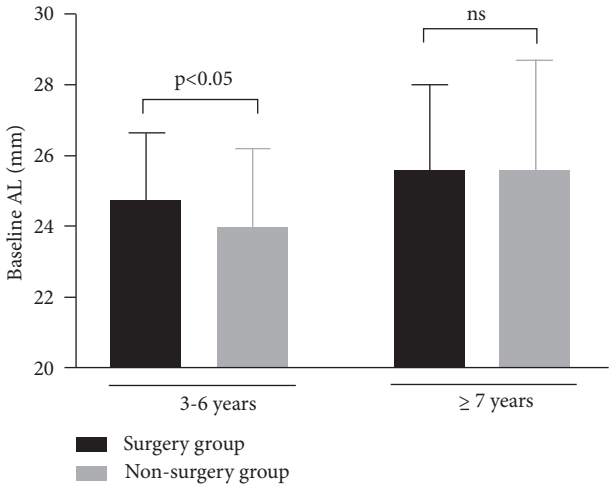

Figure 2: Comparison of the baseline axial length in the surgery group and the nonsurgery group of CEL patients.

axial growth in early years of life [17]. As the patient gets older, the development of axial length slows and stabilizes and the influence of lens dislocation decreases.

To explore the associated factors of AL changing in CEL patients who undergo surgery, several potential associated factors were also analyzed in this study and age and baseline BCVA were identified as factors that affect the AL elongation. For healthy children, a number of different factors including the age [17], gender [18], and BMI [19] have been identified as factors having the potential to affect the rate of AL growth. Previous studies also showed that the longitudinal growth of the AL can be divided into 3 growth periods: a rapid postnatal phase with an increase in length of 3.7–3.8 mm in the first year and a half, followed by a slower infantile phase from the 2nd to the 5th year of life with an increase in length of 1.1–1.2 mm, and finally by a slow juvenile phase lasting until the age of 13 years, with an increase of 1.3–1.4 mm [17]. For patients who had undergone surgery, our results indicated that participants with older age demonstrated a smaller degree of axial length elongation after adjusting for age and gender. This may help further verify the conclusions of previous studies that younger children were shown to undergo faster rates of axial elongation [20–22]. In addition, we found that a better postoperative BCVA was negatively associated with the AL change rate after IOL implantation. The association between BCVA (log MAR) and AL has not been widely studied. However, animal experiments showed that the visual deprivation could result in an elongation of AL and a myopic shift in the refractive state [23]. And previous studies also showed that alterations of the visual input in early life could affect axial growth of the ocular in experimental animals, and neural factors evoked by abnormal visual experience are thought to influence the growth of the posterior segment of the ocular [24].

For the nonsurgery group, multivariate analyses showed that the factors associated with the AL change rate were younger age and a longer baseline AL. It has been well demonstrated that the growth rate of the eyeball is most rapid in the first 3 to 4 years of life; then, the subsequent annual increase in length appears to be slight [17]. In Japanese youth (7 to 21 years old) with myopia, the AL elongation rate decreased with age, especially in the group older than 15 years [25]. Our results was similar to a previous study [26] conducted by Li et al. in Shanghai, which showed that AL elongation was associated with a longer AL at baseline. Thus, the baseline AL may provide a predictive factor in the axial length change in CEL patients.

Our result indicated that for patients aged 3 to 6 years, the baseline AL in the surgery group were longer than that in the nonsurgery group. In addition, the surgery group had worse BCVA than the nonsurgery group. However, for patients 7 years or older, both the baseline AL and BCVA were comparable between the surgery group and the nonsurgery group. The differences of the baseline AL and BCVA in patients aged 3–6 years between the surgery group and the nonsurgery group were probably due to the surgical criteria. As a previous study [27] reported, CEL can be managed with conservative treatments such as spectacle or contact lens correction when symptoms are mild. However, for those

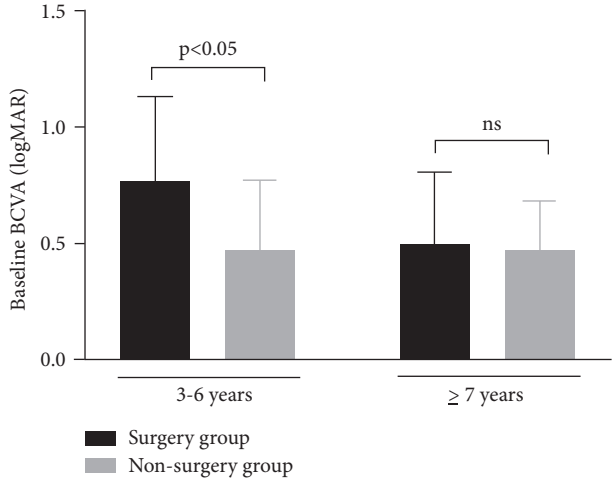

Figure 3: Comparison of baseline best-corrected visual acuity in the surgery group and the nonsurgery group of CEL patients.

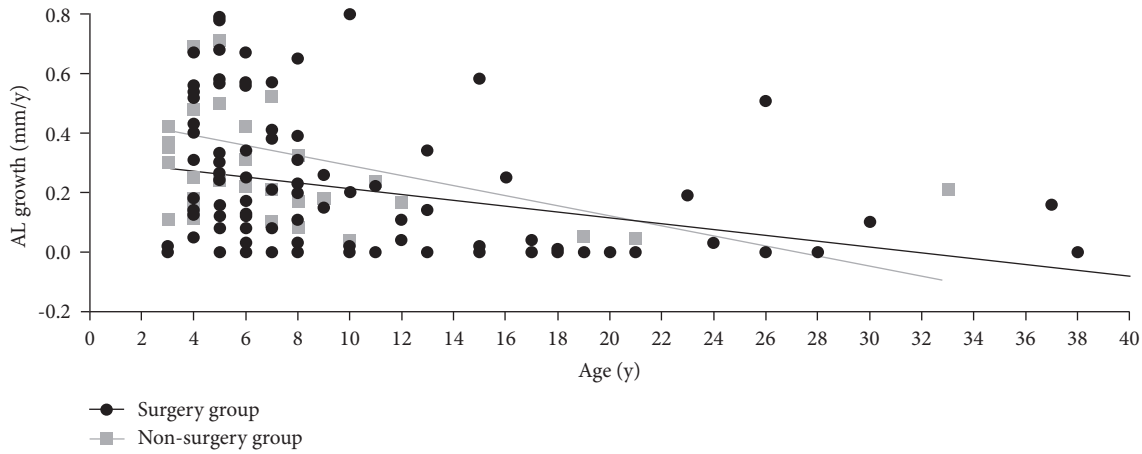

Figure 4: Scatter plot between the growth rate of axial length and age in the surgery group and the nonsurgery group of CEL patients.

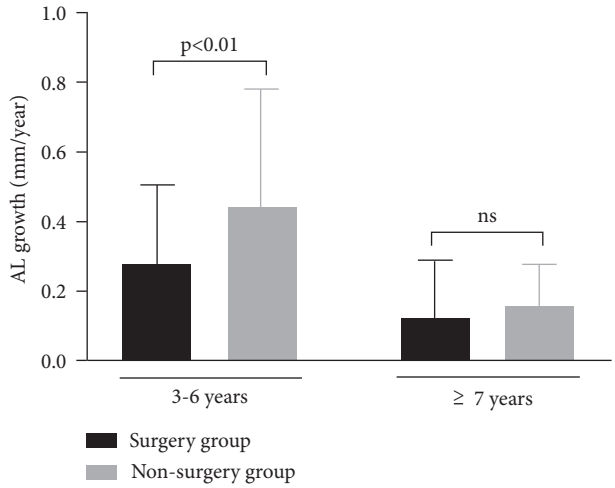

Figure 5: Comparison of the growth rate of axial length in the surgery group and the nonsurgery group of CEL patients.

Table 3: Potential associated factors for axial length growth in CEL patients.

	Surgery group				Nonsurgery group			
	Univariate regression		Multiple regression		Univariate regression		Multiple regression	
	β (95% CI)	P	β (95% CI)	P	β (95% CI)	P	β (95% CI)	P
Female	−0.046 (−0.136, 0.044)	0.310	—	—	0.065 (−0.118, 0.248)	0.475	—	—
Age (years)	−0.008 (−0.013, −0.003)	0.001*	−0.009 (−0.014, −0.003)	0.002*	−0.016 (−0.031, −0.002)	0.029*	−0.027 (−0.048, −0.007)	0.01*
AL (mm)	0.007 (−0.011, 0.025)	0.441	—	—	0.078 (0.037, 0.118)	<0.001*	0.073 (0.023, 0.122)	0.006*
IOP (mmHg)	0.000 (−0.012, 0.013)	0.944	—	—	−0.041 (−0.080, −0.003)	0.036*	−0.031 (−0.064, 0.001)	0.060
BCVA (logMAR)	0.181 (0.012, 0.352)	0.036*	0.256 (0.072, 0.439)	0.007*	0.366 (0.114, 0.618)	0.006*	—	—
CCT (mm)	0.001 (−0.001, 0.001)	0.426	0.001 (−0.001, 0.002)	0.080	—	—	—	—
SE (D)	−0.007 (−0.018,0.003)	0.174	—	—	−0.009 (−0.021, 0.002)	0.117	—	—
Km (D)	−0.003 (−0.025, 0.019)	0.801	—	—	−0.014 (−0.071, 0.043)	0.622	0.038 (−0.018, 0.094)	0.175

Surgery group: AL, IOP, BCVA (logMAR), CCT, SE, and Km were detected at baseline; nonsurgery group: AL, IOP, BCVA (logMAR), CCT, SE, and Km were performed at 3 months after operation.

with severe complications, surgery would be a better treatment strategy for patients to achieve a better visual acuity. As previously discussed, significant changes in AL usually occur in CEL patients during the early period of eyeball development.

The limitations of this study are as follows: Firstly, bias may exist, for not all the patients could be reviewed consistently on a consistent follow-up schedule. Secondly, although a number of factors have been taken into consideration, some potential associated factors for AL changing were not included for analysis, which may affect the accuracy of the conclusion to some extent. Despite these limitations, this longitudinal study with a large sample size for a rare disease offers a view of evaluating and comparing an AL change between different treatment strategies and these findings could provide useful information for the treatment and management of CEL.

5. Conclusions

In conclusion, our results suggested that surgical treatment had an obvious effect on curbing the AL elongation during the early period (3–6 years old) of eyeball development, but little influence was observed when patients were older than 7 years of age. For younger patients who met the surgical criteria, surgery should be performed earlier to promote a normal development of AL. For CEL patients, regular follow-up should be emphasized especially for those with a longer AL, younger age, and worse BCVA.

Data Availability

Data are available upon reasonable request.

Ethical Approval

The study was approved by our ethics committee and adhered to the tenets of the Declaration of Helsinki.

Consent

Informed consent was obtained from all participants included in the study.

Conflicts of Interest

The authors declare that there are no conflicts of interest.

Authors' Contributions

GM Jin and DY Zheng designed the study, initiated the collaborative project, and revised the paper; JX He and ZK Lian performed data acquisition and data analysis/interpretation, and drafted the manuscript; QZ Cao, ZZ Liu, and CA Young cleaned and analyzed the data; XY Zhang, DY Zheng, and GM Jin were responsible for administrative, technical, or logistic support; DY Zheng and GM Jin approved the manuscript. Jingxin He and Zhangkai Lian contributed equally to this work.

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References

[1] J. Fuchs and T. Rosenberg, "Congenital ectopia lentis a Danish national survey," *Acta Ophthalmologica Scandinavica*, vol. 76, no. 1, pp. 20–26, 1998.

[2] M. A. Sadiq and D. Vanderveen, "Genetics of ectopia lentis," *Seminars in Ophthalmology*, vol. 28, no. 5-6, pp. 313–320, 2013.

[3] S. K. McClatchey, E. Dahan, E. Maselli et al., "A comparison of the rate of refractive growth in pediatric aphakic and pseudophakic eyes," *Ophthalmology*, vol. 107, no. 1, pp. 118–122, 2000.

[4] K. Nb, P. Kohli, B. P. S. Pangtey, and K. Ramasamy, "Evaluation of sutureless, glueless, flapless, intrascleral fixated posterior chamber intraocular lens in children with ectopia lentis," *Journal of Ophthalmology*, vol. 2018, Article ID 3212740, 6 pages, 2018.

[5] Z. Zhang and S. Li, "The visual deprivation and increase in axial length in patients with cataracts," *Yan Ke Xue Bao*, vol. 12, no. 3, pp. 135–137, 1996.

[6] T. N. Wiesel and E. Raviola, "Myopia and eye enlargement after neonatal lid fusion in monkeys," *Nature*, vol. 266, no. 5597, pp. 66–68, 1977.

[7] E. D. Griener, E. Dahan, and S. R. Lambert, "Effect of age at time of cataract surgery on subsequent axial length growth in infant eyes," *Journal of Cataract & Refractive Surgery*, vol. 25, no. 9, pp. 1209–1213, 1999.

[8] Y. Zhang, G. Jin, Q. Cao et al., "Distribution of axial length in Chinese congenital ectopia lentis patients: a retrospective study," *BMC Ophthalmology*, vol. 17, no. 1, p. 113, 2017.

[9] J. Sridhar and J. S. Chang, "Marfan's syndrome with ectopia lentis," *New England Journal of Medicine*, vol. 377, no. 11, p. 1076, 2017.

[10] S. Rezar-Dreindl, E. Stifter, T. Neumayer, A. Papp, A. Gschliesser, and U. Schmidt-Erfurth, "Visual outcome and surgical results in children with marfan syndrome," *Clinical and Experimental Ophthalmology*, vol. 47, no. 9, pp. 1138–1145, 2019.

[11] M. Halpert and D. BenEzra, "Surgery of the hereditary subluxated lens in children," *Ophthalmology*, vol. 103, no. 4, pp. 681–686, 1996.

[12] A. Chandra and D. Charteris, "Molecular pathogenesis and management strategies of ectopia lentis," *Eye*, vol. 28, no. 2, pp. 162–168, 2014.

[13] S. Weiss and F. Schaeffel, "Diurnal growth rhythms in the chicken eye: relation to myopia development and retinal dopamine levels," *Journal of Comparative Physiology*, vol. 172, no. 3, pp. 263–270, 1993.

[14] L. Deng, J. Gwiazda, R. E. Manny et al., "Limited change in anisometropia and aniso-axial length over 13 years in myopic children enrolled in the correction of myopia evaluation trial," *Investigative Ophthalmology & Visual Science*, vol. 55, no. 4, 2014.

[15] Z. Chen, J. Zhou, X. Qu, X. Zhou, F. Xue, and Shanghai Orthokeratology Study Group, "Effects of orthokeratology on axial length growth in myopic anisometropes," *Contact Lens and Anterior Eye*, vol. 41, no. 3, pp. 263–266, 2018.

[16] P. E. Romano, N. C. Kerr, and G. M. Hope, "Bilateral ametropic functional amblyopia in genetic ectopia lentis: its relation to the amount of subluxation, an indicator for early surgical management," *Binocular Vision & Strabismus Quarterly*, vol. 17, no. 3, pp. 235–241, 2002.

[17] J. S. Larsen, "The sagittal growth of the eye. IV. Ultrasonic measurement of the axial length of the eye from birth to puberty," *Acta Ophthalmologica*, vol. 49, no. 6, pp. 873–886, 2009.

[18] K. Zadnik, R. E. Manny, J. A. Yu et al., "Ocular component data in school children as a function of age and gender," *Optometry and Vision Science*, vol. 80, no. 3, pp. 226–236, 2003.

[19] V. Nangia, J. B. Jonas, A. Sinha, A. Matin, M. Kulkarni, and S. Panda-Jonas, "Ocular axial length and its associations in an adult population of central rural India: the central India eye and medical study," *Ophthalmology*, vol. 117, no. 7, pp. 1360–1366, 2010.

[20] S. M. Saw, F. J. Nieto, J. Katz, O. D. Schein, B. Levy, and S. J. Chew, "Factors related to the progression of myopia in Singaporean children," *Optometry and Vision Science*, vol. 77, no. 10, pp. 549–554, 2000.

[21] D. S. P. Fan, D. S. C. Lam, R. F. Lam et al., "Prevalence, incidence, and progression of myopia of school children in Hong Kong," *Investigative Ophthalmology & Visual Science*, vol. 45, no. 4, p. 1071, 2004.

[22] P. Cho and S. W. Cheung, "Retardation of myopia in orthokeratology (ROMIO) study: a 2-year randomized clinical trial," *Investigative Ophthalmology & Visual Science*, vol. 53, no. 11, p. 7077, 2012.

[23] F. Schaeffel, E. Burkhardt, H. C. Howland, and R. W. Williams, "Measurement of refractive state and deprivation myopia in two strains of mice," *Optometry and Vision Science*, vol. 81, no. 2, pp. 99–110, 2004.

[24] A. V. Tkatchenko, P. A. Walsh, T. V. Tkatchenko, S. Gustincich, and E. Raviola, "Form deprivation modulates retinal neurogenesis in primate experimental myopia," *Proceedings of the National Academy of Sciences of the USA*, vol. 103, no. 12, pp. 4681–4686, 2006.

[25] M. Itoi and I. Motozumi, "Axial length elongation in Japanese youth with myopia," *Eye and Contact Lens: Science and Clinical Practice*, vol. 47, no. 2, pp. 104–107, 2021.

[26] T. Li, B. Jiang, and X. Zhou, "Axial length elongation in primary school-age children: a 3-year cohort study in Shanghai," *BMJ Open*, vol. 9, no. 10, Article ID e029896, 2019.

[27] A. D. Hubbard, D. G. Charteris, and R. J. Cooling, "Vitreolensectomy in marfan's syndrome," *Eye*, vol. 12, no. 3, pp. 412–416, 1998.

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Research Article

A Prospective Comparative Study between Implantable Phakic Intraocular Contact Lens and Implantable Collamer Lens in Treatment of Myopia in Adults

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Purpose. To compare implantable collamer lenses (ICLs) and acrylic implantable phakic contact lenses (IPCLs) in the treatment of myopia in adults, as regards refractive outcome and adverse effects. *Methods*. Prospective, randomized comparative study with phakic intraocular lenses (IOLs) was carried out for treatment of myopia. Patients were randomized into two groups: one for ICL and the other for IPCL. Preoperative assessments included a full examination, pentacam, endothelial cell count, and biometry. We compared the adverse effects and refractive outcomes between both groups. The study was registered in clinical trials and the registration number is NCT04624035. *Results*. Sixty eyes of sixty patients (28 in the ICL group and 32 in the IPCL group) with a follow-up period of 12 months. The mean preoperative spherical equivalent was -12.7 ± 3.4 D and -13.6 ± 4.4 D in the ICL and IPCL groups, respectively ($P = 0.37$). The mean postoperative spherical equivalent value was $\pm 0.4 \pm 0.2$ D and $\pm 0.6 \pm 0.1$ D in the ICL and IPCL groups, respectively. Uncorrected visual acuity (UCVA) has improved from 1.3 ± 0.06 to 0.15 ± 0.02 Log MAR in the ICL group ($P < 0.001$) and from 1.3 ± 0.02 to 0.15 ± 0.01 Log MAR in the IPCL group ($P < 0.001$). The mean endothelial cell count was reduced by 3.3% in the IPCL group and by 3.2% in the IPCL group. *Conclusion*. Both ICL and IPCL are effective methods to correct high myopia in adults with no statistically significant differences between the two lenses as regarding adverse effects.

1. Introduction

Phakic intraocular lenses (pIOLs) of different designs and materials have been used effectively instead of corneal refractive surgery in certain situations [1]. Moreover, the pIOL exhibits several advantages, as it is suitable for high myopia, with lower production of aberrations and superior contrast sensitivity [2–4]. Ordinarily, keeping accommodation is its definite advantage [5].

The Visian implantable collamer lens (ICL; Staar Surgical, Monrovia, CA), a posterior chamber pIOL, has been shown to be useful for the correction of high myopia [4–6]. Nevertheless, as an intraocular procedure, it is associated with a risk of complications such as probable injury to the anterior segment, retinal detachment, and endophthalmitis [7].

The implantable phakic contact lens (IPCL V2, Care Group Sight Solutions, India) has been developed as an alternative to ICL, with a noticeable financial advantage. Furthermore, the ICL has a power range up to −18.0 D, while the IPCL is available up to −30 D [8].

Previous studies have assessed the safety and efficiency of ICL implantation [1, 2, 4, 5, 9]. Other studies evaluated various devices for anterior segment imaging postoperatively and identified changes in the anterior segment after surgery [6, 10, 11]. A study determined the safety of IPCL over a minimum follow-up period of 1 year [8]. In this study, we aimed to compare the refractive results and

adverse effects of IPCL and ICL in the treatment of myopia in adults.

2. Patients and Methods

This is a prospective, randomized, comparative study of myopic patients assigned for pIOL implantation. The study was approved by the Institutional Review Board of Assiut University, Egypt. Written informed consent was obtained from all patients. All procedures were performed according to the guidelines of the Declaration of Helsinki and its updates. The trial was registered in Clinical Trials. Its registration number is NCT04624035 [12].

This study was conducted at three private centers: Tiba Eye Center, Assiut, Egypt; Masa Eye Center, Benha, Egypt; and Alpha Vision Center, Zagazig, Egypt. Patients were recruited started in September 2020.

The study included 60 eyes of 60 patients who underwent pIOL implantation for correction of myopia. Inclusion criteria were age over 18 years with at least one year of stable refraction, myopia of more than six diopters, refractive astigmatism within three diopters with no other ocular or systemic disease, central anterior chamber depth (ACD) >2.8 mm (measured from the corneal endothelium to the anterior lens capsule), and an endothelial cell count ≥3000 cell/mm2. We included one eye from each patient for statistical purposes. Eyes were randomized by the sealed envelope method into two groups: the ICL group with ICL-implanted and the IPCL group with IPCL implanted. We offered the patient two sealed envelopes, and the patient chose one. The specifications of both ICL and IPCL, as found in the manufacturer's brochure, are listed in Table 1.

2.1. Preoperative Assessments. First, a full ophthalmic examination, pentacam, and biometry were performed. Essential measurements for pIOL implantation were performed by an experienced surgeon. Then, anterior segment ocular coherent tomography (OCT) was used to measure internal ACD and confirmed by IOL Master ACD with consideration of corneal thickness. The IOL calculation was performed according to the manufacturer's guidelines. ICL power was calculated using the modified vertex formula. Meanwhile, IPCL power was calculated using the online IPCL calculator. The size of the pIOL was selected according to WTW and ACD.

Refraction was measured objectively using an autorefractometer (Topcon KR-800, Japan), then refined to the BCVA subjectively using the trial frame. For statistical purposes, visual acuity was transformed to Log MAR. Endothelial cell counts were performed preoperatively using a specular microscope, CEM-530 (Nidek, Aichi, Japan). Intraocular pressure (IOP) was measured using an air puff tonometer (Topcon, CT-80, Japan) and was noted as normal (8–21 mmHg), low (below 8 mmHg), or high (above 21 mmHg).

2.2. Surgical Procedures

2.2.1. ICL Group. After mydriatic eye drops and topical anesthesia instillation, a 3-mm temporal corneal incision was made. The viscoelastic material was injected into the anterior chamber (AC). An injector cartridge (STAAR Surgical) was used to insert the ICL V4c model with a central hole. The four footplates of the ICL were positioned on the ciliary sulcus along the 180° axis. The viscoelastic material was removed entirely.

2.2.2. IPCL Group. Topical anesthetics and mydriatic agents were administered before surgery. The IPCL (V2 model with a central hole) was implanted into the AC through a 3 mm clear corneal incision after viscoelastic material injection. Consequently, the footplates were tucked behind the iris, followed by a thorough viscoelastic removal.

2.3. Postoperative Care and Follow-Up. Postoperatively, tobramycin 0.3% dexamethasone 0.1% (Tobradex) and moxifloxacin 0.5% (Vigamox) eye drops were administered topically three times daily for 2 weeks. Patients were followed up on the first day, first week, and every two months for 12 months. Specular microscopy was performed 12 months postoperatively. We compared the adverse effects and refractive outcomes between the groups.

2.4. Statistical Analysis. The data were examined, coded by the researchers, and analyzed with SPSS version 21 (IBM, Armonk). Descriptive statistics such as means, standard deviations, medians, ranges, and percentages were calculated. Test of significance: the chi-square test was used to compare the difference in the distribution of frequencies among different groups. For continuous variables, an independent t-test analysis was carried out to compare the means of normally distributed data. A paired sample t-test analysis was performed to compare the means of the repeated measure data. For repeated analysis of more than two intervals, repeated measures ANOVA was performed. Statistical significance was set at $P \leq 0.05$.

3. Results

This study included 60 eyes of 60 patients randomized into two groups: the ICL group, 28 eyes of 28 patients with ICL implanted, and the IPCL group, 32 eyes of 32 patients with acrylic IPCL implanted. The mean age of the patients was 24.71 ± 3.3. Females accounted for 73.3% of the cases. The mean preoperative refractive error was −13.17 ± 3.9, diopters of myopia and −2.04 ± 0.9 diopters of astigmatism. The mean preoperative UCVA and the mean preoperative best corrected visual acuity (BCVA) were 1.3 ± 0.02 and 0.2 ± 0.01 LogMAR, successively (Table 2). There was no statistically significant difference between the ICL and IPCL groups in terms of age, sex, preoperative refractive error, and preoperative visual acuity (Table 2).

Table 1: Specification of ICL and IPCL.

	ICL	IPCL
Material	Hydrophilic copolymer (collamer)	Reinforced acrylic with medium water content
Design	Plate haptic	Plate haptic
Vault	Central anterior	Central anterior
Optic hole	Central	Central and 2 others
Optic diameter	4.9–5.8 mm	6.2 mm
Widest length	12.1, 12.6, 13.2, and 13.7 mm	11–14 mm (in 0.25 mm steps)
Power range	−3.0 to −18.0 diopter	−3.0 to −30.0 diopter
Manufacturer	STAAR, Nidau, Switzerland	Care Group, Baroda, India

Table 2: Baseline data comparisons between the study groups.

	ICL ($n = 28$)	IPCL ($n = 32$)	Pvalue
Age/years	25.14 ± 3.6	23.94 ± 2.7	0.154
Sex			
(i) Male	8 (28.6%)	8 (25%)	
(ii) Female	20 (71.4%)	24 (75%)	0.438
Eye			
(i) Od	16 (57.1%)	14 (43.8%)	0.219
(ii) OS	12 (42.9%)	18 (56.2%)	
Refraction at baseline			
(i) Sphere	−12.7 ± 3.4	−13.6 ± 4.4	0.368
(ii) Astigmatism	−2.3 ± 1.2	−1.8 ± 0.7	0.071
Visual acuity at baseline			
(i) UCVA in LogMAR	1.3 ± 0.06	1.3 ± 0.02	0.732
(ii) BCVA in LogMAR	0.2 ± 0.03	0.2 ± 0.03	0.969

As for the mean refractive error in both groups, there was a significant reduction in postoperative myopia and astigmatism. There was no statistically significant difference between refraction in the ICL and IPCL groups at all postoperative visits (Table 3). The UCVA and BCVA improved significantly in the postoperative visits compared with the preoperative UCVA and BCVA. There was no statistically significant difference between UCVA and BCVA in the ICL and IPCL groups at all postoperative visits (Table 4).

The mean endothelial cell count was reduced by 3.3% and 3.2% in the IPCL and ICL groups, respectively, with no significant difference between the two groups.

As for complications, one case in the IPCL group showed lens opacity, which did not affect the final UCDVA. None of the patients had an elevated IOP.

4. Discussion

Posterior chamber phakic intraocular lens implantation shows several advantages over keratorefractive methods for high myopic correction. This procedure provides better optical results, and there is no risk of regression. However, this technique is invasive, with increased susceptibility to complications such as cataracts, infections, and endothelial cell loss.

The use of the ICL is restricted by its increased cost, especially in developing countries. Conversely, the IPCL is a feasible alternative for refractive correction [13]. Accordingly, we conducted this study to compare the outcomes of acrylic IPCL and ICL as options for the management of high myopia. We implanted ICLs in 28 eyes and IPCLs in 32 eyes. We followed our cases for 12 months. Both ICL and IPCL were found to be able for correcting high myopia.

Developing cataracts and elevated IOP are the most frequently recorded complications associated with phakic PCIOL implantation [7]. In our study, one case in the IPCL group showed demonstrable lens opacity, which did not influence the final UCVA. This is better than the previously reported results of Sachdev et al., who used non-holed IPCL [8]. The advantage of Hole ICL, which may decrease the risk of cataract formation, is the possible circulation of the aqueous humor through the hole, reducing the risk of lens malnutrition [14].

None of our patients had an elevated IOP during the follow-up period as holed ICLs and holed IPCLs were used. In the implantation of conventional ICLs, surgeons perform preoperative Nd: YAG iridectomies to minimize increases in the IOP [15]. This procedure is commonly accompanied by pain, especially in young patients, or with intraoperative iris hemorrhage and increased IOP. However, the central hole in the optic of the V4c Visian ICL and V2 IPCL permits near-normal aqueous humor circulation, and Nd: YAG iridotomies are not required [16].

Endothelial cell loss was 3.3% in the IPCL group and 3.2% in the ICL group, with no significant difference between the two groups. This is comparable to previously published data, with a mean ECD loss ranging from 0.3% to 7.8% in the previous studies [8, 17–19].

Table 3: Preoperative, 1, 3, 6, and 12-months postoperative refraction in eyes undergoing implantable ICL vs. IPCL.

		ICL ($n = 28$)	IPCL ($n = 32$)	P1 value
Refraction				
(i) Sphere	(1) Preoperative	-12.7 ± 3.4	-13.6 ± 4.4	0.368
	(2) 1 month	0.1 ± 0.1	0.5 ± 0.1	0.221
	(3) 3 months	-0.2 ± 0.2	-0.2 ± 0.1	0.669
	(4) 6 months	-0.6 ± 0.2	-0.7 ± 0.1	0.338
	(5) 12 months	-0.4 ± 0.2	-0.6 ± 0.1	0.167
P2 value		<0.001*	<0.001*	
(ii) Astigmatism	(1) Preoperative	-2.3 ± 1.2	-1.8 ± 0.7	0.071
	(2) 1 month	-1.6 ± 0.1	-1.4 ± 0.1	0.168
	(3) 3 months	-1.5 ± 0.1	-1.4 ± 0.1	0.195
	(4) 6 months	-1.4 ± 0.1	-1.4 ± 0.1	0.208
	(5) 12 months	-1.4 ± 0.1	-1.3 ± 0.1	0.221
P2 value		=0.002*	=0.013*	

P1 between the two groups; P2 between preoperative and postoperative visits.

Table 4: Preoperative vs. postoperative patient's visual activity in eyes undergoing implantable ICL vs. IPCL.

		ICL ($n = 28$)	IPCL ($n = 32$)	P1 value
Visual acuity in LogMAR				
(i) UCVA	(1) Preoperative	1.3 ± 0.06	1.3 ± 0.02	0.732
	(2) Postoperative	0.76 ± 0.2	0.74 ± 0.1	0.793
P2 value		<0.001*	<0.001*	
(ii) BCVA	(1) Preoperative	0.2 ± 0.03	0.2 ± 0.03	0.969
	(2) Postoperative	0.15 ± 0.01	0.15 ± 0.01	0.600
P2 value		<0.001*	<0.001*	

P1 between the two groups; P2 between preoperative and postoperative visits.

In this study, a significant reduction in myopia and astigmatism was observed postoperatively, with no statistically significant difference between the refraction in the ICL and IPCL groups. Significant improvement in UCVA and BCVA was detected postoperatively, with no significant difference between the two groups. This is in line with the results reported by Sachdev, GS, and associates. They retrospectively investigated eyes that underwent phakic IPCL or ICL implantation with a minimum follow-up period of 1 year [13].

This study has some limitations. The small sample size may have been inadequate to achieve statistically significant differences between the two groups for each IOL. However, the small differences between groups for outcome measures suggests this limitation did not affect the overall study results. Another limitation is that the quality of vision was not measured, which may have been able to detect any differences in optical quality between IOLs. A study with a longer follow-up (3–5 years) is required to monitor the incidence of posterior capsule opacification in both phakic IOLs.

We concluded that both ICL and IPCL are effective tools for the management of high myopia in adults. After 12 months of follow-up, there were no statistically significant differences between the two lenses in terms of efficacy and complications.

Data Availability

The data used to support the findings of this study are available from the corresponding author upon request.

Ethical Approval

All procedures in this study were approved by the Assuit University Research Ethics Committee and with the 1964 Declaration of Helsinki and its later revisions.

Consent

Informed consent was obtained from all participants included in this study.

Conflicts of Interest

All the authors have no conflicts of interest.

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References

[1] R. D. Stulting, M. E. John, R. K. Maloney et al., "Three-year results of artisan/verisyse phakic intraocular lens implantation results of the United States food and drug administration clinical trial," *Ophthalmology*, vol. 115, no. 3, pp. 464–472, 2008.

[2] K. Kamiya, A. Igarashi, K. Shimizu, K. Matsumura, and M. Komatsu, "Visual performance after posterior chamber phakic intraocular lens implantation and wavefront-guided laser in situ keratomileusis for low to moderate myopia,"

American Journal of Ophthalmology, vol. 153, no. 6, pp. 1178–1186, 2012.

[3] D. Sanders and J. A. Vukich, "Comparison of implantable collamer lens (ICL) and laser-assisted in situ keratomileusis (LASIK) for low myopia," *Cornea*, vol. 25, no. 10, pp. 1139–1146, 2006.

[4] A. Igarashi, K. Kamiya, K. Shimizu, and M. Komatsu, "Visual performance after implantable collamer lens implantation and wavefront-guided laser in situ keratomileusis for high myopia," *American Journal of Ophthalmology*, vol. 148, no. 1, pp. 164–170, 2009.

[5] A. Pineda-Fernández, J. Jaramillo, J. Vargas, M. Jaramillo, J. Jaramillo, and A. Galíndez, "Phakic posterior chamber intraocular lens for high myopia," *Journal of Cataract and Refractive Surgery*, vol. 30, no. 11, pp. 2277–2283, 2004.

[6] M. N. Elmohamady and W. Abdelghaffar, "Anterior chamber changes after implantable collamer lens implantation in high myopia using pentacam: a prospective study," *Ophthalmology and Therapy*, vol. 6, no. 2, pp. 343–349, 2017.

[7] P. Fernandes, J. M. González-Méijome, D. Madrid-Costa, T. Ferrer-Blasco, J. Jorge, and R. Montés-Micó, "Implantable collamer posterior chamber intraocular lenses: a review of potential complications," *Journal of Refractive Surgery*, vol. 27, no. 10, pp. 765–776, 2011.

[8] G. Sachdev and D. Ramamurthy, "Long-term safety of posterior chamber implantable phakic contact lens for the correction of myopia," *Clinical Ophthalmology*, vol. 13, pp. 137–142, 2019.

[9] Y. Ju, X. W. Gao, and B. Ren, "Posterior chamber phakic intraocular lens implantation for high myopia," *International Journal of Ophthalmology*, vol. 6, no. 6, pp. 831–835, 2013.

[10] J. Zhang, H. H. Luo, J. Zhuang, and K. M. Yu, "Comparison of anterior section parameters using anterior segment optical coherence tomography and ultrasound biomicroscopy in myopic patients after ICL implantation," *International Journal of Ophthalmology*, vol. 9, no. 1, pp. 58–62, 2016.

[11] X. Chen, H. Miao, R. K. Naidu, X. Wang, and X. Zhou, "Comparison of early changes in and factors affecting vault following posterior chamber phakic implantable collamer lens implantation without and with a central hole (ICL V4 and ICL V4c)," *BMC Ophthalmology*, vol. 16, no. 1, p. 161, 2016.

[12] https://www.clinicaltrials.gov/ct2/show/NCT04624035.

[13] G. Sachdev, S. Singh, S. Ramamurthy, N. Rajpal, and R. Dandapani, "Comparative analysis of clinical outcomes between two types of posterior chamber phakic intraocular lenses for correction of myopia and myopic astigmatism," *Indian Journal of Ophthalmology*, vol. 67, no. 7, p. 1061, 2019.

[14] K. Kamiya, K. Shimizu, A. Saito, A. Igarashi, and H. Kobashi, "Comparison of optical quality and intraocular scattering after posterior chamber phakic intraocular lens with and without a central hole (Hole ICL and Conventional ICL) implantation using the double-pass instrument," *PLoS One*, vol. 8, no. 6, Article ID e66846, 2013.

[15] C. A. Sánchez-Galeana, D. Zadok, M. Montes, M. A. Cortés, and A. S. Chayet, "Refractory intraocular pressure increase after phakic posterior chamber intraocular lens implantation," *American Journal of Ophthalmology*, vol. 134, no. 1, pp. 121–123, 2002.

[16] T. Huseynova, S. Ozaki, T. Ishizuka, M. Mita, and M. Tomita, "Comparative study of 2 types of implantable collamer lenses, 1 with and 1 without a central artificial hole," *American Journal of Ophthalmology*, vol. 157, no. 6, pp. 1136–1143, 2014.

[17] J. F. Alfonso, B. Baamonde, L. Fernández-Vega, P. Fernandes, J. M. González-Méijome, and R. Montés-Micó, "Posterior chamber collagen copolymer phakic intraocular lenses to correct myopia: five-year follow-up," *Journal of Cataract and Refractive Surgery*, vol. 37, no. 5, pp. 873–880, 2011.

[18] J. Lee, Y. Kim, S. Park et al., "Long-term clinical results of posterior chamber phakic intraocular lens implantation to correct myopia," *Clinical and Experimental Ophthalmology*, vol. 44, no. 6, pp. 481–487, 2016.

[19] K. Shimizu, K. Kamiya, A. Igarashi, and H. Kobashi, "Long-Term comparison of posterior chamber phakic intraocular lens with and without a central hole (hole ICL and conventional ICL) implantation for moderate to high myopia and myopic astigmatism," *Medicine*, vol. 95, no. 14, Article ID e3270, 2016.

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Research Article

Myopic Correction with Iris-Fixated Phakic Intraocular Lenses: Twelve-Year Results

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Purpose. To evaluate a 12-year follow-up of myopic patients after iris-fixated phakic intraocular lenses (IF pIOLs) implantation. *Setting*. Ophthalmology Department, Military University Hospital in Prague (Czech Republic). *Design*. Single-center retrospective cohort study. *Methods*. We describe the results of a cohort study that included 85 eyes of 46 myopic patients who underwent implantation of Verisyse myopia, Veriflex, and Verisyse myopia toric (all Abbott Medical Optics, Inc.) intraocular lenses. Refractive functions and adverse events were assessed preoperatively, at 6 months, and 1, 2, 5, and 12 years after IF pIOL implantation. *Results*. Mean spherical equivalent was measured as -9.37 ± 2.87 D, 0.14 ± 0.61 D, and -0.42 ± 1.08 D, preoperatively, at 6 months and 12 years postoperatively, respectively. There was a significant reduction in the cylinder after surgery. At 12 years postoperatively, 90% of eyes had uncorrected distance visual acuity (UDVA) of 20/40 and 64% of 20/20. The safety index was 1.10 for the whole postoperative follow-up period. We found cataract formation in 3 eyes (3.5%). The endothelial cells loss (EC loss) directly caused by IF pIOL implantation was 6.0%, 8.10%, 12.8%, and 11.9%, at 1, 2, 5, and 12 years, respectively. In our cohort, 95% of eyes lost a higher percentage of EC than would be expected from a physiological loss at 12 years postoperatively. We found a significant negative interaction between preoperative pachymetry and EC loss, indicating that the lower pachymetry leads to a faster decline in endothelial cells density (ECD). IF pIOL re-enclavation was found in 28% of eyes. 7% of subluxations were caused by trauma. The mean time of nontraumatic re-enclavation was 6 years postoperatively. *Conclusions*. The study confirmed the advantages of IF pIOL implantation due to rapid visual recovery and stable visual function over the 12-year follow-up and also showed the influence of lower corneal pachymetry regarding EC loss.

1. Introduction

Phakic intraocular lens (pIOL) implantation has been a powerful solution for moderate and high myopia for more than 30 years. It helps patients who may have some contraindication to excimer laser surgery to be glasses independent. The first models of the pIOLs implanted in the 1980s and 1990s were angle-supported anterior chamber pIOLs. Because of unacceptable complication rate, especially corneal endothelial cells loss (EC loss) from the pIOL's proximity to the corneal endothelium, they were consequently removed from the market.

EC loss was also the problem with the Worst–Fechner iris-fixated IOLs (IF pIOLs), a coplanar single-piece PMMA pIOLs that were enclavated in the folds of midperipheral iris stroma, a relatively immobile portion of the iris. The first implantation of IF pIOL in myopic patient occurred in 1986. By the end of the 1990s, a newly designed, safer model of PMMA IF anterior chamber pIOLs was introduced. First, a foldable single-piece Artisan (Ophtec BV)/Verisyse (Abbott Medial Optics, Inc.) made from Perspex CQ-UV appeared on the market. Subsequently, a foldable variant of an IF anterior chamber pIOL Artiflex (Ophtec BV)/Veriflex (Abbott Medial

Optics, Inc.) composed of hydrophobic polysiloxane was designed. The optic vault measured approximately 0.87 mm anterior from the iris and provided good clearance for the anterior lens capsule and the endothelium of the cornea [1–3].

During the past 10 years, several long-term reports about IF pIOLs were published. The EC loss and cataract formation were found to be more frequent than under physiological conditions. Detection of basic risk factors showed to be important for correct indication and minimization of postoperative complications. Most of the publications reported 5-year results [4–8], but only a few of them spanned more than 10 years [9–15]. In this paper, we show our results of a 12-year follow-up of myopic patients cohort after implantation of Verisyse myopia, Verisyse myopia toric, and Veriflex pIOL (Abbott Medical Optics, Inc.) lenses.

2. Patients and Methods

2.1. Study Design. We describe the results of our cohort study that includes a group of 85 eyes in 46 myopic patients, 13 men (28%) and 33 women (72%). The patients underwent implantation of IF pIOLs from January 2005 to November 2010, and we were tracking their refractive results and complications over 12 years. All surgeries were performed by one surgeon in the Department of Ophthalmology, Military University Hospital, Prague (Czech Republic). The study was approved by the Medical Ethics Committee at University Medical Centre in accordance with tenets of the Declaration of Helsinki.

2.2. Inclusion and Exclusion Criteria. We strictly adhered to the following inclusion criteria. All patients had to be older than 18 years of age and their refractive error had to be stable at least for 1 year. The IF pIOL implantation was carried out only in patients where excimer laser surgery was not indicated for the correction of existing ametropia. We respected the following criteria in the operated eye: ECD (endothelial cells density) >2300 cells/mm^2, ACD (anterior chamber depth) from endothelium (the distance between endothelium and anterior surface of the clear lens) >2.9 mm, iridocorneal angle ≥30°, no anomaly of iris or pupil and mesopic pupil size <6 mm. One eye (1.2%) of 1 patient underwent a keratoplasty prior to pIOL implantation. Seven eyes (8.2%) in 5 patients had a previous scleroplasty procedure, and their refraction had been stable for more than 2 years before the IF pIOL was implanted. Preventative laser photocoagulation was carried out in one patient (2 eyes) to treat lattice degeneration to decrease the risk of retinal detachment.

As for exclusion criteria, we excluded glaucoma and IOP >21 mmHg, active disease in the anterior segment, recurrent or chronic uveitis, any form of cataract, preexisting macular pathology or abnormal retinal condition, as well as any systemic disease (autoimmune disorders, connective tissue disease, atopy, and diabetes mellitus) [1]. None of the patients had keratoconus.

2.3. Types of PIOLs, Power Calculation, and Surgical Technique. Three types of IF pIOLs were implanted. In myopic patients with the cylinder under 2 dioptres, we used the PMMA Verisyse myopia (Abbott Medical Optics, Inc.) in the period 2005–2008 and the foldable Veriflex pIOL (Abbott Medical Optics, Inc.) in the period 2008–2010, 40 eyes (57%) and 28 eyes (33%), respectively. In 17 eyes (20%), myopic eyes with cylinder higher than 2 dioptres PMMA Verisyse myopia toric (Abbott Medical Optics, Inc.) was implanted.

The pIOL power calculation was carried out before lens implantation. The commonly used IF pIOLs calculator worked with Van der Heijde nomogram [1]. It was based on keratometry, ACD, and the best spectacle correction and was axial length independent.

We proceeded with standard surgical technique as described by Güell et al. [1] based on the type of IF pIOL. In all cases, we used a scleral incision secured by an infinity suture in the end.

2.4. Outcome Measurements. Our data were collected preoperatively, at 6 months, and at 1, 2, 5, and 12 years after the IF pIOL implantation. All preoperative data are given in Table 1.

Firstly, we concentrated on refractive outcomes after IF pIOLs implantation. The objective refraction was measured out on the autorefractor (Nidek) and subjective refraction and visual acuity on the Snellen projection chart (Nidek). We compared preoperative corrected distance visual acuity (CDVA) with postoperative CDVA and uncorrected visual acuity (UCVA). We evaluated spherical equivalent (D) and cylinder (D) postoperatively and formed Efficacy Index (EI) and Safety Index (SI).

Secondly, we concentrated on intraocular pressure changes (measured by noncontact tonometer, Topcon) and adverse events after the IF pIOLs implantation, such as cataract formation, traumatic or spontaneous luxation, and subluxation. The latter was solved by reposition or reenclavation of IF pIOL. We checked for a presence of retinal detachment. Patients were also asked regarding subjective problems with glare and halo phenomena.

Thirdly, we focused on ECD and EC loss which was carried out by one type of endothelial microscope (CSO) during the whole period. We carefully observed baseline topometric parameters such as ACD, keratometry, pachymetry (Pentacam, Oculus), the axial length of the globe (IOL Master 500, Zeiss), and compared them with postoperative follow-up ECD to identify a possible cause of long-time EC loss.

2.5. Statistical Analysis. In the first step, we computed basic descriptive statistics of central tendency (mean, median, percentage), dispersion (variance, standard deviation), and shape (kurtosis, skewness) for all variables under study. A linear mixed-effects model was applied to study the longitudinal changes in refractive results, intraocular pressure, and EC loss. In these models, the repeated measures during the study period were nested within each eye, and an

Table 1: Baseline characteristics of patients.

Parameters at baseline	Mean ± SD [range]
No. of eyes	85
No. of patients	46
Age	29.3 ± 5.5 [18; 43]
Gender male/female (%)	28/72
Sphere (D)	9.37 ± 2.87 [−16.75; −2]
Cylinder (D)	1.37 ± 1.44 [0; 6,75]
CDVA, Snellen decimal scale	0.91 ± 0.17 [0.4; 1.13]
IOP (mmHg)	14.8 ± 3.0 [8.5; 22.5]
ACD from endothelium (mm)	3.30 ± 0.23 [2.75; 3.77]
Mean keratometry (D)	43.8 ± 1.6 [39.4; 47.1]
Mean axial length (mm)	26.99 ± 1.27 [24.99; 31.39]
Mean corneal pachymetry (μm)	521 ± 31,95 [453; 585]
ECD	2588 ± 285 [1481; 3215]
Type of implanted lens	*No.*
Verisyse (Abbott)	40
Verisyse Toric (Abbott)	17
Veriflex (Abbott)	28

SD: standard deviation; No.: number; D: dioptres; CDVA: corrected distance visual acuity; IOP: intraocular pressure; ACD: anterior chamber depth; ECD: endothelial cells density.

unstructured covariance matrix was used to model the relationships amongst the observed variables. We next extended the model by including time-invariant covariates (gender, degree of myopia, keratometry, ACD, pachymetry) to examine the effects of baseline "risk factors" on longitudinal changes in ECD. The level of statistical significance was set at $\alpha = 0.05$. Statistical analyses were performed using IBM SPSS version 25.0 (Chicago, IL).

3. Results

3.1. Refractive Results. The mean refractive spherical equivalent (MRSE) of cohort patients was −9.37 ± 2.87 [−16,75; −2] D and mean cylinder 1.37 ± 1.44 [0; 6.75] D. Postoperative MRSE and cylinder are shown in Table 2. Six months after the surgery, the refractive result was excellent, with MRSE in mild hyperopia, 0.14 ± 0.61 D. The MRSE was stable 1 year after the surgery, but between 2 years (−0.06 ± 0.67 D), 5 years (−0.34 ± 0.84 D), and 12 years (−0.42 ± 1.08 D) after the surgery, there was a statistically important shift into myopia, with p values of $p < 0.05$, $p < 0.01$, and $p < 0.05$, respectively.

There was a statistically significant reduction of cylinder 6 months after IF pIOL implantation, 0.70 ± 0.48 D ($p < 0.01$). The cylinder was stable 2 years after surgery. There was a statistically significant change 5 years after the surgery of 0.86 ± 0.51 D ($p < 0.05$). 12 years after the implantation, the cylinder was again without statistically significant changes compared to the previous value.

Uncorrected (UDVA) and corrected (CDVA) distance visual acuity, efficacy index (EI), and safety index (SI) are common parameters to assess the effect of the iris-claw IOLs implantation. Visual acuity was measured in the Snellen decimal scale and is summarized in Table 3. The results showed that the mean UDVA 6 months postimplantation (0.94 ± 0.15) was statistically significantly higher than mean CDVA (0.91 ± 0.17) before the surgery ($p < 0.05$). The mean postoperative CDVA (0.98 ± 0.12) was also statistically better than the mean preoperative CDVA values ($p < 0.01$). The follow-up mean CDVA results showed statistically significant improvement 5 years after the surgery, 1.00 ± 0.07 ($p < 0.05$). With respect to UDVA, we noted statistically significant worsening between 5 and 12 years after the surgery, 0.93 ± 0.17 and 0.86 ± 0.21, respectively ($p < 0.01$).

We had to proceed with excimer laser surgery (photorefractive keratectomy-PRK) for residual refractive error in 1 eye (1.2%), one year postoperatively. There was a progression of myopia >−1.0 D in 3 eyes (3.5%) of 2 patients.

Efficacy is commonly reported as the cumulative percentage of eyes within the visual acuity range [14, 16]. The pooled median of the percentage of myopic eyes with a UDVA 20/40 or better at 1, 2, 5, and 12 years was 99%, 98%, 96.0%, and 90%, respectively. The pooled median of the percentage of myopic eyes with a UDVA 20/20 or better at 1, 2, 5, and 12 years was 77%, 72%, 75%, and 64%, respectively (Figure 1). The Efficacy index (EI) reflects the ratio between preoperative CDVA and postoperative UDVA (mean postoperative UDVA)/(mean preoperative CDVA) [13]. The pooled median EI was 1.06, 1.03, 1.03, and 0.96 at 1, 2, 5, and 12 years after surgery, respectively (Table 4).

Safety is commonly reported as the change in visual acuity preimplantation vs. visual acuity postimplantation [14, 16]. In our series, 99%, 98%, 99%, and 99% of eyes had stable or gain in CDVA at 1, 2, 5, and 12 years after IF pIOL implantation (Figure 2). The Safety index (SI) is defined as the ratio of (mean postoperative CDVA)/mean preoperative CDVA) [4]. The pooled median SI at 1, 2, 5, and 12 years of follow-up was 1.10, 1.10, 1.10, and 1.10, respectively (Table 4).

3.2. Intraocular Pressure. The incidence of secondary angle-closed glaucoma (SACG) was 4.7% in the early postoperative period. Due to the intraocular pressure elevation, we had to enlarge iridotomies in 2 eyes (2.3%) of one patient just after the primary IF pIOL implantation and in one eye (1.2%) 2 months after the IF pIOL re-enclavation. One eye (1.2%) experienced an attack of acute pupillary block glaucoma on the first night after the surgery. Iridotomies had to be enlarged 20 hours after the surgery, but pupilloplegia remained. It was rectified later with a pupilloplasty procedure. There was no pigment dispersion glaucoma in our cohort.

From the long-time perspective, the patients remained without statistically significant changes in intraocular pressure after the IF pIOLs surgery. This is supported by the values before and 5 years after the implantation, of 14.8 ± 3.0 mmHg and 15.2 ± 3.0 mmHg, respectively ($p = 0.957$). All values are summarized in Table 5.

3.3. Adverse Events. High myopia is considered an important risk factor in peripheral retinal degeneration and the subsequent development of retinal detachment [17]. Prophylactic laser barrage treatment was used in 2 eyes (2.3%) of 1 patient. This method seems to be an effective way to prevent retinal detachment (RD) in these patients because 12

Table 2: Refractive results.

Time after the pIOL implantation	No. of eyes	Sphere (D)	p value	Cylinder (D)	p value
6 months	80	0.14 ± 0.61 [−1.5; 1]	<0.001	0.70 ± 0.48 [0; 2]	0.001
1 year	75	0.04 ± 0.67 [−2.0; 1.5]	0.139	0.64 ± 0.48 [0; 2]	0.623
2 years	61	−0.06 ± 0.67 [−2.25; 1.25]	0.019	0.72 ± 0.67 [0; 2]	0.304
5 years	60	−0.34 ± 0.84 [−3.5; 1.25]	0.001	0.86 ± 0.51 [0; 2]	0.019
12 years	42	−0.42 ± 1.08 [−5.5; 1.50]	0.024	0.87 ± 0.55 [0; 2.5]	0.425

No.: number; D: dioptres; p value: probability value.

Table 3: Postoperative visual acuity results (Snellen decimal scale).

Time after the pIOL implantation	No. of eyes	UDVA	p value	CDVA	p value
6 months	80	0.94 ± 0.15 [0.55; 1.25]	0.040	0.98 ± 0.12 [0.65; 1.25]	0.001
1 year	75	0.95 ± 0.15 [0.50; 1.25]	0.666	0.99 ± 0.10 [0.70; 1.25]	0.281
2 years	61	0.93 ± 0.13 [0.40; 1.00]	0.972	0.99 ± 0.07 [0.75; 1.25]	0.729
5 years	60	0.93 ± 0.17 [0.30; 1.10]	0.972	1.00 ± 0.07 [0.8; 1.25]	0.020
12 years	42	0.86 ± 0.21 [0.30; 1.05]	0.005	1.00 ± 0.06 [0.9; 1.25]	0.063

IF pIOL: iris-fixated phakic intraocular lens; UDVA: uncorrected distance visual acuity; CDVA: corrected distance visual acuity.

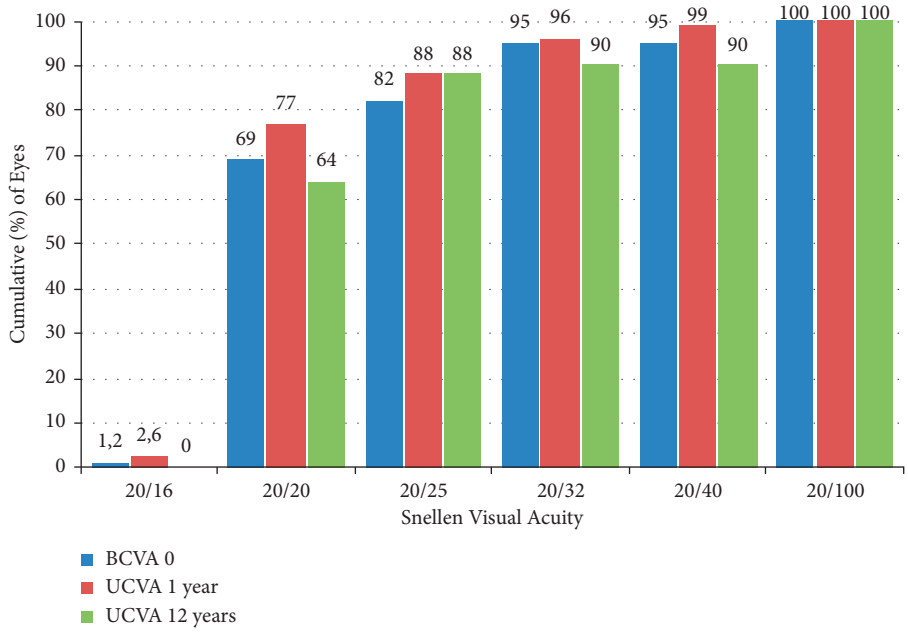

Figure 1: Cumulative distance visual acuity.

Table 4: Efficacy and safety indices.

Time (years after the implantation)	1	2	5	12
Efficacy indices (EI)	1.06	1.03	1.03	0.96
Mean postoperative UDVA/mean preoperative CDVA	—	—	—	—
Safety indices (SI)	1.10	1.10	1.10	1.10
Mean postoperative CDVA/mean preoperative CDVA	—	—	—	—

UCVA: uncorrected distance visual acuity; CDVA: corrected distance visual acuity.

years after surgery, we did not register any cases of this complication.

One of the most frequent complications was the improper position of the phakic intraocular lens in some cases. Repositioning of the IF pIOL may be necessary due to the inadequate surgical fixation or due to the inadequate fixation after trauma [14, 18]. Overall, IF pIOL reposition or re-enclavation had to be carried out in 24 eyes (28%) of 15

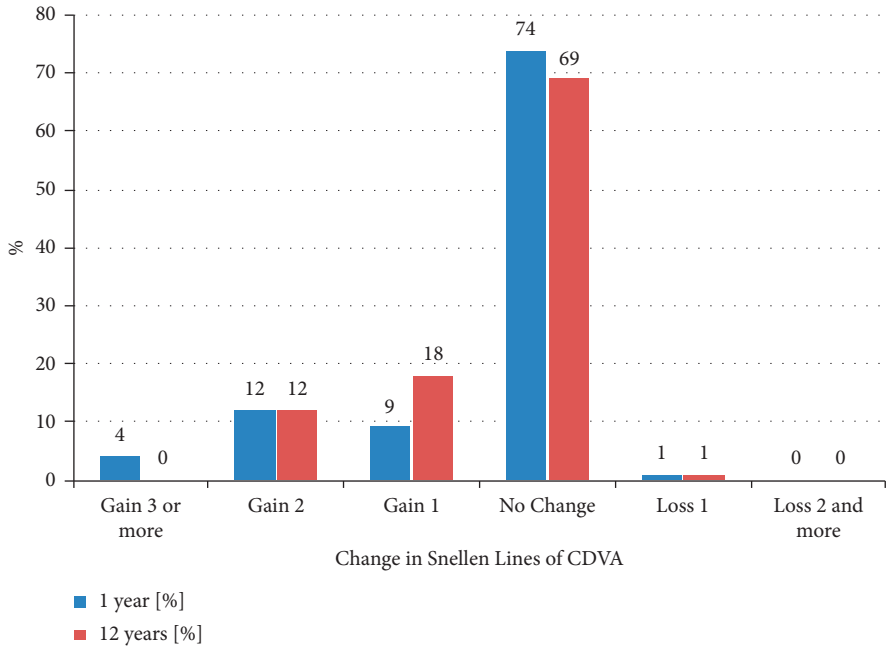

Figure 2: Change in corrected distance visual acuity.

Table 5: Intraocular pressure.

Time after the IF pIOL implantation	No. of eyes	IOP (mmHg)
0 months	85	14.8 ± 3.0 [8.5; 22.5]
1 months	82	14.5 ± 2.4 [11.5; 22.0]
2 years	61	14.8 ± 2.8 [10.0; 22.5]
5 years	60	15.2 ± 3.0 [9.0; 21.5]

IF pIOL: iris-fixated phakic intraocular lens; No.: number; IOP: intraocular pressure.

patients. In 6 eyes (7%) of 6 patients the luxation of IF pIOL was caused by trauma. The mean time of nontraumatic re-enclavation was 6 years after the IF pIOL implantation.

Obviously, the most important reason for the explantation of an IF pIOL was cataract formation [4]. The incidence of cataract was 3 eyes (3.5%) of 2 patients, and it appeared at 9, 10.5, and 12 years postimplantation in our cohort.

The second most important reason for IF pIOL explantation is a high EC loss [4]. We had to carry out one pIOL explantation (1.2%) for corneal endothelium decompensation after 14 years. This patient then underwent Descemet Stripping Automated Endothelial Keratoplasty (DSAEK) and refractive lens exchange. Both surgeries went smoothly without complication, and the final UCVA was 20/20. In the end, the patient had to use glasses only occasionally for reading.

Subjective satisfaction after the IF pIOL implantation was high, and there occurred only minimum bothersome phenomena such as glare or halo. This problem was found in 2 patients with 5 mm diameter of optics in toric IF pIOLs in 2 eyes (2.3%) and with iridotomy in 1 eye (1.2%). Any sign of optics decentration did not occur, and there was no need of miotic eye drops application.

3.4. Endothelial Cell Loss. The mean preoperative ECD value was 2588 ± 285 cells/mm^2. We recorded ECD at 1, 2, 5, and 12 years after the implantation, with values of 2430 ± 312 cells/mm^2, 2369 ± 262 cells/mm^2, 2175 ± 298 cells/mm^2, 2091 ± 312 cells/mm^2, respectively (Figure 3). We computed total chronic EC loss and corrected it for a physiological EC loss of 0.6% per year (3% and 7.2% after 5 and 12 years, respectively) [14, 19]. This EC loss, directly caused by IF pIOL presence, was 6.0%, 8.1%, 12.8%, and 11.9%, at 1, 2, 5, and 12 years after IF pIOL implantation, respectively. All these EC loss values were statistically significant (Table 6).

During the postoperative 5- and 12-year follow-up, 93% and 95% of the eyes lost a higher percentage of EC than the expected physiological loss, respectively, in our cohort. According to the AAO Task Force guideline for standardized reporting on EC loss in studies of pIOLs [9, 20], we report a percentage of eyes with ≥25% EC loss. In the period 5 and 12 years after the IF pIOL implantation, it was 15% and 20% of eyes, respectively. Only 44% of eyes, which lost >25% of endothelial cells, needed a re-enclavation of pIOL after spontaneous subluxation or trauma. On the other hand, just 6.6% and 9% of eyes after the IF pIOL reposition or re-enclavation had ≥25% EC loss at 5 and 12 years after the IF pIOL implantation, respectively. In the follow-up, 3 eyes (3.5%) of 2 patients were noted to have ECD <1500 cells/mm^2 12 years after IF pIOL implantation, one of these eyes (1.2%) suffered trauma and underwent subsequent re-enclavation.

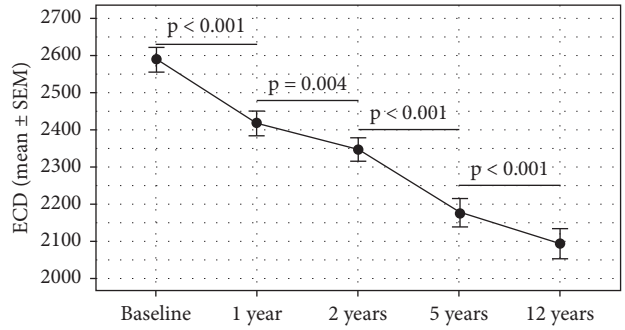

Figure 3: Mean endothelial cell density (ECD, cells/mm^2) from the preoperative status to 12-year postoperative status in eyes implanted with iris-fixated phakic intraocular lenses.

Table 6: Endothelial cell density after the IF pIOL Implantation.

Time after the IF pIOL implantation	Number of eyes	ECD (cells/mm^2)	EC loss (%)	Corrected EC loss (%)*
1 year	75	2430 ± 312 [1421; 3221]	6.6	6.0
2 years	61	2369 ± 262 [1715; 3009]	9.3	8.1
5 years	60	2175 ± 298 [1286; 2937]	15.8	12.8
12 years	42	2091 ± 312 [1196; 2674]	19.1	11.9

IF pIOL: iris-fixated phakic intraocular lens; No. number; ECD: endothelial cells density; EC loss: endothelial cells loss; *endothelial cells loss corrected to physiological endothelial cells loss.

Next, we tested the association between baseline risk factors and long-time EC loss. We found a significant inverse relationship between preoperative pachymetry and EC loss ($p = 0.006$), indicating that the lower pachymetry leads to a faster decline in ECD. The longitudinal decrease in ECD was not significantly related to gender ($p = 0.425$), degree of myopia ($p = 0.449$), or keratometry ($p = 0.520$). Higher baseline ACD values have shown to be indicative of slower EC loss. However, the effect was slightly above the selected significance level ($p = 0.057$).

4. Discussion

Three different types of IF pIOLs were implanted and evaluated together in our study. Yasa and Ağca referred to no significant difference of result between particular IF pIOLs (Verisyse and Veriflex group) [21].

4.1. Refractive Results. Refractive stability for at least 1 year is one of the main conditions before pIOL implantation [1]. In our center, we preferred stability at least 2 years to get the best results. We preferred patients older than 20 years of age, with one exception of an 18-year old patient with bilateral progressive myopia, who also underwent surgery.

Because we worked with younger patients, we calculated IF pIOL on the side of slight hypermetropia. There was a statistically significant shift into myopia 12 years after surgery, −0.42 ± 1.08 D. There was also a statistically significant reduction in the cylinder at 6 months after IF pIOL implantation. For the rest of the 12 years postoperatively, the cylinder remained stable without statistically significant changes.

We proceeded with excimer laser correction of residual refractive error in one eye (1.2%) at 1 year postimplantation. We elected PRK because Güell et al. hypothesized that laser in situ keratomileuses in an eye with anterior chamber or IF pIOL might induce contact between the corneal endothelium and the pIOL when the microkeratome (or applanation of femtosecond laser at the present time) is used [11, 22].

We closely monitored the efficacy of this method. UDVA of 20/40 or better was found in 99% of patients at 1 year and 90% of patients at 12 years after surgery. UDVA of 20/20 or better was noted in 77% of patients at 1 year and 64% of patients 12 years after surgery. The EI remained stable at 12 years after IF pIOL implantation. The safety of IF pIOL implantation was high (99%) and stable at 12 years after surgery. Just one eye (1.2%) lost one Snellen line of BDVA. The postoperative value of the SI was 1.10 and was also stable for 12 years postoperatively.

Our results are in good agreement with other studies which showed successful refractive results of IF pIOLs implantation [7, 10, 11, 14, 23, 24]. Tahzib et al. reported the MRSE −0.7 ± 1.0 D after 10 years, with no significant change in MRSE between 1, 6, and 10 years. UDVA 20/40 or better was reached in 82% of eyes, BDVA 20/40 or better in 93.3% of eyes, and only 2.6% of eyes lost more than 2 Snellen lines of BDVA [10]. Monteiro et al. calculated 6-year post-IF pIOL implantation EI and SI, 0.94 and 1.15, respectively [24]. Jonker et al. mentioned the mean myopization −0.79 D over 10 years after surgery. UDVA 20/40 or better was found in 96% of eyes, and 7% of eyes lost 2 or more lines of CDVA. They found the explanation in higher (7.6%) incidence of eyes requiring cataract surgery [11].

4.2. Intraocular Pressure. There is a danger of secondary glaucoma due to the pigment dispersion or pupillary block in the early postoperative period [14]. The pigment

dispersion is likely caused by abnormal pressure on the iris [25, 26]. Baikoff et al. and others reported the occurrence of pigment dispersion typically in hyperopic eyes [14, 25]. On the opposite side, Monteiro et al. found pigment precipitates in 10.17% of myopic eyes in the early postoperative period and treated them successfully with topical steroids [24]. We did not register any case of pigment dispersion in our myopic group of patients.

To prevent pupillary block, an iridotomy or iridectomy is done in the eyes with IF pIOLs. Like Monteiro et al. [24], we had one case of severe acute hypertension and pupillary block (Urrets-Zavalia syndrome) [27, 28, 29], which resulted in secondary sphincter atrophy and permanent mydriasis.

In keeping with the literature, we did not find any long-term statistical change of intraocular pressure after surgery [5, 10, 14, 24, 27].

4.3. Adverse Events. Jiang et al. [17] found the incidence of the RD after pIOLs implantation low and without any significant difference from the natural history of RD in highly myopic eyes. We did not record any incidence of RD over 12 years postimplantation.

Subluxation of IF pIOLs can occur spontaneously or after trauma. Spontaneous haptic disenclavation is usually connected with iris depigmentation and iris atrophy [18]. Peres-Santoja et al. [30] found iris atrophy near the enclavation site of both haptics in 81.0% of cases, but he made re-enclavation only in 9.3% of cases. Budo et al. [5] and Moran et al. [31] reported repositioning of IF pIOL in 2% of cases between 4 and 11 years postoperatively. In contrast with these reports, we carried out re-enclavation in 21% of cases. The reasons were iris stroma atrophy and poor fixation of the IF pIOL. The average time of nontraumatic re-enclavation was 6 years after IF pIOL implantation. 7% of repositioning was done for IF pIOL luxation caused by trauma. There are conflicting results in the literature regarding EC loss after primary IF pIOL enclavation and subsequent re-enclavation after subluxation of IF pIOLs. Menezo et al. [32] described 30.5% EC loss at six months after traumatic IF pIOL subluxation. In the contrary, De Sanctis et al. [33] and Titiyal et al. [18] found long-term EC loss after traumatic subluxation and repositioning of IF pIOL comparable to the EC loss after uneventful pIOL implantation. We used a special technique of re-enclavation with a 2.2 mm main corneal incision and 2 side paracentesis and did not record any statistically significant subsequent EC loss after the procedure.

Cataract development has been noted after IF pIOLs implantation. Several factors may be involved including surgical trauma, age, pIOL-crystalline lens touch (including intermittent contact during accommodation), myopia, the biocompatibility of the pIOL, change in the blood-aqueous barrier, and chronic subclinical inflammation [34]. Most cataracts reported after IF pIOL implantation were of the nuclear type [34]. Alio et al. also described that almost half of the cases of IF pIOL explantation were caused by nuclear cataract formation, and the mean time to cataract formation was 9.19 years [14, 35]. Menezo et al. reported an incidence of cataracts of 3%, and the mean time of cataract extraction was 11.4 years [36]. Consistently, the incidence of cataract formation was 3.5% in our study, and cataract extraction was performed after a mean period of 10.5 years. On the other hand, Jonker et al. explanted 10% of IF pIOLs because of cataract formation after a mean of 8 years. They cited a higher preoperative age as a risk factor for cataract formation [11]. Duignan et al. [37] summarized that removal of IF pIOLs was necessitated most frequently by cataracts (followed by endothelial cells loss). He stressed that explantation with concurrent phacoemulsification is a safe procedure with good visual outcomes. This procedure will be more frequent in the future as more patients with pIOLs reach the age of cataracts.

4.4. Endothelial Cell Loss. As in many other studies, our inclusion criteria were based on a minimum amount of preoperative ECD [3, 5, 6, 9, 10, 16]. Recently published studies described the minimum threshold of the preoperative ECD according to age [2]. Jonker et al. used ECD >2800 cells/mm^2 for patients aged 21 to 25 years, >2650 cells/mm^2 for patients aged 26 to 30 years, >2400 cells/mm^2 for patients aged 31 to 35 years, >2200 cells/mm^2 for patients aged 36 to 45 years, and >2000 cells/mm^2 for patients aged more than 45 years [9]. These criteria are more strict than those that were previously recommended by Gűell et al. and others [1, 3, 7, 16].

We found that the total chronic EC loss that was significantly higher than the expected physiological dropout. We measured corrected EC loss to demonstrate the EC loss directly caused by the IF pIOL presence. The values were 6.0%, 8.1%, 12.8%, and 11.9%, at 1, 2, 5, and 12 years postoperatively. During the postoperative 5- and 12- year follow-up, 93% and 95% of the eyes lost a higher percentage than the expected physiological loss, respectively. In the period 5 and 12 years after IF pIOL implantation, 15% and 20% of eyes had an EC loss of ≥25% of the preoperative value, respectively. In the 12-year follow-up, we noticed an ECD of <1500 cells/mm^2 in 3% of cases. We had to carry out one IF pIOL explantation (1.2%) due to corneal endothelium decompensation 14 years after the initial surgery.

Jonker et al. calculated the total chronicle EC loss in 507 eyes of 289 patients receiving the Artisan myopia® or Artisan Toric ® (Ophtec B.V.) IF pIOL. Like us, he reported the EC loss corrected for physiologic EC loss (0.6% per year), at 5.2% and 7.5% from 6 months to 5 years, and 10.9% and 15.8% from 6 months to 10 years, respectively. Ten years after implantation, ECD had decreased by ≥ 25% in 7.9% and 6.3%, whereas the ECD was <1500 cells/mm^2 in 3.9% and 4% in the myopic and toric group. In 6% of eyes in the myopic group and 4.8% of eyes in the toric group, excessive EC loss or corneal decompensation resulted in IF pIOL explantation after 11.9 and 7.4 years, respectively [9]. Tahzib et al. found out EC loss 8.86% in a group of 89 eyes of 49 patients 10 years after Artisan® pIOL implantation [10]. Worst–Fechner et al. spoke about a statistically significant decrease of ECD in 13.4% of 127 IF pIOL implanted eyes and further four eyes undergoing penetrating keratoplasty 8 years after the pIOL

implantation [13]. Galvis et al. mentioned a group of 67 eyes with implantation of an Artisan® pIOL. During the 9-year postoperative follow-up of the myopic group, 60.8% of the eyes lost a higher percentage of ECD than was physiologically expected. 3% of eyes had a final cell density of fewer than 1200 cells/mm^2 and 1 phakic lens was explanted due to a severe decrease of the endothelial density (862 cells/mm^2) [15]. A Paired-eye comparison of corneal endothelial cell counts after unilateral IF pIOL implantation was reported by Morral et al. [12]. The patients had implantation in 1 eye and refractive surgery (Group 1) or no surgery (Group 2) in the following eye. Both groups comprised 29 patients. The mean EC loss was 6.41% (Group 1, IF pIOLs), 5.59% (Group 1, corneal refractive surgery), 7.84% (Group 2, IF pIOLs), and 6.74% (Group 2, no surgery). He concluded that IF pIOL implantation did not produce significant EC loss up to 10 years after surgery compared with corneal refractive surgery and unoperated eyes when strict inclusion criteria were met. The limitation of this study was that a lot of patients dropped out of postoperative follow-up. Moreover, there was high intraindividual variability and some patients presented with high anisometropia (one eye was hyperopic while the following eye was highly myopic) [12].

Some papers try to predict the mean time from initial surgery to IF pIOL explantation. Bouheraoua et al. performed a linear model analysis of the 5-year follow-up to present a model that describes endothelial cell loss as a linear decrease. This model predicted that for patients with preoperative ECD of 3000, 2500, and 2000 cells/mm^2, a critical ECD of 1500 cells/mm^2 will be reached at 39, 28, and 15 years after the implantation, respectively [7]. Such a model seems to be very useful and helps us to improve the inclusion criteria. However, the question is whether the EC loss is really linear. We measured the corrected EC loss decelerated between 5 and 12 years after the IF pIOL implantation, at 12.78% and 11.86%, respectively. Fechner, who was together with Worst involved in the design and clinical application of the IF pIOLs in the 1980s, published a 2010 case report of late severe endothelial loss in the myopic patient between 12 years and 20 years after IF pIOL implantation. This patient had preoperatively a very rich endothelial layer and baseline ACD was more than 3.8 mm measured from corneal surface to surface of the natural lens. He pointed that the cause of the decrease of ECD was not clear and increased eye rubbing connected with age-related dry eyes was one of the possibilities [23].

As we mentioned above, the general aim is to evaluate each patient for basic risk factors to avoid unexpected postoperative EC loss. We tested the correlation between postoperative EC loss and basic factors like gender, degree of myopia, keratometry, pachymetry of the cornea, and ACD. In line with some previous studies, we did not find any significant relationship between gender, age, degree of myopia, and either basic keratometry [6]. Moreover, we did not find any significant relationship between preoperative ACD (the most discussed risk factor) and follow-up EC loss. This fact was supported by some studies [10, 15, 24], but others found a significant inverse correlation between these two parameters [6, 9, 13]. Because there was the effect of ACD only slightly above the selected significance level in our cohort, we can predict that the higher baseline ACD values are indicative of slower EC loss. Some papers presented the idea that the age of patients leads to a more shallow anterior chamber, resulting in intermittent contact between the IF pIOL and the posterior corneal surface [23]. On the contrary, Jonker et al. wrote about fluctuating ACD rising from greater accommodative capacity in younger patients [9]. But in the end, no author proved the impact of age on long-time EC loss after the IF pIOLs implantation [6, 9, 10, 15, 24].

Our outcomes describe, for the first time, the inverse correlation between the baseline corneal pachymetry and the EC loss at 12 years postoperatively. We noted slower EC loss in patients with thicker corneas and faster EC loss in those with thinner corneas. The most likely explanation of this finding could be just the effect of eye rubbing. The corneas with lower pachymetry have a stronger tendency to be deformed than the corneas with higher pachymetry. Shallowing of ACD could lead to contact between IF pIOL and endothelium. This finding corresponds with Galvis's suggestion [15] that the EC loss could be linked with chronic intermittent endothelial touch during ocular rubbing or pressure exerted on the eye at night, related to a particular sleeping position [15, 38, 39]. Currently, high refractive error and low corneal pachymetry belong to the most frequent contraindication to excimer laser surgery. According to our findings, we have to be very careful about recommending IF pIOLs to patients with a lower value of baseline pachymetry.

5. Conclusions

In conclusion, this study confirms the advantages of IF pIOLs implantation due to rapid visual recovery and stable visual function in the 12-year follow-up. This method is safe, effective, and predictable in the long term and seems to be the better alternative to laser corneal refractive surgery for younger patients with high myopia and the ability to accommodate. Patients with IF pIOLs have to be regularly monitored because of the risk of EC loss and cataract formation, which is higher than in the general population. We proved the relationship of lower corneal pachymetry to increased EC loss. In addition to keeping in mind the safety limits of ECD (corrected to the age) and ACD, we recommend focusing on corneal thickness measurement prior to IF pIOL implantation.

Data Availability

The data used to support the conclusions of this study are available from the corresponding author upon request.

Disclosure

The research was performed as a part of the authors' employment at the Ophthalmology Department of Military University Hospital in Prague (Czech Republic).

Conflicts of Interest

The authors declare that there are no conflicts of interest regarding the publication of this study.

References

[1] J. L. Güell, M. Morral, D. Kook, and T. Kohnen, "Phakic intraocular lenses," *Journal of Cataract and Refractive Surgery*, vol. 36, no. 11, pp. 1976–1993, 2010.

[2] T. Kohnen, "Phakic intraocular lenses: where are we now?" *Journal of Cataract and Refractive Surgery*, vol. 44, no. 2, pp. 121–123, 2018.

[3] R. Maloney, "Artisan phakic intraocular lens for myopia short-term results of a prospective, multicenter study," *Ophthalmology*, vol. 109, no. 9, pp. 1631–1641, 2002.

[4] M. Shajari, M. Scheffel, M. J. Koss, and T. Kohnen, "Dependency of endothelial cell loss on anterior chamber depth within first 4 years after implantation of iris-supported phakic intraocular lenses to treat high myopia," *Journal of Cataract and Refractive Surgery*, vol. 42, no. 11, pp. 1562–1569, 2016.

[5] C. Budo, J. C. Hessloehl, M. Izak et al., "Multicenter study of the Artisan phakic intraocular lens," *Journal of Cataract and Refractive Surgery*, vol. 26, no. 8, pp. 1163–1171, 2000.

[6] R. Saxena, S. S. Boekhoorn, P. G. H. Mulder, B. Noordzij, G. Van Rij, and G. P. M. Luyten, "Long-term follow-up of endothelial cell change after artisan phakic intraocular lens implantation," *Ophthalmology*, vol. 115, no. 4, pp. 608.e1–613.e1, 2008.

[7] N. Bouheraoua, C. Bonnet, A. Labbé et al., "Iris-fixated phakic intraocular lens implantation to correct myopia and a predictive model of endothelial cell loss," *Journal of Cataract and Refractive Surgery*, vol. 41, no. 11, pp. 2450–2457, 2015.

[8] S. M. R. Jonker, T. T. J. M. Berendschot, A. E. Ronden, I. E. Y. Saelens, N. J. C. Bauer, and R. M. M. A. Nuijts, "Five-year endothelial cell loss after implantation with Artiflex myopia and Artiflex toric phakic intraocular lenses," *American Journal of Ophthalmology*, vol. 194, pp. 110–119, 2018.

[9] S. M. R. Jonker, T. T. J. M. Berendschot, A. E. Ronden, I. E. Y. Saelens, N. J. C. Bauer, and R. M. M. A. Nuijts, "Long-term endothelial cell loss in patients with artisan myopia and artisan toric phakic intraocular lenses," *Ophthalmology*, vol. 125, no. 4, pp. 486–494, 2018.

[10] N. G. Tahzib, R. M. Nuijts, W. Y. Wu, and C. J. Budo, "Long-term study of artisan phakic intraocular lens implantation for the correction of moderate to high myopia," *Ophthalmology*, vol. 114, no. 6, pp. 1133–1142, 2007.

[11] S. M. R. Jonker, T. T. J. M. Berendschot, A. E. Ronden, I. E. Y. Saelens, N. J. C. Bauer, and M. M. A. Nuijts, "Long-term changes in visual outcomes and ocular morphometrics after myopic and toric phakic intraocular lens implantation: five- and 10-year results," *Journal of Cataract and Refractive Surgery*, vol. 45, no. 10, pp. 1470–1479, 2019.

[12] M. Morral, J. L. Güell, M. A. El Husseiny, D. Elies, O. Gris, and F. Manero, "Paired-eye comparison of corneal endothelial cell counts after unilateral iris-claw phakic intraocular lens implantation," *Journal of Cataract and Refractive Surgery*, vol. 42, no. 1, pp. 117–126, 2016.

[13] P. U. Fechner, I. Haubitz, W. Wichmann, and K. Wulff, "Worst-Fechner biconcave minus power phakic iris-claw lens," *Journal of Refractive Surgery (Thorofare, N.J.: 1995)*, vol. 15, no. 2, pp. 93–105, 1999.

[14] G. A. Van Rijn, Z. S. Gaurisankar, A. P. Ilgenfritz et al., "Middle- and long-term results after iris-fixated phakic intraocular lens implantation in myopic and hyperopic patients: a meta-analysis," *Journal of Cataract and Refractive Surgery*, vol. 46, no. 1, pp. 125–137, 2020.

[15] V. Galvis, J. F. Villamil, M. F. Acuña et al., "Long-term endothelial cell loss with the iris-claw intraocular phakic lenses (Artisan)," *Graefe's Archive for Clinical and Experimental Ophthalmology*, vol. 257, no. 12, pp. 2775–2787, 2019.

[16] H. B. Dick, J. Alió, M. Bianchetti et al., "Toric phakic intraocular lens," *Ophthalmology*, vol. 110, no. 1, pp. 150–162, 2003.

[17] T. Jiang, Q. Chang, X. Wang, and X. Huang, "Retinal detachment after phakic intraocular lens implantation in severe myopic eyes," *Graefe's Archive for Clinical and Experimental Ophthalmology*, vol. 250, no. 12, pp. 1725–1730, 2012.

[18] J. S. Titiyal, N. Sharma, R. Mannan, A. Pruthi, and R. B. Vajpayee, "Outcomes of reenclavation of subluxated iris-fixated phakic intraocular lenses: comparison with primary surgery outcomes," *Journal of Cataract and Refractive Surgery*, vol. 36, no. 4, pp. 577–581, 2010.

[19] S. P. Patel and W. M. Bourne, "Corneal endothelial cell proliferation: a function of cell density," *Investigative Ophthalmology & Visual Science*, vol. 50, no. 6, pp. 2742–2746, 2009.

[20] S. MacRae, J. T. Holladay, G. Hilmantel et al., "Special report: American academy of Ophthalmology Task Force recommendations for specular microscopy for phakic intraocular lenses," *Ophthalmology*, vol. 124, no. 1, pp. 141-142, 2017.

[21] D. Yaşa and A. Ağca, "Verisyse versus Veriflex phakic intraocular lenses: refractive outcomes and endothelial cell density 5 Years after surgery," *Journal of Ophthalmology*, vol. 20188 pages, 2018, https://doi.org/10.1155/2018/4210460, Article ID 4210460.

[22] J. L. Güell, M. Vázquez, and O. Gris, "Adjustable refractive surgery: 6-mm Artisan lens plus laser in situ keratomileusis for the correction of high myopia," *Ophthalmology*, vol. 108, no. 5, pp. 945–952, 2001.

[23] P. U. Fechner, "Late loss of corneal endothelial density with refractive iris-claw IOLs," *Journal of Cataract and Refractive Surgery*, vol. 36, no. 2, pp. 352-353, 2010.

[24] T. Monteiro, F. F. Correia, N. Franqueira, J. C. Mendes, C. Pinto, and F. Vaz, "Long-term efficacy and safety results after iris-fixated foldable phakic intraocular lens for myopia and astigmatism: 6-year follow-up," *Journal of Cataract and Refractive Surgery*, vol. 47, no. 2, pp. 211–220, 2021.

[25] G. Baïkoff, G. Bourgeon, H. J. Jodai, A. Fontaine, F. V. Lellis, and L. Trinquet, "Pigment dispersion and Artisan phakic intraocular lenses," *Journal of Cataract and Refractive Surgery*, vol. 31, no. 4, pp. 674–680, 2005.

[26] J. L. Alió, M. E. Mulet, and A. M. M. Shalaby, "Artisan phakic iris claw intraocular lens for high primary and secondary hyperopia," *Journal of Refractive Surgery*, vol. 18, no. 6, pp. 697–707, 2002.

[27] T. Kohnen, D. Kook, M. Morral, and J. L. Güell, "Phakic intraocular lenses: part 2: results and complications," *Journal of Cataract and Refractive Surgery*, vol. 36, pp. 2168–2194, 2010.

[28] S. J. Tuft and R. J. Buckley, "Iris ischaemia following penetrating keratoplasty for keratoconus (Urrets-Zavalia syndrome)," *Cornea*, vol. 14, no. 6, pp. 618–622, 1995.

[29] O. Spierer and M. Lazar, "Urrets-Zavalia syndrome (fixed and dilated pupil following penetrating keratoplasty for keratoconus) and its variants," *Survey of Ophthalmology*, vol. 59, no. 3, pp. 304–310, 2014.

[30] J. J. Pérez-Santonja, J. L. Bueno, and M. A. Zato, "Surgical correction of high myopia in phakic eyes with Worst-Fechner myopia intraocular lenses," *Journal of Cataract and Refractive Surgery*, vol. 13, no. 3, pp. 268–281, 1997.

[31] S. Moran, C. Kirwan, M. O'Keefe, A. Leccisotti, and T. Moore, "Incidence of dislocated and subluxed iris-fixated phakic

intraocular lens and outcomes following re-enclavation," *Clinical & Experimental Ophthalmology*, vol. 42, no. 7, pp. 623–628, 2014.

[32] J. L. Menezo, A. L. Cisneros, and V. Rodriguez-Salvador, "Endothelial study of iris-claw phakic lens: four year follow-up," *Journal of Cataract and Refractive Surgery*, vol. 24, no. 8, pp. 1039–1049, 1998.

[33] U. De Sanctis, B. Mutani, and F. M. Grignolo, "Long-term endothelial cell loss after traumatic dislocation and repositioning of artisan phakic IOL," *Journal of Refractive Surgery*, vol. 24, no. 5, pp. 546–548, 2008.

[34] L.-J. Chen, Y.-J. Chang, J. C. Kuo, R. Rajagopal, and D. T. Azar, "Metaanalysis of cataract development after phakic intraocular lens surgery," *Journal of Cataract and Refractive Surgery*, vol. 34, no. 7, pp. 1181–1200, 2008.

[35] J. L. Alió, B. T. Toffaha, P. Peña-Garcia, L. M. Sádaba, and R. I. Barraquer, "Phakic intraocular lens explantation: causes in 240 cases," *Journal of Refractive Surgery*, vol. 31, no. 1, pp. 30–35, 2015.

[36] J. L. Menezo, C. Peris-Martínez, A. L. Cisneros-Lanuza, and R. Martínez-Costa, "Rate of cataract formation in 343 highly myopic eyes after implantation of three types of phakic intraocular lenses," *Journal of Refractive Surgery*, vol. 20, no. 4, pp. 317–324, 2004.

[37] E. S. Duignan, C. Quigley, M. P. Treacy, A. Eldouri, and M. O'Keefe, "Iris-fixated phakic intraocular lens explantation," *European Journal of Ophthalmology*, vol. 31, no. 3, pp. 988–993, Article ID 1120672120934985, 2020.

[38] M. Doors, T. T. J. M. Berendschot, C. A. B. Webers, and R. M. M. A. Nuijts, "Model to predict endothelial cell loss after iris-fixated phakic intraocular lens implantation," *Investigative Opthalmology & Visual Science*, vol. 51, no. 2, p. 811, 2010.

[39] W. W. Culbertson and S. C. G. Tseng, "Corneal disorders in floppy eyelid syndrome," *Cornea*, vol. 12, no. 1, p. 86, 1993.