ORIGINAL ARTICLE

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Long Term (4 years) Refractive Outcomes of Eyecryl® Phakic Intraocular Lens Implantation in Myopia

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Abstract

Objective: To evaluate the long term (4 years) outcomes of Eyecryl phakic intraocular lens (pIOL) implantation in myopia.

Methods: Medical records of patients, who had implantation of Eyecryl pIOL implantation were retrospectively reviewed. Patients with a follow up period of 4 years were included in the study. Refractive results, endothelial cell density, vault, and complications were evaluated.

Results: Preoperative and postoperative spherical equivalent of manifest refraction were -12.98±3.05 and -0.72±0.86 D, respectively. The efficacy index was 1.05±0.45 and safety index was 1.51±0.53. Preoperative corrected distance visual acuity (CDVA) was 0.26±0.15. Postoperative uncorrected and CDVA were 0.27±0.21 and 0.10±0.10 respectively at the last visit (4 years). The mean vault was 570±155 µ at the first month and decreased to 500±133 µ at the 4th year. Endothelial cell loss was 3.9% in the first 2 years. No significance difference was seen between 2nd and 4 years ($p>0.005$). No significant cataract formation was seen.

Conclusion: Eyecryl pIOL implantation for the correction of myopia may be a safe and effective surgical procedure.

Keywords: Myopia, refractive surgery, phakic intraocular lens

INTRODUCTION

Methods used for the surgical correction of refractive errors are, corneal refractive surgery, clear lens extraction and phakic intraocular lens (pIOL) implantation (1-3). pIOLs are used especially when the corneal refractive surgical techniques are impossible, as in the high myopic patients. Maintenance of accommodation and better quality of vision, when compared with corneal surgeries the main advantages (4). The efficacy and safety of some models of anterior and posterior chamber pIOLs have been reported (5-11).

Eyecryl® pIOL (Biotech Vision Care, Ahmedabad India) is a relatively newer posterior chamber pIOL. It is a hydrophilic acrylic, single piece, foldable, plate haptic pIOL placed in the ciliary sulcus. It has an aspheric optics (4.65 to 5.50 mm) with zero aberration. The optic has a 320 µm central hole to improve the aqueous humor circulation. Early results of the efficacy and safety of these lenses are promising (11-13). However, the long-term refractive results and complications are not known.

In this study, we evaluated the long term (4 years) efficacy and safety of Eyecryl® posterior chamber pIOL implantation in patients with high myopia.

METHODS

This study was designed and conducted in accordance with the Declaration of Helsinki and ethics committee approval was obtained from the Ethics Committee for Clinical Research of Taksim Training and Research Hospital (decision no: 35, date: 05.02.2020). Inclusion criteria were Eyecryl® pIOL implantation and a follow-up for at least 4 years. The exclusion criteria were age <20 and preexisting ocular pathology. Patients with retinal

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breaks were also excluded. Informed consent was obtained from all patients before the surgery.

Preoperative and postoperative uncorrected visual acuity (UDVA) and corrected distance visual acuity (CDVA) were measured using an LCD chart and a digital phoropter. Scheimpflug camera combined with Placido-disk corneal topography (Sirius, Costruzione Strumenti Oftalmici, Firenze, Italy) was used for topography and pachymetry mapping as well as anterior chamber depth and horizontal white-to-white measurements. Endothelial cell count was measured using a specular microscope (CEM-530; Nidek Co. Ltd., Aichi, Japan) at annual visits. In all postoperative visits, the pIOL vault (the distance between pIOL and the crystalline lens) was measured using an anterior segment optical coherence tomography (OCT) device (Visante OCT, Carl Zeiss AG, Germany).

Power calculation for the pIOL was performed using the modified vergence formula provided by the manufacturer. Our goal in this study was to achieve emmetropia in all cases. All surgeries were performed with sub-tenon anesthesia. Two side-port incisions and a 2.8 mm clear corneal temporal incision were created. The anterior chamber was filled with a cohesive ophthalmic viscosurgical device (OVD) (Provisc; Alcon Laboratories Inc, Fort Worth, TX, USA). The pIOL was loaded onto the cartridge-injector system provided by the manufacturer and it was injected into the anterior chamber through the 2.8 mm temporal incision. Its haptics were placed under the iris one by one. The OVD was washed out of the anterior chamber by simple irrigation. The incisions were hydrated with balanced salt solution.

Statistical Analysis

Statistical analysis was performed using SPSS software (version 21.0; IBM, Armonk, NY). Mean, standard deviation, minimum-maximum (min-max), and frequency values were used in descriptive statistical analyses. Kolmogorov-Smirnov test was used to analyze the distribution of variables. The efficacy (postoperative UDVA/preoperative CDVA) and safety (postoperative CDVA/preoperative CDVA) indices were calculated for each patient. Visual acuity were converted to logMAR for statistical analysis. A paired samples t-test was used to compare the preoperative and postoperative measurements. A p value <0.05 was considered statistically significant.

RESULTS

Thirty six eyes of 18 patients were included in the study. Thirteen (72%) patients were women, 5 (28%) patients were men. The mean age of patients was 32.67±7.33. Preoperative spherical equivalent (SE) was (-12.98±3.05) and eighty-one percent of the eyes were between -10.00 and -20.00 D. Preoperative patient characteristics are shown in Table 1.

Visual Acuity, Efficacy, and Safety

The intended target was emetropia in all cases. The mean CDVA was 0.26±0.15 logMAR preoperatively. Postoperative UDVA was 0.27±0.21 logMAR and CDVA was 0.10±0.10 logMAR at 4 years postoperatively. At 4 years follow up the efficacy index (postoperative UDVA/preoperative CDVA) was 1.05±0.45. Figure 1A shows patients with preoperative CDVA and postoperative UDVA. Change in the best CDVA of the patients at the end of 4 years, compared to preoperative period is shown in Figure 1B. The safety index (postoperative CDVA/preoperative CDVA) was 1.51±0.53 at the last follow-up. Twenty four (66.7%) patients gained one or more Snellen lines of CDVA. Twelve (33.3%) patients corrected vision remained unchanged and no Snellen loss was seen.

Figure 1C shows the attempted versus achieved refractive correction. The mean SE at the end of 4 years was -0.72±0.86 (-3.38-0.25) D. 86% of patients was with in ±1.00 D and 64% of patients within ±0.50 D, respectively (Figure 1D).

Figure 1F shows the stabilitity of manifest refraction throughout follow-up period. The SE was -0.43±0.58 D at the first year and 0.72±0.86 D at the fourth year (p<0.005, paired samples t-test, 2-tailed p value).

Figure 2 shows the changes in central endothelial cell density (ECD). The mean preoperative ECD was 2742.83±316 cells/mm^2. At first year it was 2609±325 cells/mm^2, and 2608±323 at 2 years. For the first two year the mean endothelial cell loss was

Table 1. Preoperative patient characteristics

	Mean ± SD	Minimum	Maximum
Age (years)	32.67±7.33	23	49
SE (D)	-12.98±3.05	-7.00	-20,00
Cylinder (D)	-0.99±0.66	0	2.00
CDVA (logMAR)	0.26±0.15	0.52	0
WTW (mm)	11.73±0.26	11.27	12.10
ECD (cells/mm^2)	2742±316.53	2062	3189
ACD (mm)	3.67±0.18	3.28	4.01
Mean Sim K (D)	44.38±1.98	38.82	47.28
IOP (mmHg)	14.6±2.46	10.00	21.00
AL (mm)	27.97±1.27	24.15	29.61
Corneal thickness (µ)	530.46±35.49	452	595

SE: Spherical equivalent, CDVA: Corrected distance visual acuity, WTW: White to white, ECD: Endothelial cell density, ACD: Anterior chamber depth, Sim K: Simulated keratometry, IOP: Intraocular pressure, AL: Axial lenght, SD: Standard deviation

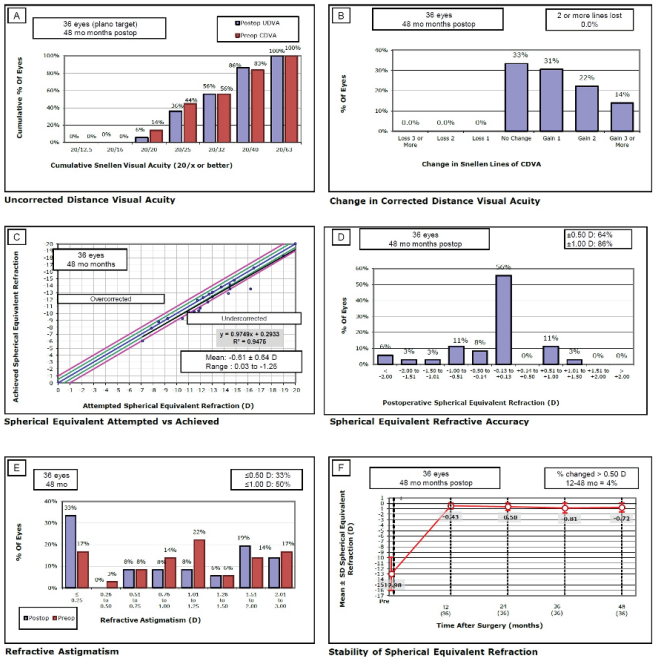

Figure 1. A) Cumulative uncorrected and corrected distance visual acuity (UDVA and CDVA, respectively), B) change in CDVA, C) spherical equivalent of attemted versus achieved refraction, D) accuracy of spherical equivalebt refraction, E) preand postoperative refractive astigmatism, F) accuracy of spherical equivalent refraction

UDVA: Preoperative and postoperative uncorrected visual acuity, CDVA: Corrected distance visual acuity

3.9% (p<0.0001). The fourth year ECD was 2505±303 cells/mm^2, and no significant cell loss (p>0.05) was seen between 2nd and 4th years.

Figure 3 shows the mean vault of the pIOL during follow-up period. The mean vault was 570±155 µ at the first month, decreased to 520±141 µ and 500±133 µ (min: 220; max: 790) at the 1th and 4th years, respectively (repeated measures ANOVA, p<0.001).

There were no cases of anterior subcapsular cataracts or opacities. No other intraoperative or postoperative complications were observed.

DISCUSSION

In this study, we analyzed the long-term refractive results of Eyecryl® pIOL implantation by using efficacy, safety, stability and predictability. At four years, we found that 64% of the patients were within 0.50 D of emmetropia. Mean SE changed from -0.43±0.58 D at the first year to 0.72±0.86 D at the fourth year (p<0.005, paired samples t-test, 2-tailed p value). The regression of the refractive effect was an expected finding in this population and probably results from the elongation of axial length. However, axial length measurements were not a

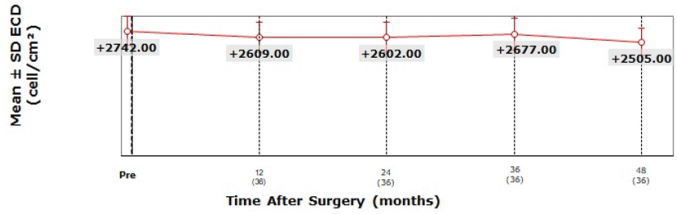

Figure 2. Endothelial cell density during follow-up

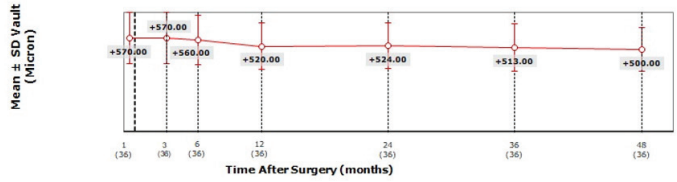

Figure 3. Mean vault during follow-up period

part of preoperative and postoperative examinations. Thus, it was impossible to evaluate axial length in this study. In high myopic patients, manifest refraction may be difficult to obtain due to a combination of low visual acuity of the patient and aberrations and minimizing effect of trial lenses. This may result in postoperative refractive surprise as manifest refraction is the most important variable in the pIOL power calculation. In addition, myopia is generally progressive and SE increases with time. In this study, preoperative SE was -12.98±3.05 and 81% of the eyes were between -10.00 and -20.00 D. Thus, early postoperative refractive surprises or an increase in myopia during long term follow-up were expected findings in this study.

However, despite the progression of myopia, the efficacy index was 1.05±0.45. An efficacy index >1 means that the mean postoperative UCVA in this study was better than mean preoperative CDVA even at postoperative 4 years despite residual postoperative refractive errors. This was a result of improved CDVA in this study as indicated by the safety index, which was 1.51±0.53 at four years. It is well-known that a definite improvement in CDVA is seen after the surgical correction of high myopia and 35-100% of the eyes experience 1 or more lines of CDVA (6,14-20). Although pIOL used in this study was different, 24 (67%) patients showed 1 or more line gain.

Vault is the distance between the pIOL and crystalline lens. It is closely related to the appropriate sizing of the pIOL to the posterior chamber. When the vault is too low or too high, it can cause some complications, such as cataract formation, pupillary block, pigment dispersion and glaucoma (20-23). In our study, the mean vault was 531±134 (min: 220, max: 790) within normal limits. We did not see any complication related to vault problems.

Endothelial cell loss is one of the biggest problems pIOL implanted patients. It is reported to be between 6.2%- 9.5 in some long-term studies of icl implantation (6,9,24,25). Urdem and Agca (12) in their 2 years-follow up study of Eyecryl® pIOL reported 4.51% endothelial cell loss at first year and no significant difference in the second year. In our study, for the first two years, the mean endothelial cell loss was 3.9% ($p<0.0001$). The fourth year ECD was 2505±303 cells/mm^2, and no significant cell loss ($p>0.05$) was seen between 2nd and 4th years.

The formation of cataracts is a well-known complication of pIOL implantation, with a reported incidence of 1.6% to 18.3% after ICL implantation (9,26). It is usually in the form of anterior subcapsular cataract, and its incidence increases with increasing follow-up period (26). Older age, low vault are the main contributing factors (9,24). The design and material properties of the pIOL may also have an effect. In our study, no cataract formation was observed at 4 years follow up.

Pupillary block, angle narrowing due to a high vault, or chronic pigment dispersion may result in increased IOP after PIOL implantation (27,28). As there is a central hole in the optics of the lens, a pupillary block is unlikely in Eyecryl® pIOL implanted eyes and we did not see a pupillary block in this study. Also, no patient developed glaucoma due to angle narrowing and or pigment dispersion.

The study population consists of high myopic (probably degenerative myopic) patients. A higher retinal detachment risk should be considered in this population. However, we did not observe any retinal complications. This may be due to the limited number of patients or exclusion of patients with a retinal break.

Study Limitations

The major limitation of this study was its retrospective nature. Axial measurements were excluded from our postoperative routine measurements. Thus, it was impossible to analyze the relationship between the axial lengths and myopic shift during the follow-up period. Also, the number of eyes is not high enough to evaluate the relatively rare complications such as cataracts.

CONCLUSION

In conclusion, we have retrospectively evaluated our long term (4 years) results of Eyecryl® pIOL implantation. The results were promising in terms of efficacy and safety indices. No serious complication was seen during follow-up time. Studies with larger patient groups and longer follow-up periods are required.

Ethics

Ethics Committee Approval: Ethics Committee for Clinical Research of Taksim Training and Research Hospital (decision no: 35, date: 05.02.2020).

Informed Consent: Written informed consent was obtained from the patients.

Peer-review: Externally and internally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: A.A., Concept: A.H., B.K., A.A., Design: A.H., B.K., A.A., Data Collection or Processing: A.H., B.K., A.A., Analysis or Interpretation: A.H., B.K., A.A., Literature Search: A.H., B.K., A.A., Writing: A.H., B.K., A.A.

Conflict of Interest: No conflict of interest was declared by the authors.

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