

The Outcomes of Posterior-Chamber Phakic Intraocular Lens Implantation in Patients with High Myopia

Yüksek Miyopisi Olan Hastalarda Arka Kamara Fakik Göz İçi Lens İmplantasyonunun Görsel Sonuçları

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ABSTRACT Objective: To evaluate the outcomes of posterior-chamber phakic intraocular lens (pIOL) implantation in patients with high myopia. **Material and Methods:** Seventy-six eyes of 38 patients who had high myopia and undergone Eyecrylphakic IOL implantation were enrolled in the study. Eighteen of them (47%) were males and 20 (53%) were females. Their mean age was 28.97±4.10 (22-36) years. Uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), autorefractive and keratometric measurements were evaluated pre and postoperatively. **Results:** The mean 1st week, 1st month and 6th month postoperative spherical, astigmatic and spherical equivalent (SE) values were significantly lower than those of preoperative values, and the mean 1st week, 1st month and 6th month postoperative UCVA and BCVA values were significantly higher than preoperative values ($p<0.05$). The mean 1st week, 1st month and 6th month postoperative anterior chamber depth (ACD) values were significantly lower than preoperative values ($p<0.05$). There were no significant differences between preoperative and postoperative central corneal thickness (CCT), endothelial cell density (ECD) and intraocular pressure (IOP) measurements ($p>0.05$). The postoperative first-week mean spherical value was 0.11±0.44 D, and it was stable until the 6th month. Postoperative 6th month mean endothelial cell loss was 3% in comparison with preoperative values. The difference was not significant ($p>0.05$). Additionally, no abnormal morphologic changes in endothelial cell layer were observed in specular microscopy. **Conclusion:** Eyecrylphakic IOL implantation is a safe, effective, predictable, and stable treatment method for high-myopia patients in the short-term. Long-term results of pIOL implantation should be investigated in further studies.

Keywords: High myopia; phakic IOL; spherical equivalent; uncorrected visual acuity

ÖZET Amaç: Yüksek miyopisi olan hastalarda arka kamara fakik intraoküler lens (pIOL) implantasyonunun görsel sonuçlarını değerlendirmek. **Gereç ve Yöntemler:** Yüksek miyopisi olan ve Eye cryl Fakik IOL implantasyonu uygulanan 38 hastanın 76 gözü çalışma kapsamına alındı. Hastaların 18'i (%47) erkek, 20'si ise (%53) kadındı. Ortalama yaşları 28,97±4,10 (22-36) yıl idi. Düzeltilmemiş görme keskinliği, düzeltilmiş görme keskinliği, otorefraktif ve keratometrik ölçümler ameliyat öncesi ve sonrasında değerlendirildi. **Bulgular:** Ortalama ameliyat sonrası 1. hafta, 1. ay ve 6. ay sferik, astigmatik ve sferik eşdeğer (SE) ameliyat öncesi değere göre anlamlı olarak daha düşüktü ve ameliyat sonrası düzeltilmemiş ve düzeltilmiş görme keskinliği, ameliyat öncesine göre anlamlı olarak daha yüksekti ($p<0,05$). Ortalama ameliyat sonrası 1. hafta, 1. ay ve 6. ay ön kamara derinliği, ameliyat öncesi değere göre anlamlı olarak daha düşüktü ($p<0,05$). Ameliyat öncesi ve ameliyat sonrası kornea kalınlığı, endotel hücre sayısı ve göziçi basıncı değerlerinde anlamlı bir değişiklik gözlenmedi ($p>0,05$). Ameliyat sonrası 1. hafta ortalama sferik değer 0,11 ± 0,44 D idi ve bu değer 6. aya kadar stabil seyretti. Postoperatif 6. aydaki endotel hücre kaybı %3'tü, preoperatif değere göre anlamlı bir düşüş değildi ($p>0,05$). Ayrıca, speküler mikroskopide endotel hücre tabakasında anormal morfolojik değişiklikler gözlenmedi. **Sonuç:** Eyecryl Fakik IOL implantasyonu, yüksek miyopisi olan hastalarda kısa dönemde güvenli, etkin ve ön görülebilir bir tedavi sağlamaktadır. Uzun dönem sonuçları için ileri çalışmaların yapılması gerekir.

Anahtar Kelimeler: Yüksek miyopi; fakik IOL; sferik eşdeğer; düzeltilmemiş görme keskinliği

Myopia is the most common ocular disorder worldwide.¹ Its prevalence has increased from 25% to 44% between 1972 and 2004 in the United

States.^{2,3} In developed regions of Asia, prevalence is over 80%,but it is seen much less in underdeveloped countries such as Nepal.⁴ The mean cost of myopia

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Peer review under responsibility of Türkiye Klinikleri Journal of Ophthalmology.

Received: 14 Nov 2019

Received in revised form: 04 Feb 2020

Accepted: 18 Feb 2020

Available online: 25 Feb 2020

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per person was calculated as 709 USD in Asia, and approximately 269 billion USD in the world's total population.^{5,6}

The first choice for the treatment of myopia is prescription of eyeglasses. However, they have no effect on the progression of myopia.^{7,8} Gas-permeable rigid contact lenses were believed to decrease the progression of myopia. In a study, it was determined that orthokeratology contact lenses decreased the progression of myopia.⁹ It was also determined that atropine had a slowing effect on the progression of myopia.¹⁰ In addition, activities in the external environment have been found to decrease myopia's progression.¹¹

Excimer laser therapy was first applied in 1988 to correct myopia.¹² Since then, excimer laser therapy has become widespread. Although LASIK has been an effective method for correcting low and moderate-level myopia, it is not preferred for correcting high myopia (>-9.00 D) due to corneal thickness. LASIK surgery has several disadvantages such as overcorrection or hypocorrection, regression, optic aberrations, dry eye symptoms, and flap-related complications. For these reasons, pIOLs that have different designs and do not require the extraction of the natural lens have been developed.¹³ Angle-supported and iris-fixated anterior-chamber phakic IOLs are no longer used due to complications like endothelial cell loss, cataract, glaucoma, and corectopia.^{14,15}

In this study, we retrospectively evaluated the efficacy of posterior chamber pIOL in eyes with high myopia.

MATERIAL AND METHODS

The study protocol was approved by the local ethics committee (Necmettin Erbakan University, Faculty of Medicine Ethics Committee, Konya, Turkey, Project No: 2019/1740, Date: 1st March 2019). An informed written consent form was obtained from all patients before surgery. The study was carried out according to the tenets of the Declaration of Helsinki.

Seventy-six eyes of 38 patients who had undergone phakic IOL (Eyecryl, Biotech Vision Care, Ahmedabad, India) implantation surgery were enrolled in the study. The mean age of the patients was

28.97±4.10 (22-36) years. Eighteen of them (47%) were males and 20 of them (53%) were females. The inclusion criteria were high myopia, greater than -8,00 D, and compatibility of topographic measurements. Patients who had any systemic or ocular diseases affecting the vision, iridocorneal angle smaller than 30 degree, anterior chamber depth lower than 3 mm, endothelial cell density (ECD) lower than 2500 and intraocular pressure (IOP) greater than 20 mmHg were not accepted for the operation. Patients who had astigmatism more than 1.00 diopter (D) were excluded from the study.

Refractive and keratometric measurements of all patients were performed preoperatively with Tonoref II autorefractometer (Nidek, Aichi, Japan), topographic measurements with Sirius Topography (Sirius, Costruzione Strumenti Oftalmici, Florence, Italy), and biometric measurements with Nidek Biometry (Aichi, Japan). UCVA and BCVA measurements were performed and converted to logMAR units. Detailed anterior and posterior segment examinations were performed and endothelial cell counts were calculated with specular microscopy (Nidek, Cem530, Japan).

We preferred phakic posterior chamber IOL with a central hole in our patients to provide aqueous humour passage in order to avoid any intervention to iris in future. We chose the model according to white-to-white (WTW) distance of the patients. The properties of phakic IOLs are shown in Table 1 and Figure 1 (A and B) (<http://www.biotechhealthcare.com/ophthalmology/vitro-retinal-product-range-2/eyecryl-phakic/>).

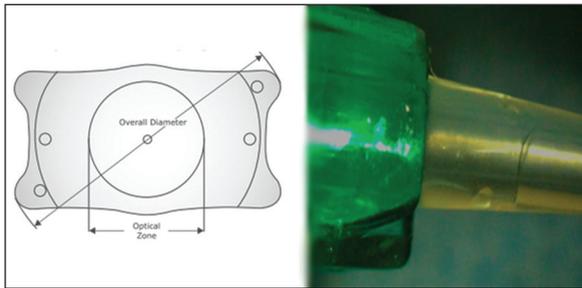
The spherical number calculations (biometric measurements) were done on the website as directed by the manufacturer (<http://www.biotechcalculators.com/>).

All surgeries were performed by the same surgeon (F.U.). Tropamid Forte (Tropicamide 1%, Bilim İlaç, Turkey), Sikloplejin (SiklopentolatHCl 1%, Abdi İbrahim, Turkey), and Mydrin (Phenylephrine HCl, Alcon, USA) were applied to the eyes before surgery. A 2.8-mm incision on the steep axis of astigmatism was made, and a dispersive viscoelastic material (Na Hyaluronate 3%, Protectalone, VSY

TABLE 1: Properties of Eyecryl Phakic IOL.

Model	Size (mm)	Optic Diameter (mm)	Effective Optical Zone at	
			Corneal Plane (mm)	Diopter Range (D)
PKC120NH	6.5 x 12.0	5.50	6.93	-3.0_-13.0
		5.25	6.61	-13.5_-16.5
		4.65	5.86	-17.0_-23.0
PKC125NH	6.5 x 12.5	5.50	6.93	-3.0_-13.0
		5.25	6.61	-13.5_-16.5
		4.65	5.86	-17.0_-23.0
PKC130NH	6.5 x 13.0	5.50	6.93	-3.0_-13.0
		5.25	6.61	-13.5_-16.5
		4.65	5.86	-17.0_-23.0

IOL: Intraocular lens, D: Diopter, mm: Millimeter.

**FIGURE 1:** The properties of phakic IOLs.

Biotechnology) was injected into the anterior chamber. Side-port incisions were made with an MVR knife, and a posterior-chamber pIOL was implanted and positioned. Viscoelastic material was extracted. The incision sites were hydrated. Postoperatively, all patients used Dexamethasone 0.1% (Liba, Turkey) 4x1 for one month, Vigamox (Moxifloxacin 0.5%, Alcon, USA) 4x1 for one week, and Acular LS (Ketorolac tromethamine 0.4%, Allergan, Ireland) 4x1 for one month. The steroid dosage was tapered and stopped at the end of one month.

All patients were examined postoperatively on the first day and during the first week, first month, and sixth month. During these examinations, UCVA, BCVA, auto refractive and keratometric measurements were controlled. Efficacy index was calculated by postoperative UCVA/preoperative BCVA. Safety index was calculated by postoperative BCVA/preoperative BCVA. Predictability was presented as percentage of eyes within ± 0.50 D, postoperatively.

Statistical analysis was performed using SPSS version 22. The comparison of data was made using paired t-test, and level of significance was accepted as 0.05. Skewness values for all variables were within +1 and -1. Kurtosis values were within +2 and -1. P values of Kolmogorov-Smirnov test for all variables were greater than 0.050. All these findings showed that the distribution of data was normal.

RESULTS

The mean 1st week, 1st month and 6th month postoperative spherical, astigmatic and SE values were significantly lower than preoperative values ($p < 0.01$, $p < 0.01$ and $p < 0.01$, respectively), and the mean 1st week, 1st month and 6th month postoperative UCVA and BCVA values were significantly higher than preoperative values ($p < 0.01$ and $p = 0.01$, respectively). The mean 1st week, 1st month and 6th month postoperative ACD values were significantly lower than preoperative values ($p = 0.044$, $p = 0.041$ and $p = 0.040$, respectively). There were no significant differences between preoperative and postoperative CCT and IOP measurements ($p = 0.567$ and $p = 0.434$, respectively). The postoperative first-week mean spherical value was 0.11 ± 0.44 D, and it was stable until the sixth month. Postoperative 6th month mean endothelial cell loss was 3% in comparison with preoperative value. The difference was not significant ($p = 0.465$). Additionally, no abnormal morphologic changes in endothelial cell layer were observed in specular microscopy. The mean WTW distance of patients was 11.63 ± 0.58 (10.80-12.49). The preoperative and post-

TABLE 2: Preoperative and postoperative findings of the patients.

Parameters	Preoperative	Postoperative 1 st Week	Postoperative 1 st Month	Postoperative 6 th Month
Spherical Value(D)	-14.28 ±3.51 (-20.75_-8.25)	0.11±0.44 (-0.75_0.75) p=0.00	0.10±0.33 (-0.75_0.75) p=0.00	0.12±0.39 (-0.75_0.75) p=0.00
Astigmatic Value (D)	-0.52 ±0.21 (-1.00_0.00)	-0.28±0.19 (-0.50_0.00) p=0.01	-0.26±0.17 (-0.50_0.00) p=0.01	-0.32±0.18 (-0.50_0.00) p=0.02
Spherical Equivalent (D)	-14.54±3.53 (-21.25_-8.25)	-0.04±0.04 (-0.75_0.75) p=0.00	-0.03±0.04 (-0.75_0.75) p=0.00	-0.04±0.04 (-0.75_0.75) p=0.00
UCVA (logMAR)	1.20±0.20 (0.90_1.50)	0.03±0.06 (-0.10_0.10) p=0.00	0.03±0.06 (-0.10_0.10) p=0.00	0.03±0.06 (-0.10_0.10) p=0.00
BCVA (logMAR)	0.04± 0.05 (0.00_0.10)	0.02± 0.05 (-0.10_0.10) p=0.01	0.02± 0.05 (-0.10_0.10) p=0.01	0.02±0.05 (-0.10_0.10) p=0.01
Intraocular Pressure (mmHg)	16.44±3.82 (10_19)	15.01±3.43 (10_19) p=0.59	15.15±3.57 (10_19) p=0.57	16.21±3.82 (10_19) p=0.43
Corneal Thickness (µ)	514.027±44.22 (450_594)	521.31±29.57 (478_063) p=0.45	517.21±30.53 (454_595) p=0.44	515.08±39.45 (451_593) p=0.56
Anterior Chamber Depth (mm)	3.38±0.31 (3.1_4.2)	2.76±0.29 (2.4_4.0) p=0.04	2.73±0.32 (2.5_4.0) p=0.04	2.79±0.33 (2.6_4.0) p=0.04
Endothelial Cell Density (mm ²)	2908.78±120 (2705_3100)	2888.61±121 (2610_3092) p=0.49	2855.88±142 (2585_3074) p=0.48	2805.76±134 (2566_3053) p=0.46

D: Diopter, UCVA: Uncorrected visual acuity, BCVA: Best corrected visual acuity mmHg: Milimeter mercury, µ: Micron, mm: Milimeter.

operative findings of the patients are presented in Table 2.

Patient satisfaction was measured in photopic, mesopic, and scotopic conditions and found to be between 1 (dissatisfied) and 10 (very satisfied). They are asked the visual acuity, quality of vision and presence of photic phenomenon like halo and glare. The patients did not have any dysphotopsic complaints. The mean satisfaction ratio was very high [9.47±0.59 (8-10)]. There were no intraoperative or postoperative complications, and postoperatively, all phakic IOLs' positions were central. The predictability value, efficacy and safety indexes of the patients were high. The postoperative 6th month predictability value was 89%, efficacy index was 1.21 and safety index was 1.27.

DISCUSSION

In this study, we evaluated postoperative spherical, astigmatic and SE values, UCVA, BCVA, IOP, ACD, ECD, CCT and intraoperative and postoperative complications after phakic IOL implantation. There were no intraoperative or postoperative complications. The spherical value decreased significantly, and UCVA increased significantly in postoperative follow-up examinations. The predictability value, efficacy and safety indexes of the patients were high. The postoperative 6th month predictability value was 89%, efficacy index was 1.21 and safety index was 1.27.

We preferred posterior chamber pIOL with a central hole in our patients to provide aqueous humour passage in order to avoid any intervention to

iris in future. We chose the model according to white-to-white (WTW) distance of the patients. Tang et al. reported that implanting phakic posterior chamber IOL with a central hole (ICL V4c) in patients with moderate to high myopia is safe and effective.¹⁶ Shimizu et al. reported that both hole and conventional ICLs corrected ametropia successfully throughout the 5-year observation period.¹⁷ It appears likely that the presence of the central hole does not significantly affect these visual and refractive outcomes.

Yaşa et al. reported that the mean preoperative SE of the patients was -13.41±3.22 D, and the mean age of the patients was 32.0±7.0 years.¹⁸ Yang et al. reported that the mean preoperative SE of the patients was -12.08±2.44 D, and the mean age of the patients was 33.15±9.28 years.¹³ In our study, the mean preoperative SE of the patients was -14.54±3.53 D, and the mean age of the patients was 28.97±4.10 years.

Yang et al. reported that, at the end of the postoperative sixth month, the visual acuities of all patients were over 0.3 logMAR; 60% of them reached 0.00 logMAR visual acuity, and the refractive power of all patients was within ±1.00 D.¹³ Yaşa et al. reported that, at the end of the postoperative sixth month, the visual acuities of all patients were better than 0.18 logMAR, and 93% of the patients' refractive powers were within ±1.00 D.¹⁸ In our study, at the end of the postoperative 6th month, the mean visual acuities of the patients was 0.03±0.06 logMAR, the mean refractive power of patients was -0.04±0.04 D. and 89% of the patients' refractive powers were within ± 0.50 D.

Endothelial cell loss is one of the most important complications of phakic IOL implantation. In our study, endothelial loss at the end of the postoperative sixth month was 3%. Yaşa et al. reported this ratio as 3.9%, and Yang et al. reported it as 3%.^{13,18} Moya et al. reported that endothelial cell loss was 6.46%, and this reduction continued every year as 1.20%.¹⁹ The safety limit was 90% in the studies.^{20,21} Galvis et al. reported that there is a significant endothelial cell loss in a low percentage of the eyes with Artisan lenses in the long term, and it can decrease to critical levels.²² Periodic endothelial density evaluations are required for these patients. The selection criteria of surgical candidates could be reevaluated. Bohac et al. reported that expected ECD loss after TICL implantation by 2 years postoperatively is predictable.²³ On average, over 3 years after implantation, there is an initial rapid decline in ECD, followed by a gradual fall in the rate of cell loss, and a gradual fall in the distance between the TICL and the crystalline lens by 2 years postoperatively, followed by a reversal by the third year. Endothelial cell loss in our study did not reach 10%, but in future follow-up examinations, this should be controlled. In long-term follow-ups, there will be 0.6% endothelial cell loss every year related to aging, and this should also be taken into account.²⁴

Cataract development is another complication of phakic IOL implantation in young patients.¹⁸ We did not encounter any cataract formation in our patients in follow-up examinations. Gube et al. identified 4.9% cataract formation in a five-year follow-up and 18.3% at a ten-year follow-up.²⁵

Glaucoma may develop after posterior phakic IOL implantation due to the pupillary block and pigment dispersion. Yaşa et al. reported that glaucoma developed in a patient related to steroid usage.¹⁸ Yang et al. reported that IOP increase was observed in two patients (8%) on the first postoperative day.¹³ Navarrete Argüello et al. reported that the effect of an ICL on IOP fluctuations, has been studied, which was found to be not statistically significant.²⁶ As in previous publications, the procedure was safe and reproducible, adding the fact that the level of training of the surgeon is not a determining factor in these findings. In our study, we did not encounter any IOP increase, neither pigment dispersion.

Eldanasoury et al. stated that smaller ACD and aqueous depth are significantly correlated with more endothelial cell loss.²⁷ Minimum ACD of 3.35 mm or aqueous depth of 2.75 mm are recommended for better long-term endothelial safety. Niu et al. observed that ICL V4c implantation in patients with high myopia and shallow ACD achieved satisfying and stable visual outcomes.²⁸ Its long-term safety and stability require further investigation. In our study, postoperative ACD values decreased significantly when compared to preoperative values, however, no problem occurred related to this in 6 months follow-up time, meaning we did not encounter severe ECD loss.

Sachdev et al. compared clinical outcomes following implantation of two types of posterior chamber phakic intraocular lenses: Visian™ Implantable Collamer Lens with Centraflow (ICL, V4C Staar Surgical, Nidau, Switzerland) and Implantable Phakic Contact Lens (IPCL, V1, Caregroup Sight Solution, India) for the correction of myopia and myopic astigmatism.²⁹ Both groups demonstrated similar efficacy and safety profile. The IPCL is an effective and economically viable option for the correction of myopia. Qin et al. evaluated the visual quality, objective scattering index, aberration, etc after Implantable Collamer Lens with center hole (EVO-ICL) implantation to treat patients with hypermyopia (diopter > -10 D).³⁰ Total aberration (TA), total low-order aberration (tLOAs), and defocus decreased at 1 week and 3 months after EVO-ICL implantation. Total highorder aberration (tHOAs) and spherical aberration were significantly increased 1 week after surgery and decreased 3 months after surgery, and the difference was statistically significant. Astigmatism, coma, and clover were not significantly different in each time period. TA, tLOAs, tHOAs, defocus, and spherical aberration were higher at 1 week than 3 months after surgery. At 3 months after surgery, the National Eye Institute Refractive Error Quality of Life Instrument-42 scale scores of the patients were all improved except that the glare was lower than that before surgery. There was no significant difference in the density of corneal endothelial cells before and 3 months after surgery. For patients with hypermyopia, the postoperative subjective and objective visual quality of EVO-ICL implantation was better than preoperative. Choi et al. reported the long-term clinical out-

comes, including efficacy and safety, of implantable collamer lens (ICL) implantation to treat myopia.³¹ The results indicated that ICL implantation provided long-term stability and good refractive outcomes. Performing this surgery in young patients, especially those 30 years or younger, may be safe in terms of long-term cataract formation.

One of our limitations in this study was the lack of lens vault measurement, which is an important parameter for angle closure glaucoma. Another one is the short duration of postoperative follow-up time, which is important for observation of development of complications such as cataract, glaucoma and endothelial cell layer insufficiency.

CONCLUSION

Eyecriphakic IOL implantation is a safe, effective, predictable and stable method in high- myopia treatment in the short-term. Long-term results of phakic IOL implantation should be investigated in further studies.

Source of Finance

During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that provides or produces medical instruments and materials which may negatively affect the evaluation process of this study.

Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

Idea/Concept: Fikret Uçar; **Design:** Fikret Uçar, Servet Çetinkaya; **Control/Supervision:** Fikret Uçar, Servet Çetinkaya; **Data Collection and/or Processing:** Fikret Uçar; **Analysis and/or Interpretation:** Fikret Uçar, Servet Çetinkaya; **Literature Review:** Fikret Uçar, Servet Çetinkaya; **Writing the Article:** Fikret Uçar, Servet Çetinkaya; **Critical Review:** Fikret Uçar, Servet Çetinkaya; **References and Fundings:** Fikret Uçar; **Materials:** Fikret Uçar.

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