Original Article

Safety and Efficacy of Intraocular Phakic Contact Lens Implantation in Keratoconus Patients

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Abstract

Purpose: To evaluate the safety and efficacy of toric implantable phakic contact lens (IPCL) use in the treatment of patients with keratoconus.
Patients and Methods: We included 17 eyes from 10 consecutive keratoconus patients who underwent toric IPCL implantation (IPCL V.2, Care Group Sight Solutions, India) in this study. The primary measures were uncorrected distance visual acuity (UCVA), best corrected distance visual acuity (BCVA), sphere, astigmatism, and intraocular pressure (IOP). These parameters were assessed preoperatively and at 1, 3, and 6 months postoperatively. Intraoperative and postoperative complications were also evaluated.
Results: The mean age of the patients entering the study was 36 ± 8.8 years. The preoperative BCVA was 0.75 ± 0.21 diopter, improving to 0.86 ± 0.11 diopter postoperatively ($P = 0.017$). The mean UCVA improved significantly from a preoperative measurement of 0.09 ± 0.11 diopter to 0.78 ± 0.15 diopter postoperatively ($P < 0.001$). The mean spherical equivalent (SE) showed an enhancement from -6.8 ± 2.1 diopters preoperatively to -0.7 ± 0.3 diopters at the postoperative assessment ($P < 0.001$). The mean IOP increased from 15.3 mmHg to 16.2 mmHg ($P = 0.007$) which was statistically significant but clinically insignificant. Additionally, none of the patients experienced postoperative complications such as endophthalmitis, uveitis, IPCL rotation, cataracts, or cystoid macular edema (CME) within the six months following the procedure.
Conclusion: The implantation of IPCL in patients with keratoconus appears to be safe and effective. However, further studies with longer follow-ups and larger sample sizes are recommended to validate these findings.

Keywords: Intraocular; Phakic; Contact Lens; Keratoconus.

Article Notes: Received: Mar. 01, 2022; Received in revised form: Apr. 11, 2022; Accepted: May. 24, 2022; Available Online: Sep. 24, 2022.

How to cite this article: Heidari H, Daryabari SH, Nejat F, Besharatzad S, Pirhadi S, Jadidi K. Safety and Efficacy of Intraocular Phakic Contact Lens Implantation in Keratoconus Patients. Journal of Ophthalmic and Optometric Sciences . 2022;6(4): 5-12.

Introduction

Keratoconus (KCN) is a progressive corneal disease that results in the steepening and thinning of the cornea, affecting 50 to 230 individuals per 100,000 worldwide [1]. Many patients with this condition also develop myopia and astigmatism [2]. While the progression of this disease can be slowed with corneal cross-linking (CXL), patients often need additional treatments to achieve optimal vision [3].

Options for restoring visual acuity include spectacles, contact lenses, intracorneal rings (ICRs), lens replacement, phakic intraocular lenses (PIOLs), and, occasionally, laser refractive surgeries. However, many KCN patients cannot tolerate contact lenses because of an irregular corneal shape and comorbidities like dry eye disease. Moreover, they are not ideal candidates for laser refractive surgeries, as their corneal thickness is reduced and their corneal biomechanical characteristics are weak, increasing the risk of complications such as ectasia following surgery [4].

Lens replacement is also not the preferred option, particularly for younger patients, as this procedure does not preserve accommodation [5]. ICRs, while providing moderate improvement in refraction, are not suitable for patients with higher refractive errors, and their success rate is limited [6].

In situations where KCN progression has been halted, either with or without CXL, PIOLs emerge as potential treatment modalities. These lenses can enhance visual acuity, even for higher refractive errors, while preserving the lens's accommodative function. The most researched PIOL, known as the intraocular collamer lens (ICL), has demonstrated significant efficiency and safety in patients with or without KCN. However, a major drawback of the ICL is its high cost, especially in developing countries [7]. Fortunately, there is a less expensive alternative available: the intraocular phakic contact lens (IPCL) introduced by Care Group India. This lens, made of hydrophilic acrylic, has recently been highlighted for its efficacy, safety, and predictability [8, 9]. Nonetheless, there is a scarcity of studies regarding the safety and effectiveness of IPCL in eyes affected by KCN. In this study, we aim to present a series of cases involving KCN patients who underwent toric IPCL implantation and were followed up for a period of six months.

Patients and Methods

This was a prospective study conducted on 17 eyes of 10 consecutive patients with keratoconus, who underwent IPCL implantation at Bina Eye Hospital, Tehran, Iran or Baqiatallah Hospital, Tehran, Iran. Our inclusion criteria encompassed patients with stable keratoconus for at least one year (following CXL surgery or during follow-up), who desired to discontinue using spectacles and had a best-corrected visual acuity (BCVA) of at least 0.5, an anterior chamber depth (ACD) of at least 3 mm from the endothelium, an endothelial cell density (ECD) of at least 2000 cells/mm2, and an intolerance to rigid gas permeable contact lenses. Exclusion criteria included being younger than 21 years or having any ophthalmic diseases other than keratoconus, such as corneal opacification, cataract, glaucoma, or diabetic retinopathy. All steps of this study followed the tenets of the Declaration of Helsinki. The ethics committee of Semnan University of Medical Sciences, Semnan, Iran, approved the protocol of the study (Ethic Code: IR.SEMUMS.REC.1400.023). All patients gave written consent before entering the present study.

Preoperative examination

All patients underwent a comprehensive slit-lamp examination, including an assessment of cornea and lens opacity and a retinal examination. Furthermore, uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), anterior chamber depth (ACD), endothelial cell density (ECD), and intraocular pressure (IOP) were evaluated preoperatively in all patients. Corneal topography was also assessed using Pentacam HR (Optikgerate GmbH, Wetzlar, Germany) and anterior segment optical coherence tomography (OCT) (Cassini SS1000, Tomey, Nagoya, Japan).

Surgical technique

The pupil was dilated using Tropicamide 30 minutes before surgery. Topical anesthesia was administered, and the zero and 180-degree horizontal axes were marked using a slit-lamp examination while the patient was sitting, to prevent cyclotorsion. The IPCL V2. 0 was placed in the IPCL cartridge using McPherson forceps, after which the cartridge was inserted into the injector.

The patient was then prepped and draped. Subsequently, a small 2.8 mm corneal incision was made using a temporal approach, and a stab incision 90 degrees away was performed. Dispersive viscoelastic was injected into the anterior chamber, followed by the insertion of the injector through the incision, and the IPCL was deployed into the anterior chamber. After the IPCL fully unfolded, each of its four footplates was gently maneuvered under the iris to its correct position (zero and 180 degrees). The dispersive viscoelastic material was aspirated, the anterior chamber was irrigated with normal saline, and the corneal incision was hydrated. Postoperatively, patients were prescribed Ciprofloxacin drops (Sinadarou, Iran) every 12 hours for a week and Betamethasone drops (Sinadarou, Iran) every four hours, which was tapered after two weeks.

Follow-Up

Each patient was initially evaluated four hours post-surgery, during which the cornea, IPCL position, and IOP were examined. Subsequent post-operative assessments were scheduled for one day, one week, one month, three months, and six months post-surgery. During each follow-up, patients underwent a slit-lamp examination to check for inflammation and IPCL position as well as IOP measurement. Additionally, the vault was measured using anterior segment OCT at each follow-up visit.

Statistical analysis

The normality of data distribution was evaluated using the Kolmogorov-Smirnov test. The relationship between various pre- and postoperative variables was examined using the non-parametric Wilcoxon rank test. Correlations between different variables were determined using Spearman's rank correlation coefficient, a non-parametric measure. Data analysis was conducted using SPSS version 23 (Armonk, NY: IBM Corp.), and a P value of less than 0.05 was considered statistically significant.

Results

A total of 17 eyes (from 10 patients) were included in our study. The patients' mean age was 36 ± 8.8 years, and 60 % were females. As shown in table 1, the average anterior chamber depth of our patients, measured from the endothelium, was 3.22 ± 0.31 mm (ranging

Table 1: Demographic characteristics of study participants

Variable	Mean ± SD (n=17)	Minimum	Maximum
Age (years)	36 ± 8.8	26	55
SE (D)	-6.8 ± 2.1	-11.5	-3.75
Sphere (D)	-5.1 ± 2.1	-10	-1.75
Cylinder (D)	-3.4 ± 2.1	-7	-1
UCVA	0.09 ± 0.11	0.01	0.40
BCVA	0.75 ± 0.21	0.5	1.0
ACD (mm)	3.22 ± 0.31	2.83	3.74
CCT (μm)	455.5 ± 44.2	334	535
K1 (D)	44.5 ± 1.8	41.4	47.8
K2 (D)	47.6 ± 2.7	41.1	52
Kmax (D)	49.7 ± 4.3	43.5	56.6
IOP (mmHg)	15.3 ± 2.1	11	18

SE: Spherical equivalent; UCVA: Uncorrected visual acuity; BCVA: Best corrected visual acuity; ACD: anterior chamber depth; CCT: central corneal thickness; IOP: intraocular pressure

from 2.83 mm to 3.74 mm), and their central corneal thickness was 455.5 ± 44.2 μm. The mean preoperative spherical equivalent (SE), sphere, and cylinder of the patients were -6.8 ± 2.1, -5.1 ± 2.1, and -3.4 ± 2.1 diopters, respectively. Moreover, all of our patients had a UCVA of less than 0.5, and 41.18 % had a BCVA of less than 0.7 before IPCL transplantation.

None of our patients encountered any intraoperative complications, such as lens breakage. After the placement of IPCL, all refractive indices of the patients significantly improved after six months (Table 2). Similarly, the sphere and cylinder of patients improved significantly (Table 2). All of our patients achieved a postoperative UCVA of more than 0.5, and 82.35 % attained a postoperative UCVA of 0.7 or higher. Furthermore, all of them reached a BCVA of 0.7 or higher after IPCL transplantation.

Notably, the mean IOP of patients increased from 15.3 mmHg to 16.2 mmHg. Although this change is not clinically significant, it reached statistical significance (Table 2).

In our patients, the vault for IPCL placement ranged from 221 to 941 μm, with a mean of 588 ± 217 μm. The majority of patients fell within the range of 250 to 750 μm (Table 2 and Figure 1).

In terms of the possible impact of keratometry indices on post-operative visual acuity, we identified a significant negative correlation between K2 and Kmax with postoperative UCVA (Table 3). However, there was no significant relationship found between keratometry indices or anterior chamber depth and postoperative cylinder and SE.

None of our patients experienced any postoperative complications after six months,

Table 2: Comparison of preoperative and six-month postoperative characteristics of patients following IPCL implantation

Variable	Preoperative Mean ± SD (n=17)	Postoperative Mean ± SD (n=17)	P-value*
SE (D)	-6.8 ± 2.1	-0.7 ± 0.3	<0.001
Sphere (D)	-5.1 ± 2.1	-0.15 ± 0.34	<0.001
Cylinder (D)	-3.4 ± 2.1	-1.1 ± 0.5	<0.001
UCVA	0.09 ± 0.11	0.78 ± 0.15	<0.001
BCVA	0.75 ± 0.21	0.86 ± 0.11	0.017
IOP (mmHg)	15.3 ± 2.1	16.2 ± 2.6	0.007
Vault (µm)	_-	588 ± 217	NA

SE: Spherical equivalent, UCVA: Uncorrected visual acuity, BCVA: Best corrected visual acuity, IOP: Intraocular pressure
* Compared to preoperative values (Wilcoxon rank test)

Table 3: Correlation of keratometry measurements, central corneal thickness, and anterior chamber depth with postoperative outcomes

Variable		Vault	UCVA	BCVA	Sphere	Cylinder	SE
K1	r	.006	-.373	-.069	.140	.104	-.092
	P-value*	.981	.141	.793	.592	.692	.724
K2	r	.061	-.744**	-.418	-.004	-.058	.001
	P-value*	.815	.001	.095	.988	.824	.996
Kmax	r	-.010	-.633**	-.296	-.023	-.166	-.174
	P-value*	.970	.006	.248	.931	.524	.503
CCT	r	.624*	.344	.483*	.424	.365	.077
	P-value*	.007	.177	.049	.090	.150	.769
AC Depth	r	.318	.358	.570**	.510**	.305	-.280
	P-value*	.214	.158	.017	.036	.235	.276

SE: Spherical equivalent, UCVA: Uncorrected visual acuity, BCVA: Best corrected visual acuity, AC Depth: Anterior chamber depth, CCT: Central corneal thickness
* Based on Spearman's rank correlation coefficient
**Statistically significant

such as endophthalmitis, uveitis, IPCL rotation, cataracts, or cystoid macular edema (CME), as assessed clinically.

Discussion

To our knowledge, this study is among the few case series of keratoconus patients who

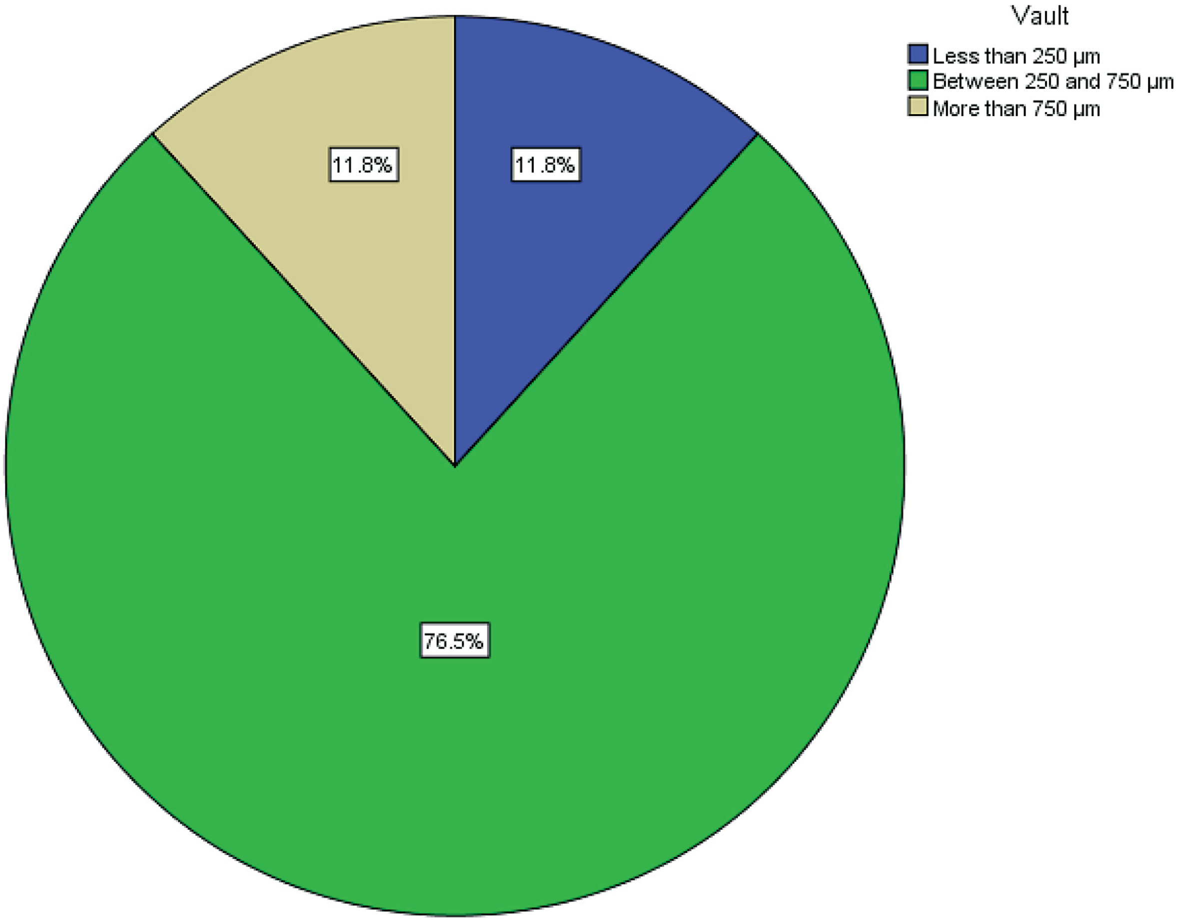

Figure 1: Percentage of patients with different vault values entering the study

underwent toric intraocular phakic contact lens (IPCL) placement. Our findings underscore the high efficacy of these lenses, as the SE, sphere, cylinder, UCVA, and BCVA of our patients all improved significantly six months after IPCL implantation. Preoperatively, none of our patients had a UCVA higher than 0.5, yet postoperatively, all achieved a UCVA of 0.5 or higher, and the majority attained a UCVA of 0.7 or higher. This underscores the high efficacy of toric IPCL implantation in improving both the sphere and cylinder of patients.

Our results revealed a significant negative correlation between keratometry readings and postoperative UCVA, suggesting that patients with more severe keratoconus might achieve suboptimal UCVA following IPCL insertion. Patients with higher keratometry readings typically have a more irregular corneal surface, leading to poorer vision that cannot be fully rectified with lenses. Moreover, eyes with advanced keratoconus exhibit high-order aberrations that further compromise vision. However, as IPCL primarily corrects refractive errors (low-order aberrations), it appears that patients with more advanced keratoconus do not attain high UCVA [10].

In research conducted by Doroodgar et al., [11] patients with stable keratoconus underwent toric IPCL implantation. Echoing our findings, the SE of patients changed markedly, from -6.9 to -0.23 after six months, corroborating the effectiveness of IPCL [11]. They also identified an acceptable mean safety index of 1.11 and reported less than a 5% endothelial cell loss

(ECL) following a six-month follow-up. Regrettably, we did not assess endothelial cell density in our participants. Other studies have similarly reported an ECL of less than 5% post-IPCL insertion [8, 12]. Although ECL is minimal, patients with a preoperative endothelial cell density below 2000 cells/mm2 are deemed unsuitable for IPCL implantation.

Concerning potential complications, none of our participants experienced cataract formation or lens rotation during the six-month follow-up. A crucial aspect of IPCL is the risk of rotation, particularly with toric lenses, as any rotation could significantly impact vision. Rotations might happen spontaneously or due to trauma. Should rotation occur, the issue can be readily resolved by repositioning the lens via a minor corneal incision. Furthermore, our patients did not report other postoperative complications, including CME, uveitis, and endophthalmitis.

A notable finding in our research was the rise in postoperative IOP, even though we utilized IPCL V.2, designed with a central hole to ease aqueous humor circulation and avert pupillary block [12]. While the increase was not clinically significant (around 1 mmHg), it was statistically significant, implying caution during patient selection and suggesting those with borderline IOP should avoid IPCL placement without peripheral iridotomy.

Cataract development remains a significant concern following intraocular phakic lens placement [13]. Two primary factors expedite lens opacification: contact between the artificial and natural lenses, potentially leading to subcapsular cataracts, and malnutrition caused by obstructed aqueous humor circulation [14]. Addressing the first issue requires ensuring the vault is within the optimal range and entails meticulous assessment of the anterior chamber anatomy prior to IPCL insertion. Regarding aqueous humor circulation, the earlier IPCL model necessitated one or two peripheral iridotomies pre- or intraoperatively. However, IPCL's second version negates the need for iridotomies, featuring a central hole and multiple peripheral holes to maintain aqueous humor flow, nourishing the lens and preventing cataract formation [12].

The primary limitations of our study were the small cohort and brief follow-up duration. Additionally, we did not assess the endothelial cell density of participants after surgery. Nevertheless, considering the limited data on IPCL usage in keratoconic eyes, our study suggests these lenses might be safe and effective for enhancing refraction in keratoconus patients.

Conclusion

The implantation of IPCL in patients with keratoconus appears to be safe and effective. However, further studies with longer follow-ups and larger sample sizes are recommended to validate these findings.

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References

1. Yan W, Chen Y, Chen X, Ye Q, Wang Y, Jiang C, et al. Diagnosis of keratoconus in a young male by electrophysiological test findings: A case report. Medicine (Baltimore). 2022;101(27):e29351.

2. Davis LJ, Schechtman KB, Wilson BS, Rosenstiel CE, Riley CH, Libassi DP, et

al. Longitudinal changes in visual acuity in keratoconus. Invest Ophthalmol Vis Sci. 2006;47(2):489-500.

3. Mazzotta C, Traversi C, Baiocchi S, Bagaglia S, Caporossi O, Villano A, et al. Corneal Collagen Cross-Linking With Riboflavin and Ultraviolet A Light for Pediatric Keratoconus: Ten-Year Results. Cornea. 2018;37(5):560-6.

4. Binder PS, Lindstrom RL, Stulting RD, Donnenfeld E, Wu H, McDonnell P, et al. Keratoconus and corneal ectasia after LASIK. J Cataract Refract Surg. 2005;31(11):2035-8.

5. Hayashi K, Hayashi H. Comparison of amplitude of apparent accommodation in pseudophakic eyes with that of normal accommodation in phakic eyes in various age groups. Eye (Lond). 2006;20(3):290-6.

6. Sedaghat MR, Momeni-Moghaddam H, Piñero DP, Akbarzadeh R, Moshirfar M, Bamdad S, et al. Predictors of Successful Outcome following Intrastromal Corneal Ring Segments Implantation. Curr Eye Res. 2019;44(7):707-15.

7. Emerah SH, Sabry MM, Saad HA, Ghobashy WA. Visual and refractive outcomes of posterior chamber phakic IOL in stable keratoconus. Int J Ophthalmol. 2019;12(5):840-3.

8. Yaşa D, Ürdem U, Ağca A, Yildirim Y, Kepez Yildiz B, Kandemir Beşek N, et al, Early Results with a New Posterior Chamber Phakic Intraocular Lens in Patients with High Myopia. J Ophthalmol. 2018;2018:1329874.

9. Sachdev G, Ramamurthy D. Long-term safety of posterior chamber implantable phakic contact lens for the correction of myopia. Clin Ophthalmol. 2019;13:137-42.

10. Colak HN, Kantarci FA, Yildirim A, Tatar MG, Goker H, Uslu H, et al. Comparison of corneal topographic measurements and high order aberrations in keratoconus and normal eyes. Cont Lens Anterior Eye. 2016;39(5):380-4.

11. Doroodgar F, Niazi F, Niazi S, Sanginabadi A, Alinia C. Visual outcomes of a new implantable Phakic contact lens in patients with stable keratoconus. Int Eye Sci. 2019;19(7): 1089-94.

12. Bianchi GR. Initial Results From a New Model of Posterior Chamber Implantable Phakic Contact Lens: IPCL V2.0. Med Hypothesis Discov Innov Ophthalmol. 2019;8(2):57-63.

13. Chen LJ, Chang YJ, Kuo JC, Rajagopal R, Azar DT. Metaanalysis of cataract development after phakic intraocular lens surgery. J Cataract Refract Surg. 2008;34(7):1181-200.

14. Fernández J, Sánchez - García A, Rodríguez - Vallejo M, Piñero DP. Systematic review of potential causes of intraocular lens opacification. Clin Exp Ophthalmol. 2020;48(1):89-97.

Footnotes and Financial Disclosures

Conflict of interest:

The authors have no conflict of interest with the subject matter of the present manuscript.