Phakic posterior chamber intraocular collamer lenses in keratoconus Running title: Phakic posterior chamber intraocular collamer lenses

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Abstract: AIM: To assess efficacy and safety of phakic posterior chamber intraocular lenses in patients with keratoconus. **METHODS**: In this prospective case series 15 eyes of 9 patients diagnosed with Keratoconus underwent implantation of phakic posterior chamber intraocular lenses. Uncorrected visual acuity (UCVA), best spectacle corrected visual acuity (BSCVA), and refractive error of patients before and 12 months after operation were compared. Efficacy index and safety index were measured at 12 months post operation. **RESULTS**: The mean refractive error of patients before and after operation was (-11.38±2.08)D and (-0.9±0.93)D, respectively. The mean UCVA improved from (1.01±.20) Logmar to (0.15±0.56) Logmar 12 months after operation. The mean BSCVA before operation was (0.40±0.17) Logmar that improved to (0.05±0.03) Logmar postoperatively. Safety index and efficacy index at 12 months were 2.10 and 1.68, respectively. **CONCLUSION**: Phakic posterior chamber intraocular lenses can considerably improve UCVA and BSCVA of patients with keratoconus. It is a safe and effective procedure in selected patients with stable keratoconus.
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1. Introduction

Keratoconus (KCN) is a non inflammatory and progressive degenerative disease of the cornea. Cornea takes a cone like configuration and corneal thickness is reduced. This cone like configuration leads to irregular astigmatism and myopia which in turn causes significant reduction in visual quality and visual acuity. Disease progression may lead to corneal scar(Alfonso, 2008; Rabinowitz, 1998; Davis, 2006; Zadnik, 2000; Ertan, 2007). First patients are advised to use glasses and soft contact lenses but due to irregular astigmatism and high myopia, patients are not usually satisfied with them. Hard contact lenses can give an excellent vision in patients with KCN. Some patients with KCN are not tolerant of contact lenses while in some cases a good fit is not possible and can have some complications such as corneal ulcer, allergic reactions and corneal neovascularisation(Davis, 2006; Ertan, 2007; Garcia-Lledo, 2006; Rabinowitz, 1991). Refractive surgeries including laser in situ keratomileusis are contraindicated in KCN(Schmitt-Bernard, 2000; Lafond, 2001).

There are some emerging alternative therapies in recent years. These include phakic intraocular lens implantation and intrastromal corneal segment implantation. Phakic intraocular lenses are reported to be effective in KCN. Some studies have used anterior chamber phakic intraocular lenses with good results in KCN(Leccisotti and Fields, 2003; Moshirfar, 2006; Budo, 2005). In a study, Alfonso et al.1 treated KCN patients with phakic posterior chamber lenses with good results. There are few studies in literature assessing the safety and effectiveness of phakic posterior chamber intraocular lenses in KCN(Alfonso, 2010).

In the present study, we aimed at evaluating the effectiveness and safety of these lenses in a series of 15 eyes with KCN.

2. Material and Methods

In this prospective study between 2008 and 2011, 15 eyes with KCN were investigated. Diagnosis of keratoconus was based on keratometry reading >47.2, posterior elevation >15μ within the 5 central circle, I-S value>1.4 and clinical signs of keratoconus including scissoring reflex, vogt lines and Fleischer ring. Inclusion criteria were patients with clear cornea and stable KCN with spectacle and soft contact lens intolerance with higher spherical refractive error than cylindrical refractive error and BCVA of 0.3 or better. Stable Keratoconus was defined as a change of 0.5D or less in manifest spherical equivalent refractive error

yearly for 2 years prior to surgery. Exclusion criteria were any intraocular surgeries, uveitis, glaucoma, endothelial cell count <2000 and anterior chamber depth <3.00mm and patients younger than 20 years old. Informed written consent was obtained from all patients.

Patients had complete slit lamp examination, gonioscopy, intraocular pressure measurement by applanation tonometry, dilated indirect fundus examination, manifest and cycloplegic refraction, best uncorrected visual acuity (UCVA) and best spectacle corrected visual acuity (BSCVA). In all patients topographic studies with pentacam and endothelial cell count by specular microscopy were performed. Patients were planned for phakic posterior chamber collamer intraocular lens implantation. The collamer phakic posterior chamber STAAR lens is made of collamer polymer to implant in sulcus in presence of naive crystalline lens. The implanted lenses were either toric or myopic. Intraocular lens (IOL) power was calculated with the software provided by manufacturer.

Operation was performed by an exprienced anterior segment surgeon under general anesthesia. Two hours prior to operation patients received an application of mydriatic tropicamide eye drop. Just before operation corneal axis was marked using axial marker, for horizontal axis limbus marking (Elies ANGOLATO 90) (e.janach). Procedure included two stab incision at 6 and 12 o'clock and 3.2mm main temporal clear corneal incision and injection of 1/100 000 adrenalin for pupil dilation. Corneal incisions were not intended to reduce astigmatism and only Toric IOLs were used to compensate the astigmatism. Forming anterior chamber with ocular viscoelastic devices, phakic posterior chamber collamer IOL was injected in to the anterior chamber. After placing haptics in sulcus, lens was rotated to advised angle by manufacturer. Miocholin was injected for pupil constriction. Ocular viscoelastic device was removed by irrigation and wound was sealed by stromal hydration. Subconjuctival cefazolin and betamethason was injected at the end of operation. Whidin surgery peripheral iridectomy was made by vitrectomy probe. Postoperatively patients were treated with topical betamethason 1% every 2 hours and chloramphenicol every 4 hours for one week and oral prednisolon 0.5mg/kg for four days. Bethametason eyedrop was used for three weeks on tapering dose. Patients were visited one day, one week, one month and then every 6 months after operation. Patients were followed up from 12 months up to 36 months after surgery for increased intraocular pressure, glaucoma, cataract, uveitis and retinal detachment. Data including uncorrected best visual acuity and spectacle corrected visual acuity and residual refractive error after surgery was collected in follow up visits. Results were compared with the corresponding preoperative values.

The data were analyzed with the SPSS statistical package (version 16; SPSS, Inc, Chicago, IL). Analysis was conducted by Wilcoxon Signed Ranks test. A P value <0.05 was considered statistically significant.

3. Results

In the present study, 9 patients (4 males and 5 females) with 15 eyes were recruited. Patients were in age range of 21-33 years old. Phakic posterior intraocular collamer lenses (10 toric lenses and 5 spherical lenses) were implanted in the studied patients. The mean follow up time of the patients was (27.4±7.47) months. Table 1 shows preoperative data of the patients. Preoperative UCVA in all the patients was in range of counting finger except for a patient with visual acuity of 0.3 (decimal scale). The mean preoperative BSCVA was 0.40±0.17 Logmar.

The mean keratometric value of the patients was (50.11±5.21). The mean anterior chamber depth was (3.63±0.24)mm. The mean refractive error of the patients was (-9.78±2.48)D in sphericity and (-3.13±1.12)D in astigmatism. The mean spherical equivalent was (-11.38±2.08)D.

The 12-month postoperative data of the patients are presented in Table 2. The mean UCVA and BSCVA of the patients were (0.15±0.56)Logmar and (0.05±0.03)Logmar, respectively. All patients had UCVA better than 20/40. There was a significant improvement in both UCVA and BSCVA values (P=0.001 and P=0.001, respectively). The mean postoperative refractive error in the spherical equivalent was (-0.90±0.93)D (range -2.25 to +0.62D) and (-2.05±1.01)D (range -0.5 to -3.75D) in the astigmatism. Figure 1 illustrates the numbers of spherical equivalent refractive error among the study patients.

Table 1. Preoperative data of patients

Eye	Sex/Age	Kmax/Kmin	Sphere (D)	Cylinder (D)	Axis (˚)	UCVA	BSCVA	ACD (mm)
1	F/25	57.50/55.00	-11.00	-4.00	160	CF	0.3	3.49
2	F/25	56.00/51.50	-10.50	-2.00	15	0.3	0.6	3.48
3	M/21	52.25/56.00	-9.00	-3.00	45	CF	0.3	3.52
4	F/22	47.60/41.75	-5.00	-4.00	60	CF	0.4	3.62
5	F/23	45.25/42.25	-11.00	-2.00	170	CF	0.6	3.41
6	F/23	47.75/43.25	-11.00	-3.00	30	CF	0.5	3.50
7	F/32	44.75/42.25	-8.00	-4.00	160	CF	0.5	3.89
8	F/32	44.00/41.75	-7.00	-3.75	25	CF	0.6	3.94
9	F/29	59.00/53.25	-8.75	-4.00	180	CF	0.3	3.70
10	F/29	56.75/53.25	-9.00	-3.75	15	CF	0.4	3.49
11	M/30	55.00/54.00	-16.00	-1.00	165	CF	0.2	4.05
12	M/30	53.75/49.50	-12.00	-1.50	115	CF	0.2	3.94
13	M/26	54.50/49.00	-9.00	-3.50	40	CF	0.6	3.68
14	M/26	56.00/50.00	-9.00	-5.00	145	CF	0.6	3.69
15	F/33	49.75/45.50	-10.50	-2.50	90	CF	0.3	3.15

Table 2. Postoperative data of patients

Eye	IOL Power	Sphere (D)	Cylinder (D)	Axis (˚)	UCVA	BSCVA	Vault
1	-20.5	+1.5	-2.5	150	0.8	0.9	2
2	-17.0	+1.0	-2.0	5	0.8	0.9	3
3	-19.0+4.5×150˚	-1.0	-0.5	90	0.9	1.0	2
4	-13.0+5.0×150˚	+1.25	-2.5	80	0.8	0.9	2
5	-18.0+2.5×86˚	-2.0	-0.5	145	0.7	0.8	2
6	-19.5+3.5×115˚	-1.0	-2.5	45	0.7	0.8	3
7	-12.0	+0.5	-3.0	155	0.6	0.9	3
8	-10.5	+0.25	-2.5	20	0.7	0.9	4
9	-21.5+5.5×111˚	+1.25	-1.25	155	0.7	0.8	3
10	-21.0+6.0×88˚	+1.75	-3.25	45	0.7	0.9	2
11	-23.0	0.0	-2.00	180	0.6	0.9	2
12	-23.0+4.0×160˚	-0.75	-.05	180	0.6	0.9	2
13	-20.+6.0×115˚	0.0	-2.5	25	0.8	1.0	3
14	-21.5+6.0×5˚	+0.5	-3.75	150˚	0.6	1.0	3
15	-18.0+3.0×161˚	-1.50	-1.5	170˚	0.8	0.9	2

There was a significant improvement in the refractive error both in spherical equivalent and astigmatism (P=0.001 and P=0.003, respectively). The spherical equivalent refractive error in 80% of the eyes was within ±1.25D and in 60% of the eyes was within ±1.00D. None of the patients lost one line in BSCVA. Efficacy index (mean postoperative UCVA/mean preoperative BSCVA) was 1.68 at 12th month. Safety index (mean postoperative BSCVA/mean preoperative BSCVA) was 2.10 at 12th month. During the follow up time, there was no complication including glaucoma, cataract, high intraocular pressure, uveitis or retinal detachment. The patients' mean intraocular pressure was 16mmHg with all patients less than 19mmHg. There was no decentration or rotation of IOL needing repositioning. In one patient with bilateral surgery, we noticed reduction of UCVA after 36 months in comparison to that of 12 months post operation due to myopic change of 1.5D in sphericity without change in astigmatism and BSCVA.

4. Discussions and conclusion

The results of this study revealed that implantation of posterior chamber phakic intraocular lenses could be an effective treatment modality for significant improvement of UCVA and BSCVA in stable KCN patients with minimal complications. The results of our study showed that this treatment modality could have a high degree of predictability in terms of aimed postoperative refractive error, UCVA and BSCVA. Safety index and efficacy index in this study were good with values of 2.10 and 1.68, respectively. After 12 months, 80% of patients were within ±1.25D. There was no line reduction of BSCVA in any patient. We did not encounter any complication and need for lens repositioning. Our findings were in line with the previous studies. Alfonso et al showed that use of collagen copolymer toric posterior phakic intraocular lenses was a predictable and effective refractive surgery in patients with KCN(Alfonso, 2010).

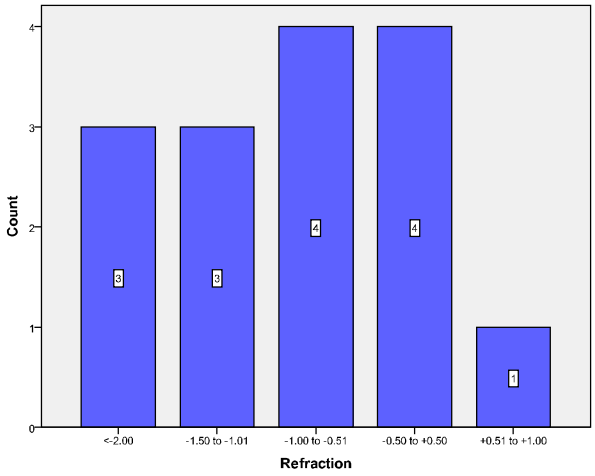

Figure 1. Numbers of spherical equivalent refractive error among the study patients

In their study on 30 eyes with KCN, the mean UCVA was (0.09±0.69) Logmar (0.81±0.2 decimal acuity) and BSCVA was (0.08±0.74) Logmar (0.83±0.18 decimal acuity) 12 months after operation. There was no significant difference between preoperative BSCVA and postoperative UCVA. All the patients were within ±1.00D of planned postoperative refraction. Safety index and efficacy index in their study at 12 months were 1.16 and 1.09, respectively. No eyes lost more than two lines of BSCVA. They reported no complication and no intraocular lens decentration or rotation(Alfonso, 2010). Predictability of their results was higher than our study as only 60% of our patients were within ±1.00 D, 12 months after operation. In both studies efficacy and safety index were good but were higher in our study that may be due to differences in patient selection with lower preoperative BSCVA of patients in our series. In another study by Alfonso et al, myopic phakic posterior intraocular lenses were applied in 25 eyes with KCN(Alfonso, 2008). The mean UCVA and BSCVA were (0.17±0.19) Logmar and (0.12±0.12) Logmar respectively. The safety index at 12 months was 1.05. Efficacy index at the same time was 0.98. Predictability was good, all the patients were within 1.00D range, and 84% were within ±0.5D range. After operation, 88% of patients had UCVA 20/40 or better and 96% of patients had BSCVA 20/40 or better. No eye lost 2 or more lines but 2 eyes lost 1 line. Postoperative BSCVA in comparison with the corresponding preoperative value was significantly improved (Alfonso, 2008). In our study, all patients had UCVA better than 20/40 decimal acuity 12 months after operation. Likewise, safety index and efficacy index in our study was higher. No eye lost even 1 line but predictability was lower in our study. In a similar study by Alfonso et al, toric phakic posterior chamber collamer lenses were used in patients with myopic astigmatism(Alfonso and Baamonde, 2010). They showed that the procedure was effective and post operative refractive error of about 80% of patients was within ±0.5D(Alfonso and Baamonde, 2010). This study shows that use of these lenses in patients with myopic astigmatism which have regular astigmatism and stable refraction is satisfactory and predictable and similar results can be anticipated in similar conditions like in patients with stable keratocnus but with a number of drawbacks.

In a study by Kurian et al, ten eyes with stable KCN were investigated. Mean UCVA of patients was (1.15±1.39) Logmar (0.07±0.04 decimal) and BSCVA was (0.08±0.60) Logmar (0.82±0.25 decimal) preoperatively(Kurian, 2012). After 6 months UCVA improved to (0.22±0.43) Logmar (0.59±0.37 decimal) and BSCVA improved to (0.03±0.85) Logmar (0.93±0.14 decimal). At six months, eight eyes had visual acuity of 20/20 or better. No eye lost two lines. At 6 months 7 (70%) eyes were within ± 1.00 D of intended refraction. Safety index was 1.13 and efficacy index was 0.72. The efficacy index in this study was lower than our study and aforementioned studies and it may be due to difficulty in accurate refraction in these patients. In this study, visual quality of patients after operation was investigated. Quality of vision was poor despite good visual acuity and acceptable postoperative refractive error. They argue that after phakic intraocular lens implantation refractive metrics are

reasonably improved but visual-quality metrics would be abnormal and should be addressed. Intacs implantation followed by pIOL implantation can be another option in patients with KCN. In a study by Coskunseven et al, 3 eyes with KCN and extreme myopia had PIOL implantation after intacs implantation for reshapening and improving corneal irregularities(Coskunseven, 2007). An improvement in UCVA and BSCVA was observed. They concluded that combination of pIOL and intacs implantation in two steps could be a reasonable procedure in KCN. In a similar study by Alfonso et al, 40 eyes with KCN had intrastromal corneal ring segment implantation (ICRS) followed by pIOL implantation(Alfonso, 2011). They had significant improvement after both ICRS implantation and pIOL implantation. UCVA and BSCVA was (0.30±0.56) Logmar (0.50 ±0.27 decimal) and (0.13±0.69) logmar (0.73 ± 0.20 decimal) 6 months after pIOL implantation. At the same time, 65% of eyes were within ±1.00 D. They concluded that ICRS and pIOL implantation could be a predictable procedure to improve visual acuity in KCN.

In our study and mentioned studies no complication was reported although anterior subcapsular cataract(Gonvers, 2003; Sanders, 2002) and increased intraocular pressure(Chung, 2009; Chun, 2006) are reported after phakic IOL. This can be due to short follow up time and inadequate number of patients. As the nature of KCN is progression over time, long-term results cannot be predicted if progression of the disease is not halted. There are new emerging studies confirming crosslinking as a procedure to stabilize disease (Vinciguerra, 2009). In recent study, none of patients had crosslinking before operation and one patient with bilateral surgery showed myopic change in 36 months follow up time that could be prevented if such a procedure was performed before operation. In recent study, we enrolled patients with KCN who were stable for two years but these criteria may be questioned as we noticed progression in two eyes during the study.

Alfonso et al, believe that intraocular phakic lens implantation is not a true alternative of penetrating keratoplasty for all patients with keratoconus but it can be an alternative in selected patients with stable and early keratoconus(Alfonso, 2010). They suggest that if following indications including BSCVA 20/50 or better, clear central cornea, keratometry less than 52.50 D, and stable refraction for 2 years are not met in patients, penetrating keratoplasty leads to better outcomes.

In conclusion, phakic posterior chamber intraocular lenses implantation is a safe and effective procedure and can improve UCVA and BSCVA of patients with stable KCN considerably.

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