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Research Article

Posterior chamber phakic intraocular lenses for correcting ametropia in stable keratoconus

Osvaldo Berger[1,2], Naveen Garikapati[1], Hasan Naveed[1], , Aida Hajjar-Sese[1], Artemis Matsou[1], Zisis Gatzioufas[3], Samer Hamada[1*] Mohamed Elalfy [1,4,5*]

1. Corneoplastic unit, Queen Victoria Hospital NHS Foundation Trust, East Grinstead, United Kingdom.
2. Clinica Pasteur. Universidad de Santiago de Chile.
3. Department of Ophthalmology, University Hospital Basel, Basel, Switzerland
4. Department of Ophthalmology, Maidstone and Tunbridge Wells NHS Trust, Maidstone, United Kingdom.
5. Research Institute of Ophthalmology, Giza, Egypt.

*SH and ME are joint last authors.

Short Title: Posterior Chamber Phakic Intraocular Lenses in Stable Keratoconus

Correspondence: Professor Zisis Gatzioufas; Department of Ophthalmology, University Hospital Basel, Basel, Switzerland. Email: zisisg@hotmail.com.

Keywords: Implantable Collamer Lens; Irregular Astigmatism; Keratoconus

Abstract

Introduction: The use of posterior chamber phakic intraocular lenses are a reasonable option in the armamentarium to treat refractive error in patients with keratoconus. We present our experience with the use of posterior chamber phakic intraocular lens (PCPIOL) for the management of ametropia in patients with keratoconus.

Methods: Patients included those with stable keratoconus treated in the Corneoplastic Unit, Queen Victoria Hospital. East Grinstead, United Kingdom, with PCPIOL (ICL Staar Surgical and IPCL Care Group) to improve their visual acuity. Data were obtained from preoperative visit and 1, 3, 6 and 12 months after surgery. Clinical characteristics, pre- and postoperative uncorrected (UDVA) and best corrected (CDVA) logMAR visual acuities and perioperative complications were analyzed.

Results: 23 eyes of 21 patients were included. UDVA changed from 0.75 preoperatively to 0.18 post-surgery (P = < 0.001) and CDVA from 0.07 to 0.12 (P = 0.12). Seventy percent of the cases increased 3 or more lines of UDVA while none of the eyes lost more than 2 lines of CDVA. No significant difference in final UDVA was found between patients with and without previous keratoplasty (0.27 and 0.18, P=0.38), previous corneal collagen crosslinking (0.16 and 0.3, P=0.24), intracorneal ring segments (0.2 and 0.2, P=0.94) or type of lens implanted (0.2 ICL and IPCL. P = 0.94). One intraoperative complication reported was an inverted PCPIOL insertion and postoperatively 4 axis rotations and 1 cataract were observed.

Conclusions: The use of PCPIOL in patients with stable keratoconus is effective in improving their UDVA, even in cases with previous corneal procedures such as keratoplasty, crosslinking and intracorneal rings. Rotation is the most common postoperative complication.

Introduction

Keratoconus is a non-inflammatory condition causing the cornea to become progressively thinner and protrude anteriorly. This deformation causes irregular astigmatism and higher order aberrations such as vertical coma [1]. Some keratoconus patients are both spectacle and contact lens intolerant. Therefore, in order to improve the quality of vision in these patients refractive procedures such as wave front or topography-guided photorefractive keratectomy (TG-PRK) combined with corneal collagen crosslinking (CXL) [2, 3, 4], intracorneal ring segments (ICRS) implantation [5] phakic [6,7,8] or pinhole [9] intraocular lens insertion, lamellar keratoplasty and a combination of the above (CXL + PCPIOL) [10], (ICRS + PCPIOL) [11, 12] (ICRS + CXL + PCPIOL) [13,14,15], (TG-PRK + CXL + PCPIOL) [16], (ICRS + CXL + PCPIOL + TG-PRK) [17] have been described.

The Visian Implantable Collamer Lens (ICL), is a posterior chamber phakic intraocular lens implanted in the sulcus through a clear corneal incision and has shown favourable outcomes for the spherical and cylindrical correction of patients with keratoconus [6,7,10,14,15,18,19,20,21]. Some complications reported after implantation of these lenses include axis rotation of more than 5 degrees requiring repositioning or lens exchange in 3-9% [8,20,22], cataract formation in 9% during 10 years of follow-up [23], increase in intraocular pressure in 1.8% [23], pigment dispersion syndrome in 0.9% [23], and pupillary block in 1.8% [23]. The Implantable Phakic Contact Lens (IPCL), another posterior chamber phakic lens, has not been reported to be used in patients with keratoconus, but has shown good results in myopic and astigmatic patients [24, 25, 26].

We describe our experience with the use of posterior chamber phakic intraocular lenses in the treatment of patients with different grades of keratoconus, including patients with previous procedures such as ICRS implantation, CXL and keratoplasty.

Methods

This study is a cohort review of patients with stable keratoconus who received a phakic intraocular lens implant (Visian ICL V4c, STAAR Surgical. Nidau, Switzerland or IPCL, Care Group, India) at the Corneoplastic Unit of Queen Victoria Hospital. East Grinstead, UK. The study was registered and approved by the Quality and Governance Department of the Queen Victoria Hospital NHS Foundation Trust, and adhered to the tenets of the Declaration of Helsinki. This type of study design did not require informed consent.

Stability was defined as no greater than 1 dioptre increase in corneal maximum keratometry and no changes in the manifest refraction for at least one year. Keratoconus staging was performed using the Amsler-Krumeich keratoconus classification classification and Belin ABCD grading was also noted (see Supplementary table 1). Exclusion criteria were patients with disease progression, anterior chamber depth less than 2.8 mm, no visual acuity improvement with refraction or pinhole, endothelial cell count less than 2000 cells / mm^2, cataract, retinal or neuro-ophthalmic diseases and ocular inflammation, pregnant or breast-feeding patients. For surgical planning, we measured the horizontal white-to-white distance and anterior chamber depth using the IOL Master 500, Carl Zeiss Meditec AG Germany. Keratometry readings were also obtained from the IOL Master and checked with the Oculus Pentacam HR readings. Lens calculation was done by the company selecting the closest available myopic residual refractive outcome to emmetropia. The surgery was performed under topical anaesthesia using a standard technique. The horizontal axis was marked preoperatively using a slit-lamp. A Mendez ring or the Zeiss Callisto, Carl Zeiss Meditec AG, suite was also used intraoperatively. The IOL was inserted through a 3.2 mm clear corneal incision with 2% hydroxypropyl methylcellulose solution, OcuCoat, Bausch & Lomb, into the anterior chamber and positioned into the ciliary sulcus avoiding any optic and phakic lens touch. The viscoelastic material was then removed, and the patient was treated postoperatively with topical antibiotics and steroid drops in tapering dosing.

Data and Statistical Analysis

Data were obtained from the preoperative visit and 1, 3, 6- and 12-month follow-up visits after surgery. Patients' clinical characteristics, pre- and post-uncorrected (UDVA) and best corrected (CDVA) distance visual acuities, perioperative complications and previous treatments were recorded and analysed. Alpins method was used for vector analysis.

Variables were collected in an Excel database and Graphpad Prism 8, La Jolla California USA, was used for statistical analysis. Data are expressed as mean ± standard deviation (SD). The primary outcome was UDVA improvement. Secondary outcomes were changes in CDVA, surgical and postoperative complications. For changes in mean, we used paired Wilcoxon test for numerical data and Fisher's exact test for categorical variables. To look for predicting variables for improving 6 or more lines in final UDVA and for lens rotation we performed multiple logistic regression. For all statistical analysis we considered significant a P value < 0.05.

Results

Twenty-two eyes of 20 patients with stable keratoconus received phakic IOL implantation in the study period (Table 1). Two eyes were excluded as they were lost to follow up in the early post-operative period . One patient was excluded as the ICL was implanted in a pseudophakic patient. Patients were followed for 9 ± 6 months on average. Keratoconus stage was I in 13 cases, II in 8 and III in 2 cases. Twelve eyes had previous ICRS implants, 16 previous corneal collagen crosslinking and 7 previous corneal grafts (5 DALK and 2 PK). We implanted 13 ICL lenses (12 toric and 1 spheric) and 9 IPCL lenses (7 toric and 2 spheric). All the patients were contact lens intolerant.

Visual and refractive outcomes:

Mean LogMAR UDVA changed from 0.76 ± 0.3 preoperative to 0.18 ± 0.17 (range -0.2 to 0.8, P = < 0.001) postoperative and CDVA LogMAR from 0.08 ± 0.2 preoperative to 0.12 ± 0.17 (-0.2 to 0.7, P = 0.12) postoperative. The efficacy index [decimal postoperative UDVA/decimal preoperative CDVA] was 1.25 and the safety index (decimal postoperative CDVA/ decimal preoperative CDVA) was 0.95. 19 eyes (86%) had a UDVA of 0.4 LogMAR or more postoperative (Figure 1A). 77% of the cases had postoperative UDVA within 1 line of CDVA and 36% the same or better (Figure 1B). The number of lines improvement in UDVA was 6 ± 3 on average while CDVA was -0.5 ± 1 lines. No eye lost more than 2 lines of CDVA and the majority (41%) remained with the same CDVA (Figure 1C). The preoperative spherical equivalent changed on average from -3.6 ± 3.9 D to -0.07 ± 0.9 D postoperatively (P = 0.0001). Predictability is shown in a scatter plot of the attempted versus the achieved spherical equivalent correction in Figure 1D. 67% of the eyes were within ± 0.5 D and 89% within ± 1 D of spherical equivalent (SE) at the final visit (Figure 1E). The refractive astigmatism changed from -4 ± 2.2 D preoperative to -1 ± 1.1 D postoperative (P = < 0.0001). 53% of the eyes were within 0.5 D and 74% within 1 D of postoperative cylinder (Figure 1F) and the predictability is shown in Figure 1G. The magnitude of target induced astigmatism (TIA) was 3.5 ± 1.8 D, and the surgically induced astigmatism (SIA) was 3.6 ± 1.9 D. No significant difference was demonstrated between SIA and TIA (P = 0.82). The difference vector (DV) was 0.99 ± 1.1. The absolute mean of the angle of error (AE) of the refractive astigmatism was 6.7 ± 12.5º. 68% of the eyes where within 5º of the target (Figure 1H). The correction index (CI = SIA / TIA) was 0.98 ± 0.2, and the magnitude of error (ME = SIA – TIA) 0.13 ± 0.8. Index of success (IOS = DV / TIA) was 0.34 ± 0.4 (Figure 2). No significant difference was found in vector analysis between ICL and IPCL (Table 2). Preoperative IOP was 14.7 mmHg and postoperative 14.4 mmHg on average (P = 0.71).

Complications: there was one case of insertion upside down and required repositioning at the same time of surgery. Postoperatively, 4 cases (18%) had lens rotation but only 2 required repositioning; and one patient developed cataract and required surgery.

Subgroup analysis

There were no significant differences in the number of lines of UDVA improved, final CDVA and UDVA and number of complications between patients with previous corneal graft and patients without previous graft, patients who received ICL or IPCL intraocular lenses, keratoconus grade I and II versus III, patients younger versus older than 40 years of age, eyes with previous ICRS implant versus no implant and between eyes with previous CXL versus without (see

Supplementary Data). No one variable predicts an improvement of 6 or more lines of UDVA or postoperative rotation (Table 3).

Discussion

In the present report of patients with different stages of keratoconus and some of them with previous procedures such as corneal transplantation, CXL and ICRS implantation, we show that posterior chamber phakic intraocular implantation is an effective and safe treatment to improve the visual acuity in this group of patients. We included post corneal graft patients because there are reports of keratoconus recurrence in the peripheral host cornea [27] or in the donor cornea [28]. The mean UDVA improved from 0.76 to 0.18 LogMAR and patients improved 6 lines on average. This is similar to the results showed by others: Alió et al. [8] from 1.31 to 0.21, Kamiya et al.[18] from 1.46 to -0.06 and Alfonso et al. [6] from 0.8 to 0.1 postoperatively.

Despite having included patients with advanced keratoconus and high preoperative SE and cylinder, our high efficacy index of 1.25 is similar to other reports: 0.88 in Alió et al. [8]; 1.07 in Alfonso et al.[6]; 0.98 in Kamiya et al. [7]; 1.38 in Abdelmassih et al. [13]; and 1.32 in Hashenian et al [21].

CDVA changed from 0.08 preoperative to 0.12 postoperative on average but this was not significant. No eye lost more than 2 lines of CDVA and 41% remained with the same or better CDVA. We think a reduction in the CDVA postoperatively can be related to the well-known difficulties in refracting patients with keratoconus. In the study of Kamiya et al. the average preoperative CDVA was -0.07 changing to -0.12 on average postoperatively and 19% of the patients lost 1 CDVA line [7]. In the report of Sanders for the FDA, 3 eyes lost 2 lines of more of CDVA after 12 months of follow-up [29]. In Alfonso et al. group [6], 3 cases lost 2 or more lines of CDVA. Our safety index of 0.95 was a little lower than other reports: 1.16 Alfonso [6]; 1.16 Alió [8]; and 1.12 Kamiya [7].

The final SE was -0.07 D and refractive cylinder -1 D. This is similar to previously reported results (-0.3 and -0.6 Emerah et al. [30]; -0.02 and -0.62 Kamiya et al. [18]; -0.89 and 1.16 Fadlallah et al. [10]; -0.78 and -1.56 Hashemian et al. [21]; 0.04 and -1.13 Alió et al. [8]; -0.08 and -0.41 Alfonso et al. [6]) There was a significant reduction in SE and cylinder after the lens implantation, with a tendency for under correction in higher SE eyes (Figure 1D). 67% of the eyes were within ± 0.5 D and 89% within ± 1 D at the final visit of SE and 53% of the eyes were within 0.5 D and 74% within 1 D of postoperative cylinder. Similar accuracies of SE have been reported before (67% 0.5 D and 86% 1 D [18]; 75% and 87.5% [10]; 86.7 and 100% [6]). The efficacy of the astigmatic correction was high (IOS 0.34), similar to results reported of ICL in non keratoconic patients (0.19 - 0.26) [31, 32].

Interestingly, there were no differences in the main and secondary outcomes between patients with and without previous procedures as well as between those younger than 40 years of age compared to older patients. Also, there were no changes in the IOP after the surgery, which is also something previously reported [21].

None of our patients showed signs of keratoconus progression during this study period, consistent with other reported literature. A 3-year follow-up study of ICL implantation in patients with keratoconus shows no disease progression associated with surgery [7]. This is also demonstrated by the study of Ali et al. which shows no corneal biomechanical changes after ICL implantation [33]. However, there is one case with reported progression two years after surgery in the study of Hashemian et al. [21] that was treated with CXL with good results.

Axis rotation was seen in 4 patients but only 2 of them required repositioning when the rotation was more than 5 degrees and visually significant for the patient. Despite this, our absolute AE was 6.7º better than previous reports [34]. One patient with rotation also developed cataract and required cataract surgery and IPCL explantation despite good vault confirmed with anterior segment OCT. This is similar to the report by Hashemian et al. [21] where 4 of their 23 eyes required IOL repositioning. Other studies have showed no significant changes in the endothelial cell density (ECD) over the follow-up period after the surgery with losses ranging between 4.4 to 7.8% in 3 to 5 years of follow-up [7, 21]. For that reason, we did not routinely evaluate ECD.

Limitations

The present work is subject to a potential methodological weakness as it was a retrograde cohort review with a broad spectrum of keratoconus patients, and some had a shorter follow-up period, without the possibility to assess the stability of the results.

Conclusion

Our study findings support that PCPIOL implantation is a safe procedure that achieves good visual outcomes in patients with non-progressive keratoconus, regardless of their age, disease stage or previous keratoconus treatment.

Word Count

2215

Statement of Ethics

The study was registered and approved by the Quality and Governance Department of the Queen Victoria Hospital NHS Foundation Trust (Project ID 520), and adhered to the tenets of the Declaration of Helsinki. This type of study design did not require written informed consent as per the approving Quality and Governance Department oft Queen Victoria Hospital NHS Foundation Trust and was in line with local guidelines.

Conflict of Interest Statement

The authors have no conflicts of interest to declare. Prof. Zisis Gatzioufas was an Editorial Board member of the journal at the time of submission.

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Data Statement

The data that support the findings of this study are not publicly or freely available due to privacy and ethical restrictions but are available from the lead author MSE and corresponding author ZG upon reasonable request. Supplementary data has been provided.

Author Contributions

OB contributed to data collection, analysis and writing the article. NG contributed to manuscript writing and data collection. HN contributed with data analysis and manuscript revision. AH contributed with data collection and manuscript revision. AM and ZG both contributed with manuscript revision and supervision. SH contributed with conceptualisation and supervision. ME contributed with study design, manuscript revision and supervision.

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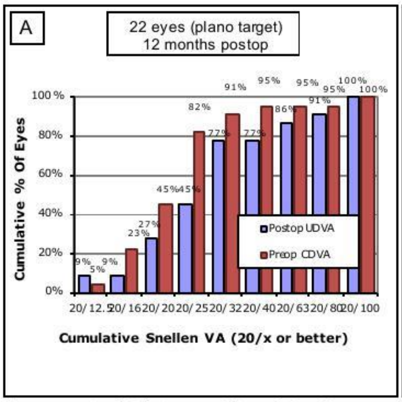
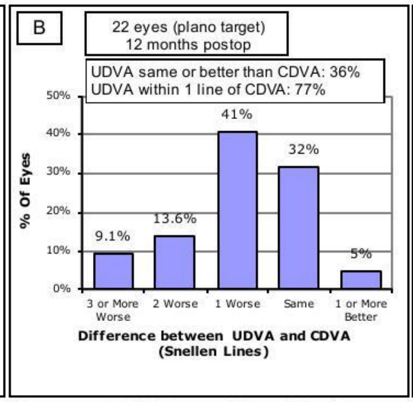
Figure Legends

Fig. 1. Results of the 23 eyes. Preoperative data is at patients' presentation before any intervention. CDVA = corrected distance visual acuity; UDVA = postoperative uncorrected distance visual acuity; SEQ = spherical equivalent refraction; TIA = target induced astigmatism; SIA = surgically induced astigmatism; D = diopters.

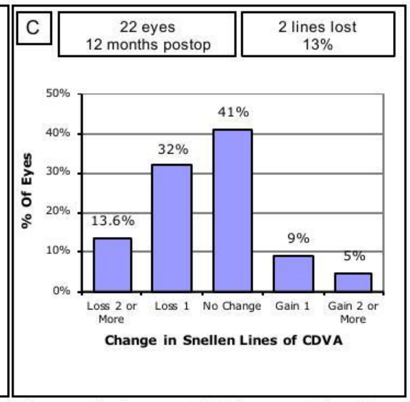
Fig. 2. Vector analysis of the 23 eyes with keratoconus implanted with posterior chamber phakic intraocular lens.



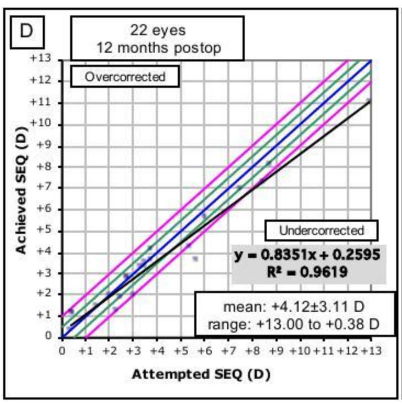
Uncorrected Distance Visual Acuity



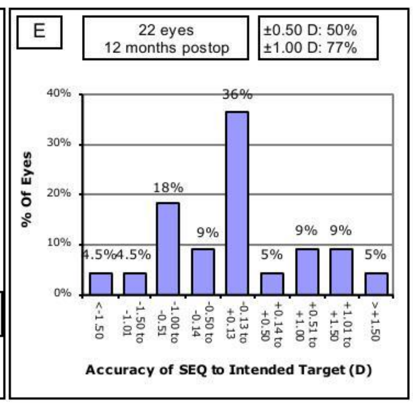
Uncorrected Distance Visual Acuity vs. Corrected Distance Visual Acuity



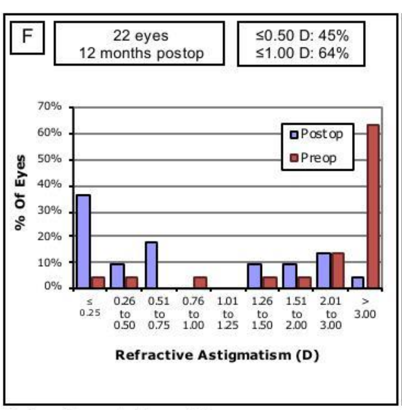
Change in Corrected Distance Visual Acuity



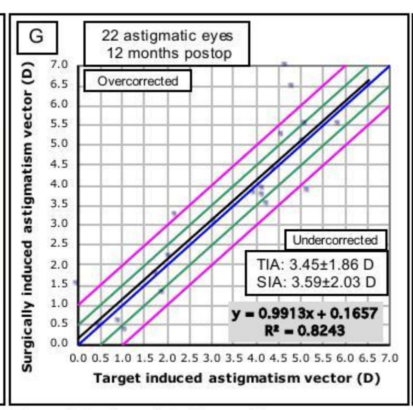
Spherical Equivalent Refraction Attempted vs Achieved



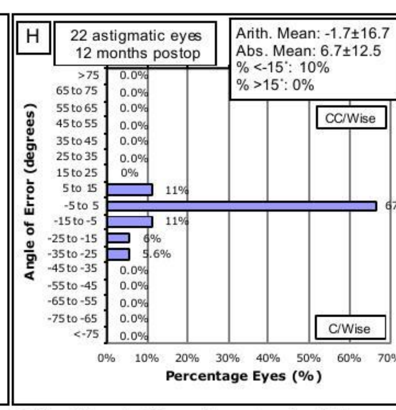
Spherical Equivalent Refraction Accuracy



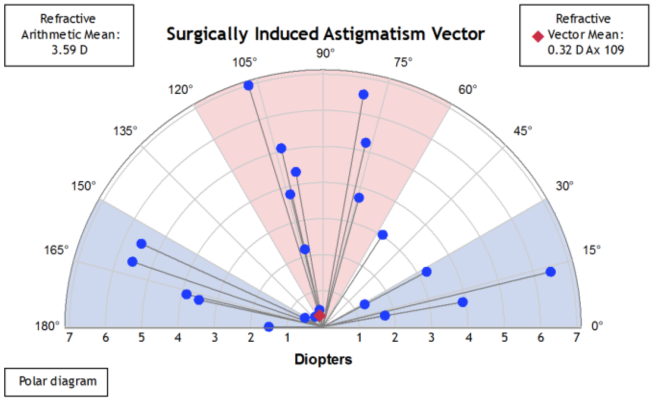
Refractive Astigmatism

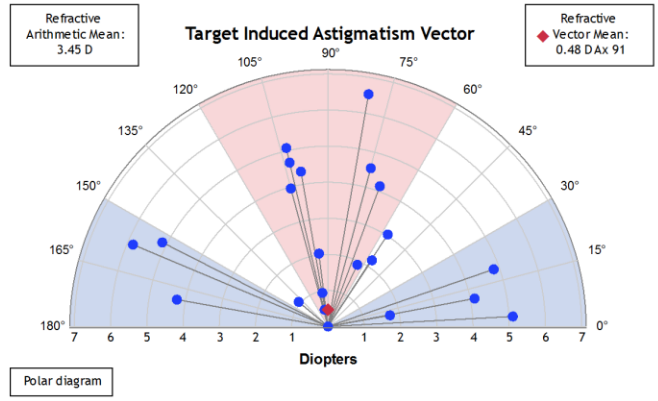


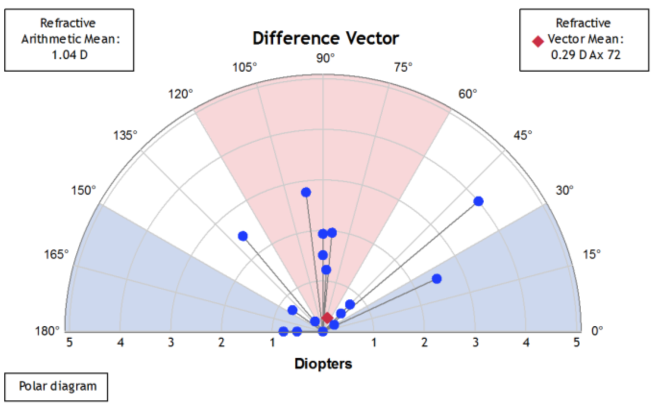
Target Induced Astigmatism vs Surgically Induced Astigmatism

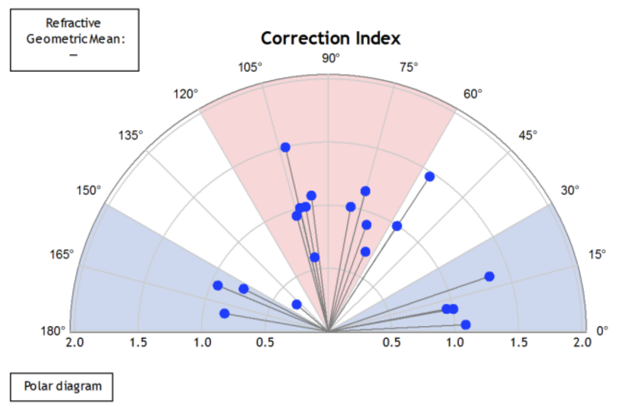


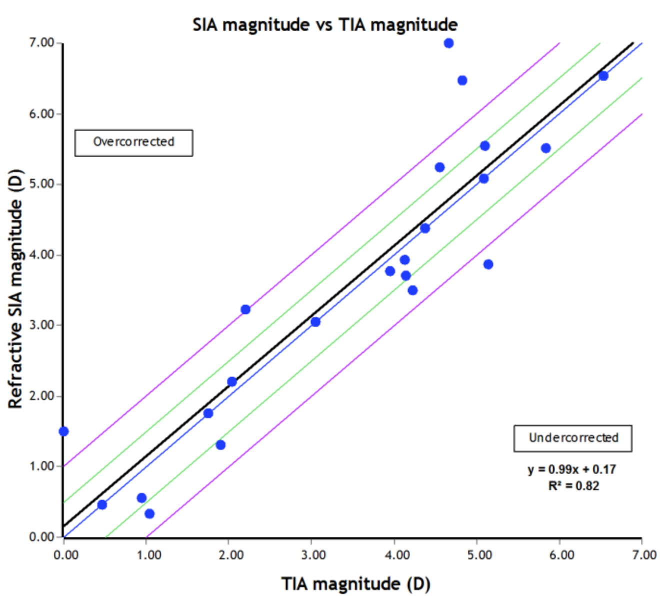
Refractive Astigmatism Angle of Error


Refractive Arithmetic Mean: 3.59 D
Surgically Induced Astigmatism Vector
Refractive Vector Mean: 0.32 D Ax 109
90° 75° 60° 45° 30° 15° 0° 105° 120° 135° 150° 165° 180°
7 6 5 4 3 2 1 1 2 3 4 5 6 7
Diopters
Polar diagram


Refractive Arithmetic Mean: 3.45 D
Target Induced Astigmatism Vector
Refractive Vector Mean: 0.48 D Ax 91
90° 75° 60° 45° 30° 15° 0° 105° 120° 135° 150° 165° 180°
7 6 5 4 3 2 1 1 2 3 4 5 6 7
Diopters
Polar diagram


Refractive Arithmetic Mean: 1.04 D
Difference Vector
Refractive Vector Mean: 0.29 D Ax 72
90° 75° 60° 45° 30° 15° 0° 105° 120° 135° 150° 165° 180°
5 4 3 2 1 1 2 3 4 5
Diopters
Polar diagram


Refractive Geometric Mean: –
Correction Index
90° 75° 60° 45° 30° 15° 0° 105° 120° 135° 150° 165° 180°
2.0 1.5 1.0 0.5 0.5 1.0 1.5 2.0
Polar diagram


SIA magnitude vs TIA magnitude
Refractive SIA magnitude (D)
7.00 6.00 5.00 4.00 3.00 2.00 1.00 0.00
Overcorrected
Undercorrected
y = 0.99x + 0.17
R² = 0.82
0.00 1.00 2.00 3.00 4.00 5.00 6.00 7.00
TIA magnitude (D)

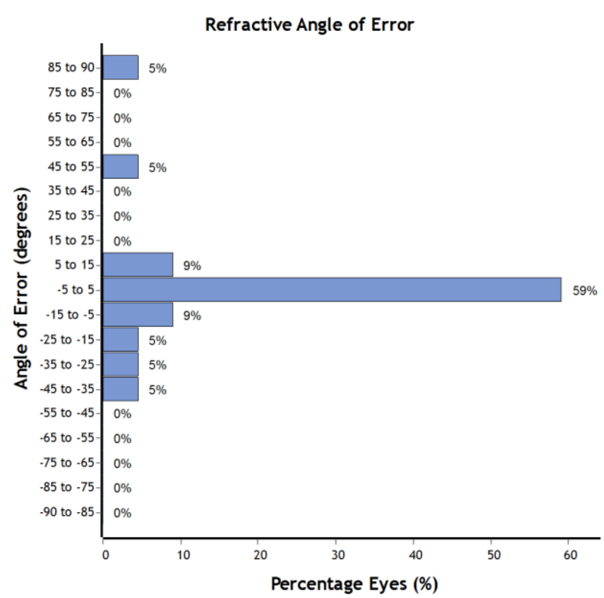

Refractive Angle of Error
Angle of Error (degrees)
85 to 90 5%
75 to 85 0%
65 to 75 0%
55 to 65 0%
45 to 55 5%
35 to 45 0%
25 to 35 0%
15 to 25 0%
5 to 15 9%
-5 to 5 59%
-15 to -5 9%
-25 to -15 5%
-35 to -25 5%
-45 to -35 5%
-55 to -45 0%
-65 to -55 0%
-75 to -65 0%
-85 to -75 0%
-90 to -85 0%
0 10 20 30 40 50 60
Percentage Eyes (%)

Table 1. Clinical characteristics of patients included in the study.

Variable	Mean ± SD	Range
Number of eyes	22 (20 patients)	
Age	34.5 ± 9.2	19 to 55
Gender	19 M, 3 F	
UDVA preop.	0.76 ± 0.3	0.3 to 1.5
CDVA preop.	0.08 ± 0.2	-0.2 to 0.7
SE	- 3.6 ± 3.9	-13 to 5.6
Cyl	- 4.0 ± 2.2	-7.5 to 0
Km	45.67 ± 4.17	35.35 to 53.75
Kmax	54.4 ± 6	43.8 to 65.7

CDVA: corrected distant visual acuity (LogMAR). Cyl: refractive cylinder, Km and Kmax of preoperative Pentacam. SE: spherical equivalent. UDVA: uncorrected distant visual acuity (LogMAR).

Table 2. Vector analysis comparing ICL vs IPCL.

	ICL	IPCL	P-value
TIA	4.1	3.1	0.6
SIA	3.8	3.1	0.89
DV	0.7	1	0.27
ME	-0.09	0	0.47
AE	-0.2	0	0.43
CI	0.96	1	0.6
IOS	0.2	0.3	0.43

No significant difference was found.

TIA = target induced astigmatism;

SIA = surgically induced astigmatism

DV = difference vector.

AE: Angle of error

SOI: Index of Success

ME= Magnitude of Error

CI = Correction Index

Table 3. Comparison of visual outcomes and complications between different patients' characteristics.

Variable	Final UDVA	P-value	Final CDVA	P-value	Postoperative complications	P-value	Lines of UCDV improvement	P-value
Previous transplant (6)	0.31	0.21	0.2	0.33	2	0.62	5.3	0.72
No previous graft (16)	0.17		0.13		3		5.9	
ICL (13)	0.2	0.82	0.16	0.49	2	0.34	5	0.18
IPCL (9)	0.2		0.11		3		7	
KC stage 1 (8)	0.14	0.43	0.07	0.07	0	0.53	5	0.3
KC stage 2-3 (15)	0.21		0.18		3		5.9	
<40 (15)	0.14	0.07	0.12	0.4	2	0.29	5.8	0.95
>40 (7)	0.33		0.2		3		5.9	
ICRS (10)	0.2	0.81	0.14	0.98	1	0.61	5.1	0.38
No ICRS (12)	0.22		0.14		4		6.3	
CXL (14)	0.16	0.14	0.14	0.9	2	0.34	6.1	0.49
No CXL (8)	0.31		0.14		3		5.2	

CDVA: corrected distance visual acuity. CXL: corneal collagen crosslinking. KC: keratoconus. ICRS: intracorneal ring segment implanted. UDVA: uncorrected distance visual acuity.