

Outcomes and Complications of Implantable Collamer Lens and Toric Implantable Collamer Lens for the Correction of High Myopia with and without Astigmatism (One Year Prospective Study)

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Abstract

Purpose: To evaluate the efficacy, safety, predictability and stability of Implantable Collamer Lens (ICL) and toric ICL for the treatment of high myopia and high myopic astigmatism

Methods: In this prospective nonrandomized clinical trial, 95 eyes of 51 patients who underwent ICL (31 eyes) and toric ICL (64 eyes) implantations were participate in Eye Research Center, Department of Ophthalmology, Rassoul Akram Hospital, Tehran University of Medical Sciences and Negah Eye Hospital, Tehran, Iran. Uncorrected visual acuity (UCVA), best spectacle corrected visual acuity (BSCVA), manifest refraction, adverse events and complications were evaluated at 5th day and 2, 6 and 12 months postoperation.

Results: The mean preoperative manifest refractive spherical equivalents (MRSE) were -11.75 ± 4.63 D (diopter) (-5.0 to -22.0) in ICL group and -11.67 ± 3.99 D (-3.0 to -21.0) in toric ICL group. Mean residual refractive spherical equivalent were -0.68 ± 1.07 D at 5th day, -0.86 ± 1.07 D at 2 months, -0.65 ± 0.72 D at 6 months, -0.71 ± 0.78 D at one year in ICL group and -0.69 ± 1.03 D, -0.59 ± 0.84 D, -0.71 ± 0.76 D and -0.89 ± 0.68 D in toric ICL group, respectively. Preoperative cylinder in toric ICL group was -3.25 ± 1.29 D (-2.0 to -6.0) and after operation was -0.81 ± 0.63 D, -0.75 ± 0.67 D, -0.93 ± 0.70 D, -0.94 ± 0.61 D, respectively. At 2 months after operation, the UCVA was $^{20}/_{40}$ or better in 74.3% in ICL group and 74.6 % in toric ICL group (efficacy=1.092 and 1.154, respectively). 71.0% and 68.2% were within ± 0.5 D and 77.5% and 85.7% were within ± 1.0 D of emmetropia, respectively. 58.1% and 63.6% gained one or more lines (safety=1.18 and 1.24) two months after operation. At 2 months after operation, 81%, of eyes in toric ICL group had < 1.0 D and 95.3% < 1.5 D cylinder. No operative and postoperative complications or adverse events were observed. One eye (1.05%) developed asymptomatic (trace) anterior subcapsular opacities.

Conclusion: ICL and toric ICL implantations were effective, predictable, and safe procedures for the treatment of high myopia and high myopic astigmatism.

Keywords: Implantable Collamer Lens, Toric ICL, High Myopia, Myopic Astigmatism

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Introduction

Numerous techniques for correction of refractive errors are currently available, but a limited number of options are available for patients with moderate to high myopia. If high refractive error patients do not tolerate contact lenses, spectacle correction may cause optical aberrations.¹ This justifies the search for a reliable refractive solution.² Artificial lens implantation is so far the only refractive treatment for high refractive errors and offers preservation of accommodation and potential reversibility.³

Implantable Collamer Lenses (ICL; STAAR Surgical Co., Monrovia, CA, USA) may have advantages over laser in situ keratomileusis (LASIK), because it is not only highly predictable but also reversible and LASIK requires more laser ablation in highly myopic eyes, resulting in higher-order aberrations (HOA), whereas ICL implantation does not require surgical tissue removal and leaves the central cornea untouched and no induced HOA.^{4,5}

ICL implantation may also present advantages over refractive lens exchange because the crystalline lens, which plays a major role in accommodative function, specially in younger patients, remains untouched.⁶

A recent alternative for astigmatic treatment is the toric phakic Intraocular lens (IOL). In complicated cases that, keratorefractive surgery is not a good or viable option, toric phakic IOLs have been shown to correct astigmatism. Although several studies have demonstrated effective treatment of astigmatism using the iris-fixated toric phakic IOL,⁷⁻⁹ concerns still exist over the level of endothelial cell loss associated with iris-fixated lenses and surgically induced astigmatism by implantation of the rigid polymethyl methacrylate (PMMA) lens through a 5.3-mm corneal incision.¹⁰

In recent years, several studies demonstrated high levels of the best corrected vision preservation and even improvement relative to preoperative values, minimal intraoperative and postoperative complications, early and stable improvement in vision and high degree of predictability by myopic ICL and toric ICL.^{3,11,12} However, most of the studies were performed in the eyes of white patients. The purpose of our study is to

evaluate the safety, efficacy, predictability and stability of ICL and toric ICL (with the current V4 ICL design) in Iranian eyes with high myopia and high myopic astigmatism.

Methods

In this prospective nonrandomized clinical trial ninety-five eyes of 51 patients (31 eyes for ICL and 64 eyes for toric ICL) were included from September 2006 to April 2009.

Patients were enrolled with baseline refractive errors between -3.0 to -22.0 D (diopter) of myopia (manifest refraction spherical equivalent [MRSE]) and for ICL group maximum of 2.50 D and for toric ICL 2.0 to 6.0 D of manifest refractive cylinder. A stable refraction over the previous 12 months was verified by patient interview with a BSCVA of at least $20/100$.

All patients underwent a baseline ophthalmic examination which included the measurement of best spectacle corrected visual acuity (BSCVA) at a vertex distance of 12 mm, uncorrected visual acuity (UCVA), cycloplegic and manifest refractions, corneal white-to-white (WTW) diameters with a caliper at a slit-lamp and scanning-slit topography system (Orbscan IIz; Bausch and Lomb, Rochester, New York, USA). We use Orbscan IIz to validate caliper measurement, anterior chamber depth (ACD) which measured from the corneal endothelium to the anterior lens capsule by Orbscan IIz and ultrasound biometry (Ocuscan; Alcon Laboratories Inc, Ft Worth, Tex), automated keratometry (Topcon kr 8000), Aberrometry and measurement of mesopic pupil size (Bausch and Lomb Inc), placido disk videokeratography (Eye Sys 2000 version 4.2, Irvine, USA), applanation tonometry, gonioscopy, endothelial cell counts (noncontact specular microscope; Konan Medical Inc, Nishinomiya, Japan), slit-lamp examination, and a dilated fundus examination.

All patients had: (1) sufficient corneal WTW diameter (>11 mm); (2) sufficient ACD (>2.8 mm); (3) irido-corneal angle > 30 degree; (4) endothelial cell counts >2500 cells/mm² in range of age 20-30 years and >2000 cells/mm² in range of age 30-40 years.

In this study, exclusion criteria were, history and/or clinical signs of iritis/uveitis, glaucoma, ocular hypertension, maculopathy, cataract,

diabetes, progressive sight-threatening disease other than myopia, iris pigment defect, previous ocular surgery, large scotopic pupile size >7.5 mm, follow-up period less than two months and less than 2 times follow-up.

The study was approved by the Institutional Research Ethics Committee at the Eye Research Center, affiliated with the Tehran University of Medical Sciences. Informed consent was obtained from the all patients after explaining the risks and benefits of surgery including nonsurgical alternatives.

Lens size and power

ICL is a soft, foldable, single-piece plate and sulcus placed posterior chamber phakic IOL made of collamer, which is a hydrophilic porcine collagen. The collamer is highly biocompatible and permeable to gas and metabolites, which would allow maintaining a normal crystalline metabolism that avoiding the development of cataract.¹¹ The ICL appears to be the first phakic IOL to be considered for Food and Drug Administration (FDA) approval in the United States.¹³

In myopic ICL group, lens power calculations were performed by the manufacturer (STAAR surgical) using a modified vertex formula and on the basis of the following variables: manifest and cycloplegic refractions for a vertex distance of 12.0 mm; keratometry; and ACD (Orbscan II_z and ultrasound biometry).

Sizing of myopic lenses (11.5-13.0 mm) was determined by the horizontal WTW measurement (caliper and Orbscan II_z) and the ACD measurement. For eyes with ACD measurements of 2.8 mm to 3.5 mm, the lens size was calculated by adding 0.5 mm to the horizontal WTW measurement. Eyes exhibiting an ACD greater than 3.5 mm required the addition of up to 1.0 mm to the WTW measurement, up to a maximum length of 13.0 mm. Patients with an ACD less than 2.8 mm were excluded from the study.¹¹ Calculated lens sizes between the available lens diameters (in 0.5-mm steps) were generally rounded down if the ACD was ≤3.5 mm and rounded up if the ACD was >3.5 mm.¹¹

Lens power calculation for the toric ICL was performed using the astigmatic decomposition method described by Sarver and Sanders.¹⁴ This formula calculates the

appropriate ICL cylinder using the patient's manifest refractive cylinder. Toric ICL calculation and implantation software allow to calculate spherical cylindrical power and length, also generate the toric ICL implantation diagram.¹⁴

Implantable collamer lens surgical procedure

In this study, the current V4 ICL design was implanted. Under topical anesthesia, dilating and cycloplegic agents were administered. In temporal approach, two paracentesis were created and after viscoelastic injection, a small 3 mm clear corneal incision was made and ICL was injected through this wound to the anterior chamber and allowed to slowly unfold.

Distal and then proximal footplates were tucked under the iris with a modified intraocular spatula. Irrigation and aspiration of viscoelastic material was done by Balance Salt Solution. Intraocular miotic (Acetylcholine) was used to decrease pupil size. At the end of operation surgical peripheral iridectomy (PI) was done by vitrectomy probe (Storz Protégé, USA) with a 200 mmHg vacuum and 30 cuts per minute.

For toric ICL implantation at first, the surgeon marked the zero horizontal axis at a slit-lamp while the patient is upright for prevention of cyclotorsion upon lying supine. Total procedure is such as spherical ICL implantation. After injection of toric ICL in the anterior chamber and unfolding of ICL, with the modified ICL manipulator, the proper motion was done for posterior pressure and slight rotation of ≤1 clock hour. This maneuver was repeated for all 4 footplates. If any adjustment of toric ICL was necessary, gentle movement touching of the toric ICL at the junction of optic and haptic was accomplished.

Toric ICLs were manufactured to minimize rotation and required the surgeon to rotate the ICL no more than 22.5° (three fourths of a clock hour) from horizontal meridian.^{11,15} All toric ICL have an implantation diagram to demonstrating the amount and direction of rotation from the horizontal axis.

All patients were examined 2 hours after operation for check of intraocular pressure (IOP), ICL vault, patent of surgical PI, ACD and position of ICL.

Alignment of the toric ICL was evaluated by slit-lamp examination at all visits

postoperatively. Vector analysis was performed by autorefractometer and recorded as degree of rotation of long axis of the lens.

BSCVA, UCVA, manifest refraction, IOP measurement, and slit-lamp biomicroscopy, any adverse events, operative and postoperative complications, lens opacity analysis (lens opacity classification system III) were evaluated at 5th day, 2, 6, 12 and 24 months postoperatively. Endothelial cell counts were measured at six months postoperatively.

Results

Of 95 eyes, 21 eyes (67.7%) in the myopic ICL group and 40 eyes (62.5%) in the toric ICL group were female. Mean age at the time of implantation (primary eye surgery in bilateral subjects) was 27.06 ± 6.39 years (range, 20 to 36) in myopic ICL group and 26.70 ± 5.72 years (range, 18 to 43) in toric ICL group. Mean follow-up duration in myopic ICL group was 11.97 ± 8.36 months (from 2 to 36) and in toric ICL group was 9.76 ± 8.73 months (from 2 to 24). Mean WTW measurement according to caliper was 11.56 ± 0.32 mm (11 to 12 mm) in myopic ICL group and 11.66 ± 0.40 mm (11 to 12 mm) in toric ICL group. Mean ACD (from the corneal endothelium to the anterior lens capsule) was 3.16 ± 0.27 mm in ICL group and 3.19 ± 0.29 mm in toric ICL group. The central corneal thickness was 514.68 ± 32.79 in ICL and 513.48 ± 38.75 in toric ICL. The mean IOP was 13.56 ± 2.21 mmHg in ICL and 13.57 ± 1.80 in toric ICL group.

Number of eyes examined at each visit in myopic ICL group were 31 (100%) at 5th day, 31 (100%) at 2 months, 23 (74.19%) at 6 months, 21 (67.74 %) at 1 year and in toric ICL group were 64 (100%), 63 (98.44%), 37 (58.73%) and 32 (50%), respectively.

Effectiveness outcomes

In ICL group mean decimal UCVA were Snellen 0.73 ± 0.30 , 0.69 ± 0.29 , 0.72 ± 0.27 and in TICL were 0.69 ± 0.26 , 0.67 ± 0.26 , 0.63 ± 0.26 when measured 2, 6 and 12 months after operation, respectively. The mean efficacy indices (mean postoperative UCVA divided by mean preoperative BSCVA) were 1.09, 1.03, 1.08 in ICL group and 1.15, 1.11, 1.06 in TICL group when determined 2, 6 and 12 months after surgery respectively.

The preoperatively BSCVA $^{20}/_{20}$ or better in myopic ICL group was 35.5% and in toric ICL was 12.5% and 2 months after operation UCVA $^{20}/_{20}$ or better in myopic ICL group was 45.2% and in toric ICL group was 28.6%.

In myopic ICL group 65.2% of eyes achieved UCVA $^{20}/_{30}$ or better 6 months after operation, whereas 64.6% of eyes had BSCVA $^{20}/_{30}$ or better preoperatively and this results for toric ICL group was 54.0%, 6 months postoperatively comparing to 56.2% BSCVA preoperatively. The proportion of eyes with $^{20}/_{30}$ or better UCVA at 6 months visit in myopic ICL and toric ICL groups were identical to the proportion with preoperative $^{20}/_{30}$ or better BSCVA (in myopic ICL group 64.6% BSCVA versus 65.2% UCVA and in toric ICL group 56.2% BSCVA versus 54% UCVA).

Figures 1, 2 provide a comparison of cumulative preoperative BSCVA values with 12 months postoperative follow-up uncorrected acuity values for the ICL and toric ICL group.

Safety outcomes

The mean preoperative decimal BSCVAs in myopic ICL group were Snellen 0.67 ± 0.33 and in toric ICL group were 0.60 ± 0.26 , after ICL implantation mean BSCVAs were 0.79 ± 0.27 , 0.81 ± 0.28 , 0.87 ± 0.21 in myopic ICL group and 0.74 ± 0.24 , 0.76 ± 0.23 , 0.74 ± 0.23 in toric ICL group at 2, 6 and 12 months, respectively. The mean safety indexes (mean postoperative BSCVA divided by mean preoperative BSCVA) were 1.18, 1.21, 1.29 in ICL group and 1.24, 1.27, 1.24 in TICL group when determined 2, 6 and 12 months after surgery, respectively.

In myopic ICL group at the 6 and 12 months follow-up 60.9% and 66.7% of eyes, respectively, had BSCVA of $^{20}/_{20}$ or better, an improvement over the baseline level of 35.5% further, BSCVA $^{20}/_{40}$ or better values were 82.6% and 90.5% at 6 and 12 months postoperatively compared with 71.1% preoperatively.

In toric ICL group at the 6 and 12 months follow-up 32.4% and 28.1% of eyes, respectively, had BSCVA of $^{20}/_{20}$ or better, an improvement over the baseline level of 12.5% further, BSCVA $^{20}/_{40}$ or better values were 83.7% and 87.5% at 6 and 12 months

postoperatively compared with 64.0% preoperatively.

Six months after operation in ICL group, 43.5%, and in TICL group 43.2% of the eyes showed no change in BSCVA, 17.4-35.1% of eyes gained one line, 13.5-26.1% of eyes gained two lines, 4.3-5.4% of eyes gained three lines and 2.7-8.7% of eyes gained four lines. Figure 5, shows the loss and the gain of the lines in BSCVA during 12 months after operation, so no loss of BSCVA occurred after myopic ICL and toric ICL implantation during this time.

Predictability

Tables 1, 2 show predictability of MRSE, attempted versus achieved in ICL and toric ICL groups, respectively.

In myopic ICL group, 80.7%, 77.5% and 81.0% of eyes were in ± 1.0 D and 58.1%, 71.0% and 47.7% in ± 0.5 D of attempted correction at 5th day, 2 and 12 months postoperative, respectively.

In toric ICL group 79.7%, 85.7% and 71.9% of patients were in ± 1.0 D and 67.2%, 68.2% and 34.4% in ± 0.5 D of attempted correction at 5th day, 2 and 12 months postoperative, respectively. At 5th day, 2 and 12 months postoperative, 79.7%, 81% and 60.4% of patients had < 1.0 D, respectively, and after 12 month follow-up 100% of patients had < 2.0 D cylinder.

Figure 4 shows scattergram of refractive predictability for ICL and toric ICL group.

Stability

Preoperative mean MRSE was -11.75 ± 4.63 D (from -5.00 to -22.0) in myopic ICL group and -11.67 ± 3.99 D (from -3.0 to -21.0) in toric ICL group. After operation, mean residual refractive spherical equivalent were -0.68 ± 1.07 , -0.86 ± 1.07 , -0.65 ± 0.72 , -0.71 ± 0.78 at 5th day, 2, 6 and 12 months in myopic ICL group and -0.69 ± 1.0 , -0.59 ± 0.84 , -0.71 ± 0.77 , -0.89 ± 0.68 in toric ICL group, respectively. Mean change in the manifest refraction from 5th day to 6th month were -0.35 ± 0.83 in ICL group and -0.24 ± 0.95 in TICL group, respectively. Figure 5 shows

stability of spherical equivalent in myopic ICL and toric ICL group, respectively, during one year follow-up period.

Preoperative mean cylinder was -0.77 ± 0.64 D in myopic ICL group and -3.25 ± 1.29 D in toric ICL group. The mean postoperatively cylinder in toric ICL group was -0.81 ± 0.63 D, -0.75 ± 0.67 D, -0.93 ± 0.70 D, -0.94 ± 0.61 D at 5th days, 2, 6, 12 months after operation, respectively. Figure 6 Shows stability of cylinder in toric ICL group during one year follow-up period.

Axial changes of toric ICL, after six months of follow-up were 5 degrees in 13.9%, 10 degrees in 8.3%, 15 degrees in 2.8%, 20 degrees in 2.8% and 72.2% of the eyes did not have axial rotation.

The mean preoperative endothelial cell densities were $2,860 \pm 341$ cells/mm² in myopic ICL group and $2,760 \pm 292$ cells/mm² in toric ICL group; which decreased to $2,848 \pm 65$ cells/mm² and $2,430 \pm 178$ cells/mm², respectively at 6th month after operation.

The mean preoperative IOP was 13.56 ± 2.21 mmHg, whereas at 6th month the postoperative value was 13.35 ± 3.08 mmHg. No statistically significant difference was found ($p=0.053$). Although two eyes (6.5%) in myopic ICL group and one eye (1.6%) in toric ICL group required IOP-lowering medication at one week, due to a transient increase in IOP (pressures of 25 to 30 mmHg) that resolved after steroidal treatment discontinuation.

There were no intraoperative complications. In 95 eyes, only one eye (1.05%) developed an asymptomatic anterior subcapsular cataract, this patient showed no change in BSCVA and no need to operation. No pupillary block, pigment dispersion syndrome, pigmentary glaucoma and retinal detachment or other vision threatening complications were seen at any time during the follow-up. No patients needed secondary surgical intervention for reposition, replacement, removal of ICL or cataract extraction.

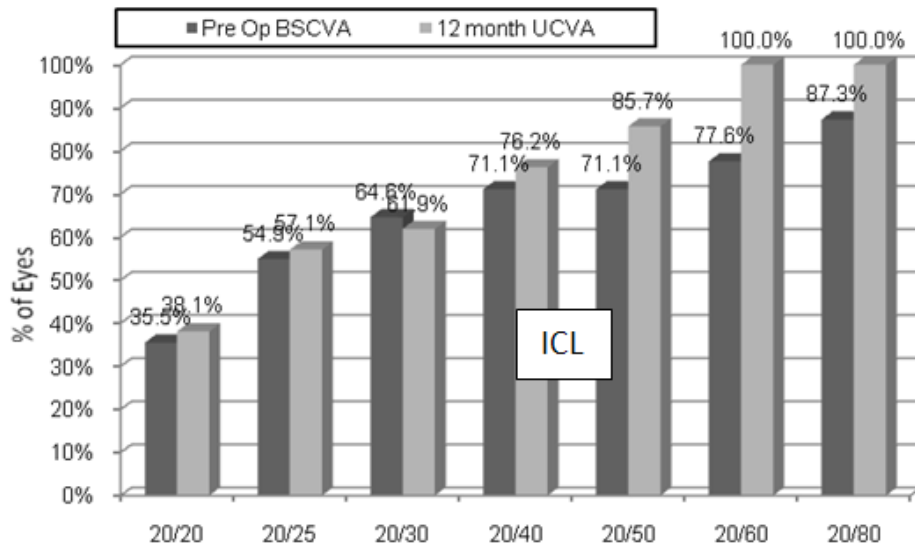


Figure 1. Cumulative preoperative best spectacle corrected visual acuity versus 12 month postoperative uncorrected visual acuity for the Implantable Collamer Lens group
Preop: Preoperative, BSCVA: Best spectacle corrected visual acuity, UCVA: uncorrected visual acuity

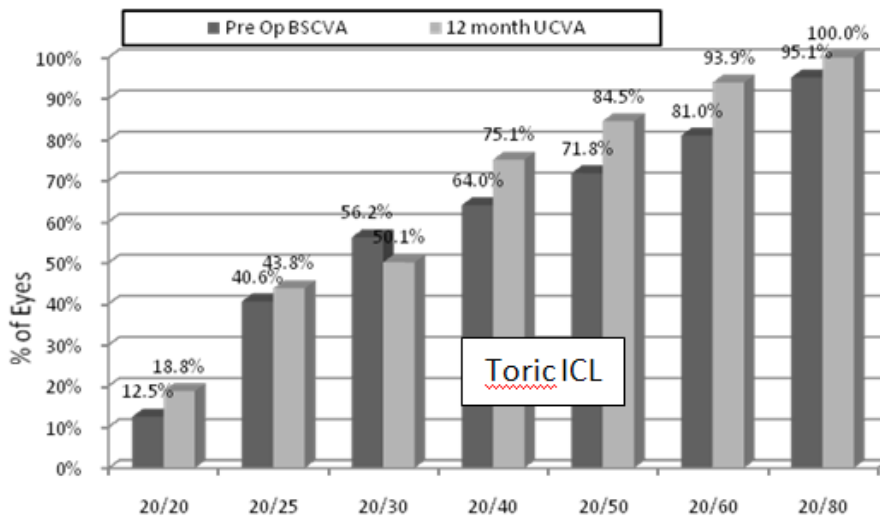


Figure 2. Cumulative preoperative best spectacle corrected visual acuity versus 12 month postoperative uncorrected visual acuity for the toric Implantable Collamer Lens group
Preop: Preoperative, BSCVA: Best spectacle corrected visual acuity, UCVA: uncorrected visual acuity

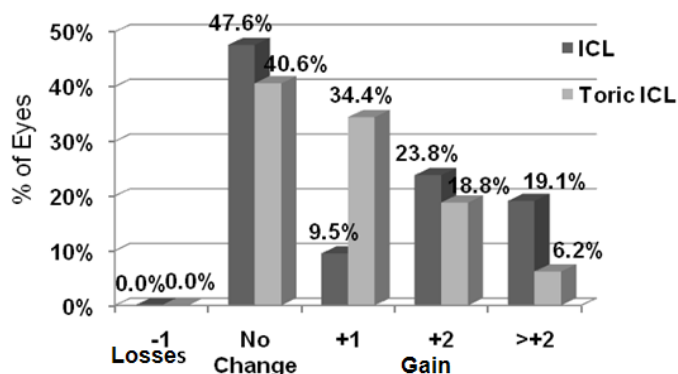


Figure 3. Preoperative versus 12 month postoperative line change in best spectacle corrected visual acuity for the ICL and toric Implantable Collamer Lens group
Preop: Preoperative, BSCVA: Best spectacle corrected visual acuity

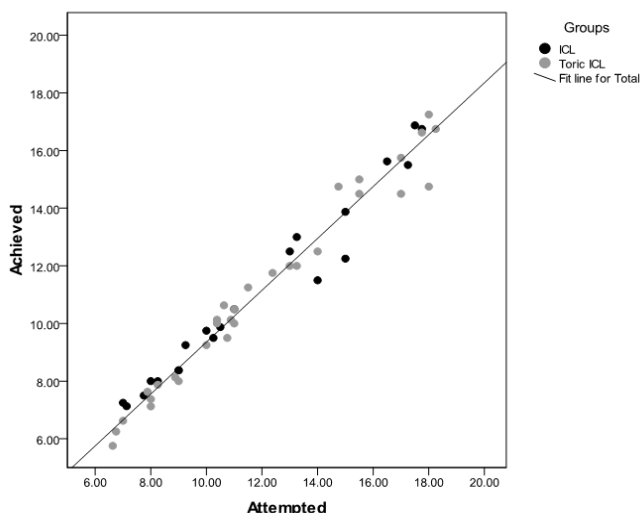


Figure 4. The scattergram in demonstrates good refractive predictability for Implantable Collamer Lens and toric Implantable Collamer Lens group

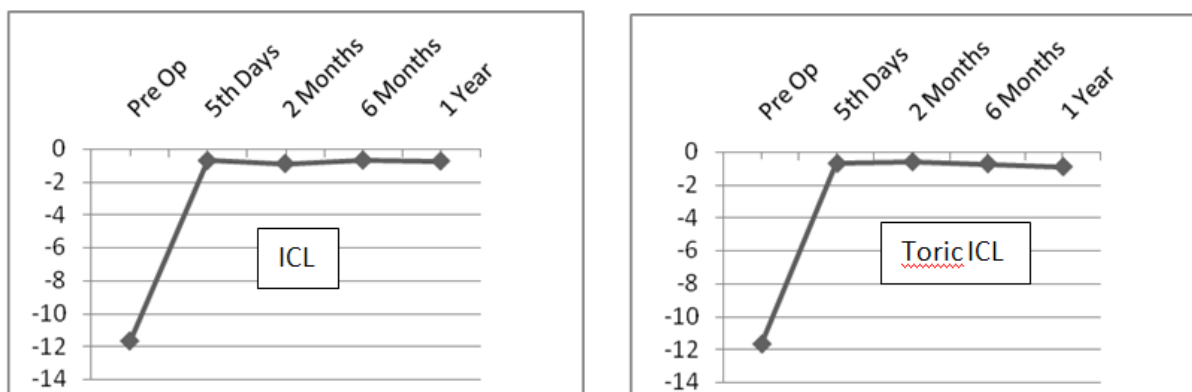


Figure 5. Stability of spherical equivalent in Implantable Collamer Lens and toric Implantable Collamer Lens group during one year follow-up

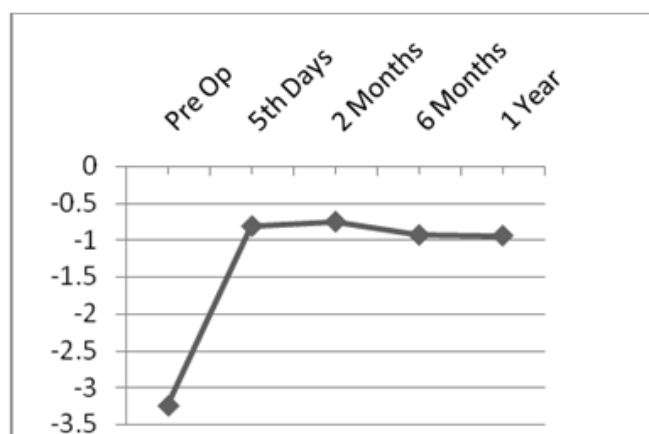


Figure 6. Stability of cylinder in toric Implantable Collamer Lens group during one year follow-up

Table 1. Predictability of manifest refraction spherical equivalent, attempted versus achieved in Implantable Collamer Lens group

	5 days [n/N (%)]	2 months [n/N (%)]	6 months [n/N (%)]	12 months [n/N (%)]
≤0.5 D	18/31 (58.1%)	22/31 (71.0%)	12/23 (52.2%)	10/21 (47.7%)
≤1.0 D	25/31 (80.7%)	24/31 (77.5%)	19/23 (82.6%)	17/21 (81.0%)
≤2.0 D	29/31 (93.6%)	25/31 (87.2%)	21/23 (91.3%)	19/21 (90.5%)
>2.0 D	2/31 (6.4%)	4/31 (12.8%)	2/23 (8.7%)	2/21 (9.5%)

Table 2. Predictability of manifest refraction spherical equivalent, attempted versus achieved in toric Implantable Collamer Lens group

	5 days [n/N (%)]	2 months [n/N (%)]	6 months [n/N (%)]	12 months [n/N (%)]
≤0.5 D	43/64 (67.2%)	43/63 (68.2%)	16/37 (40.5%)	11/32 (34.4%)
≤1.0 D	51/64 (79.7%)	54/63 (85.7%)	27/37 (72.9%)	23/32 (71.9%)
≤2.0 D	57/64 (89.1%)	59/63 (93.6%)	35/37 (94.6%)	30/32 (93.8%)
>2.0 D	7/64 (10.9%)	4/63 (6.4%)	2/31 (5.4%)	2/32 (6.2%)

Discussion

Patients with high refractive errors are not appropriate candidates for LASIK or other excimer procedures or in eyes where quick visual recovery is mandatory, an alternative treatment can be phakic IOLs, which are able to correct high levels of refractive error without ablating the cornea, or removing the natural lens.¹⁶

Several studies^{3,9,11,15} suggested that implantation in the posterior chamber could be considered a safe option for the phakic IOL. In addition Fechner et al¹⁷ reported that ICL implantation has better cosmetic appearance compared with anterior chamber phakic IOLs.

UCVA represents the primary efficacy variable for the ICL clinical study and the majority of refractive laser surgery clinical investigations.¹⁵ In this study efficacy in myopic ICL group was 1.09, 1.03, 1.08 and in toric ICL group was 1.15, 1.11, 1.06 at 2, 6 and 12 months after operation, respectively. According to this study, efficacy appeared better with the toric ICL group comparing to myopic ICL group. Sander et al¹⁸ reported similar results, so that postoperative UCVA was $\geq 20/20$ or better in 50.4% of spherical ICL series, compared with 83.1% of the toric series.

Preservation of BSCVA, commonly considered the primary criterion for assessing the safety of a refractive surgical procedure, was extremely high in the large study of U.S FDA spherical ICL series.¹¹ In our study, BSCVA improved after ICL and toric ICL implantation with no accompanying intraoperative or postoperative complications, so an improvement in BSCVA ($^{20}/_{20}$ or better) was achieved at 6th month (60.9%) and 12th month (66.7%) compared with preoperative levels (35.5%) in ICL group and this results for toric ICL group was at 6th month (32.4%) and 12th month (28.1%) compared with preoperative levels (12.5%). These results are comparable with U.S FDA spherical ICL series that best corrected vision ($^{20}/_{20}$ or better) was achieved at 6th month (83.7%) and 12th month (82.4%) compared with preoperative levels (67.7%).¹¹

Figure 3 shows preoperative versus 12 months postoperative line changes in BSCVA for ICL and toric ICL. At the 12th month follow-up, 52.4% of eyes had an increase in BSCVA and 47.6% of eyes with no change in BSCVA in myopic ICL group, and these results for toric ICL group were 59.4% and 40.6% with no patient loss of BSCVA. At the last follow-up, so we found that 100.0% of eyes either maintained or gained BSCVA after myopic or toric ICL implantation.

BSCVA was maintained or improved in previously published ICL studies such as (Gonvers et al,¹⁹ Menezo et al,²⁰ and Pesando et al²¹).

We found that the predictability and stability of MRSE and manifest cylinder were excellent in this study. Predictability (Table 2 and 3) was achieved very early with myopic ICL and toric ICL group (80.7% within ± 1.0 D in ICL group and 79.7% in toric ICL group at 5th day visit and was maintained during the follow-up period). At 12th month postoperatively, 34.4%, 59.4% of eyes in toric ICL were within ± 0.50 D and ± 1.0 D of their attempted cylinder. At 12 months after operation 47.7%, 81% of eyes in myopic ICL and 34.4%, 71.9% of eyes in toric ICL group were within ± 0.50 D and ± 1.0 D of attempted MRSE. The results of our study are very similar to the FDA-reported outcomes for toric ICL.¹⁸ For example, at 12th month postoperatively the FDA outcomes reported 48.40% of eyes were within 0.50 D and 85.50% of eyes were within 1.0 D of the

attempted cylinder.¹⁸ At 12th month postoperatively, 76.90% and 97.30% of eyes achieved MRSE within 0.50 D and 1.00 D of the attempted MRSE, respectively, in the FDA trial.¹⁸

In this study patients had spherical refractive error over -20.00. We explain about postoperative residual refractive error and those patient were not excluded of this study, so this data may influence on the refractive outcomes.

One of the important keys to success with the ICL and toric ICL implantation is an appropriate estimation of the eye's ciliary sulcus diameter to ensure the appropriate lens size. There is not one ideal method to accurately measure the sulcus-to-sulcus diameter, and many publications have shown poor correlation between external and internal dimensions of the anterior segment.²²⁻²⁶ Internal angle-to-angle direct measurement has become possible only recently with very high frequency (VHF) ultrasound (Artemis, USA0) and with anterior chamber optical coherence tomography (AC OCT, Ziess-Meditec).²⁷ To improve the accuracy of ICL and toric ICL sizing, accurate preoperative measurements are fundamental.

In this study, except one eye (1.05%) with asymptomatic anterior subcapsular cataract, there were not complications of incorrect IOL sizing such as, IOL rotation, erosion of the angular structures induced glaucoma, pupil deformation. These results may be due to ACD measurements were done by Orbscan II and verified by ultrasound biometry and corneal WTW diameters were measured by calipers and verified by Orbscan II.

The Visian implantable Collamer lens FDA trial reported approximately 6% to 7% of eyes developed anterior subcapsular opacities ≥ 7 years after Collamer lens implantation, of which only 1% to 2% progressed to clinically significant cataract.²⁸ Studies reporting long-term results with the V4 model report an increased incidence of asymptomatic anterior subcapsular cataract (2.6% to 6.0%) and of clinically significant cataract (0.6% to 2.3%).²⁹ In our study, only one eye developed asymptomatic anterior subcapsular cataract and no patients needed reposition, explanation or exchange of the lens.

Since in this study the patients were followed up for one year, longer follow-up may show greater cataract formation.

In this study no patient developed pupillary block which may be due to surgical PI done by vitrectomy probe.

Conclusion

ICL and toric ICL implantation appears to be an effective, safe, predictable, and stable technique for the correction of high level of myopia and myopic astigmatism. Further randomized, masked clinical studies are needed to confirm these results.

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