

Comparison of Outcomes of Posterior Chamber and Iris-Claw Anterior Chamber Phakic Intraocular Lens Implantation for Moderate to High Myopia

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Abstract

Purpose: To compare visual acuity and contrast sensitivity between Posterior Chamber Phakic Intraocular Lens (ICL) and Iris-Claw Anterior Chamber Phakic Intraocular Lens (Artiflex) implantation for moderate to high myopia.

Setting: Dr. Lütfi Kırdar Kartal Training and Research Hospital, Eye Clinic, Istanbul, Turkey.

Participants: Sixty eyes of 30 myopic patients were included in the study. Thirty eyes of 15 patients underwent implantation of ICL (24)/toric ICL (6) and 30 eyes of 15 patients underwent implantation of Artiflex.

Methods: Preoperative and postoperative 1, 6 and 12 months, logarithm of the minimum angle of resolution (log MAR) uncorrected visual acuity (UCVA), log MAR best spectacle-corrected visual acuity (BSCVA), manifest refraction, intraocular pressure (IOP), endothelial cell density (ECD) and complications were evaluated. Contrast sensitivity (CS) was also evaluated at 1.5, 2.52, 4.23, 7.10 and 11.91 cycles per degree spatial frequencies by CC-100 Topcon LCD preoperative and postoperative 1-year.

Main outcome measures: Improvement in visual acuity (VA) and CS, percentage change in ECD and IOP.

Results: Preoperatively, there was no significant difference in the mean UCVA, BSCVA and CS between the ICL and Artiflex groups ($p=0.798$; 0.672 ; 0.510) and the mean spherical equivalent (SE) was significantly better in the ICL group than the Artiflex group ($p=0.003$). One year postoperatively, the mean UCVA and BSCVA were significantly better in the ICL group than the Artiflex group ($p=0.002$; 0.0001). We found no significant difference in the mean SE between the ICL and Artiflex groups ($p=0.809$). The mean photopic CS increased considerably at all spatial frequencies compared with preoperative levels in the ICL and Artiflex groups ($p=0.0001$).

Conclusion: After 1-year follow-up, the phakic IOLs performed well in correcting moderate to high myopia. Preoperatively and 1-year postoperatively, there was no significant difference in the mean photopic CS between the ICL and Artiflex group at all spatial frequencies. No vision-threatening complications occurred during the observation period.

Keywords: Iris-Claw; ICL; Phakic intraocular lens; Visual acuity; Contrast sensitivity

Introduction

Implantation of phakic intraocular lenses (pIOLs) is a recent alternative for high refractive errors management in patients who are not candidates for refractive lens exchange or corneal refractive procedures [1,2]. Laser in situ keratomileusis (LASIK), laser-assisted subepithelial keratectomy (LASEK) and photorefractive keratectomy (PRK) are the most commonly used methods for correcting low to moderate myopia. For correction of high myopia, these methods have higher corneal complications rate than pIOL [3]. In addition to this, corneal refractive procedures induce optical aberrations than pIOL for the correction myopia [4]. Eyes with large amounts of aberration have poor spatial vision and more glare and halos [4]. For treatment of moderate and high myopia, pIOL implantation provides a better visual outcome than keratorefractive procedures[4]. In addition, the pIOL is removable and has potential to be reversible, whereas with keratorefractive surgery, this cannot be done even when unexpected results happen after surgery [5].

Phakic IOLs are currently available in 3 basic models: angle-supported, iris-claw anterior chamber and posterior chamber Angle-

supported IOLs stay in contact with peripheral iris and chamber angle structures. Iris-claw lenses pinch the mid-peripheral iris tissue. Posterior chamber phakic IOLs are vaulted between the posterior pigmented layers of the iris and the anterior crystalline lens with the anterior zonules [6]. Previous studies evaluated the clinical and refractive results of this pIOLs [7].

The purpose of this study was to compare the outcomes of the Visian Implantable Collomer Lens (ICL; STAAR Surgical, Nidau, Switzerland) posterior chamber and Artiflex (Ophtec BV, Groningen,

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The Netherlands) foldable iris-claw anterior chamber phakic intraocular lens implantation for moderate to high myopia.

Materials and Method

The study comprised 60 eyes of 30 patients scheduled for implantation of pIOL to correct high myopia from February 2005 to September 2009 at the Dr. Lutfi Kırdar Kartal Training and Research Hospital, Eye Clinic, Istanbul, Turkey. Thirty eyes of 15 patients underwent implantation of ICL (24 eyes)/toric ICL (6 eyes) (group 1) and 30 eyes of 15 patients underwent implantation of Artiflex (group 2). All patients were fully informed about details and possible risks and benefits of the surgery and signed a consent form. The study adhered to the tenets of the Declaration of Helsinki. Surgeries were performed by the same surgeon.

Eyes with a previous history of refractive, corneal or intraocular surgery, glaucoma, cataract, corneal degeneration, recurrent or chronic uveitis, retinopathy, shallow anterior chamber depth (ACD) (from the epithelium) of less than 3.2 mm in Artiflex and 2.8 mm in ICL group, endothelial cell count (ECC) of less than 2000 cells/mm² were excluded from this study. All patients were older than 18 years and had stable myopia for at least 2 years.

All patients underwent a complete ophthalmic examination preoperatively. It included uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), cycloplegic and manifest refraction, applanation tonometry for intraocular pressure (IOP), anterior chamber depth (ACD) (IOLmaster, Carl Zeiss Meditec AG), endothelial cell density (ECD) (Topcon-SP, Tokyo, Japan), corneal topography, photopic contrast sensitivity testing (CC-100 Topcon LCD), slit lamp evaluation, biometry (IOLmaster, Carl Zeiss Meditec AG) measurement and dilated fundus evaluation. White-to-white (WTW) diameter by surgical calipers and corneal pachymetry were also measured in ICL groups.

Uncorrected visual acuity, BSCVA, manifest refraction, IOP measurement, ECD, slit-lamp biomicroscopy and dilated fundus examination were repeated at 1 day, 1 week, 1, 3, 6 and 12 months. Photopic contrast sensitivity testing was also measured at 12 months postoperatively.

The 1-piece ICL is a posterior chamber pIOL made of Collamer, a hydrophilic material composed of collagen and a poly-hydroxyethyl methacrylate-based copolymer. The lens, which is 6.5 mm wide and 11.5 to 13.0 mm long, is available in powers ranging from -3.00 to -23.00 D for myopic patients. The toric lens is available in spherical powers ranging from -3.00 to -23.00 D and astigmatic correction of -1 to -6 D. The dioptric power of the ICLs and toric ICLs was calculated with the published formulas for PIOLs by Sarver and Sanders [8,9].

The Artiflex foldable pIOL has a 3-piece design and consists of a 6.0 mm convex-concave flexible silicone optic of ultraviolet (UV)-filtering polysiloxane and rigid haptics of compression-molded polymethyl methacrylate (PMMA). The pIOL powers range from -2.00 to -14.50 D in 0.50 steps. The dioptric power of the pIOL was calculated with the van der Heijde formula [10].

In all patients in the ICL/toric ICL group, neodymium-YAG laser iridotomies at the 10 and 2 o'clock positions were created 1 week before surgery. The surgery was done under cycloplegia using topical anesthesia (0.5 % proparacaine HCl) (Alcain, Alcon) combined with 40 mg 2% lidocaine hydrochloride intracameral anesthesia (Aritmal, Osel). An ophthalmic viscoelastic material sodium hyaluronate was

instilled into the anterior chamber and ICL/toric ICL was inserted with an injector (Staar Surgical Co.) through a 3.2 mm clear corneal incision. The 0 horizontal axis was marked before surgery and a Mendez ring was used for measuring during surgery the required rotation from the horizontal axis in the toric ICL group. After the lens was placed in the posterior chamber, the remaining viscoelastic material was gently irrigated with balanced salt solution. 0.1 cc 1% of cefuroxime sodium (Zinnat, Glaxo Smithkline) and 0.01% acetylcholine chloride (Miochol-E, Novartis) was injected into the anterior chamber.

The Artiflex implantation was performed under topical anesthesia (Alcain) combined with intracameral anesthesia (Aritmal). In cases of developed pupil mydriasis, intracameral 0.01% acetylcholine chloride was injected. Two vertical paracenteses at the 10 and 2 o'clock positions and 3.2 mm clear corneal incisions at the 12 o'clock position were created. The viscoelastic material was instilled into the anterior chamber and the lens was inserted with the dedicated spatula. After the lens positioning, the iris tissue was grasped and enclavated into the haptics with enclavation needle. An iridotomy was made surgically during surgery. Removal of the viscoelastic material and injection of 0.1 cc 1% of cefuroxime sodium finalized the procedure.

Statistical calculations were performed with GraphPad Prisma V.3 program for Windows. Besides standard descriptive statistical calculations (mean and standard deviation), Man Whitney U-test was used in the comparison of groups, Wilcoxon test was employed in the assessment of pre and post treatment values, and Chi-square test was performed during the evaluation qualitative data. Statistical significance level was established at $p < 0.05$.

Results

Table 1 shows the patients' preoperative data by group. The mean age of the patients was 27.62 ± 6.35 (range 18-39) years in the ICL group and 27.87 ± 8.7 (range 18-45) years in the Artiflex group. Preoperatively there was no significant difference in the mean UCVA ($p=0.798$), BSCVA ($p=0.672$), ECD ($p=0.093$) and IOP ($p=0.06$) between the ICL and Artiflex groups. Preoperative the mean spherical equivalent (SE) was significantly better in the ICL group than in the Artiflex group ($p=0.003$).

Table 2 shows the patients' postoperative results. One-year after surgery the mean UCVA ($p=0.002$) and BSCVA ($p=0.0001$) were significantly better in the ICL group than the Artiflex group. The mean IOP was significantly less in the ICL group than the Artiflex group ($p=0.018$). The mean ECD was significantly less in the Artiflex group than the ICL group ($p=0.006$). There was no significant difference in the mean SE between the ICL and Artiflex groups ($p=0.809$). Figures 1 and 2 shows the UCVA and BSCVA preoperatively and 1 year after surgery.

Table 3 shows the mean preoperative photopic contrast sensitivity values at 1.5, 2.52, 4.23, 7.10 and 11.91 cycles per degree (cs/deg) spatial frequencies and Table 4 shows the mean 12-month postoperative photopic contrast sensitivity values at all spatial frequencies. One-year after surgery the mean CS was significantly better in the ICL and Artiflex groups than the preoperative values in two groups at all spatial frequencies ($p=0.0001$). There was no significant difference in the mean CS between the ICL and Artiflex groups preoperative and one-year after surgery at all spatial frequencies. Figure 3 shows the mean preoperative and 1-year after surgery photopic contrast sensitivity values at all spatial frequencies. No vision-threatening complications occurred during the observation period.

| | ICL Group | Artiflex Group | P |
|---|------------------|------------------|-------|
| Eyes (n) | 30 | 30 | |
| Age (y) | | | |
| Mean ± SD | 27.62 ± 6.35 | 27.87 ± 8.7 | 0.75 |
| Range | 18 to 39 | 18 to 45 | |
| Sex (F-M) | | | |
| F | 7 | 7 | |
| M | 8 | 8 | |
| Sphere (D) | | | |
| Mean ± SD | -8.08 ± 6.39 | -12.09 ± 2.57 | 0.006 |
| Range | -5.00 to -14.00 | -7.00 to -15.00 | |
| Cylinder (D) | | | |
| Mean ± SD | -1.13 ± 1.17 | -1.25 ± 0.96 | 0.884 |
| Range | 0.00 to -2.00 | 0.00 to -2.00 | |
| SE(D) | | | |
| Mean ± SD | -7.77 ± 6.85 | -12.55 ± 2.43 | 0.003 |
| Range | -5.25 to -15.75 | -8.00 to -16.00 | |
| logMAR UCVA | | | |
| Mean ± SD | 1.43 ± 0.3 | 1.44 ± 0.26 | 0.798 |
| Range | 1.60 to 0.88 | 2.00 to 1.00 | |
| logMAR BSCVA | | | |
| Mean ± SD | 0.43 ± 0.22 | 0.38 ± 0.15 | 0.672 |
| Range | 1.00 to 0.10 | 0.70 to 0.18 | |
| IOP (mmHg) (Mean ± SD) | 14.29 ± 2.7 | 15.7 ± 1.87 | 0.06 |
| ECD (cell/mm ²) (Mean ± SD) | 2872.39 ± 403.42 | 2640.76 ± 333.49 | 0.093 |
| ACD (mm) (Mean ± SD) | 3.19 ± 0.2 | 3.4 ± 0.25 | 0.002 |

UCVA: Uncorrected Visual Acuity; BSCVA: Best Spectacle-Corrected Visual Acuity; SE: Spherical Equivalent; ACD: Anterior Chamber Depth; ECD: Endothelial Cell Density; IOP: Intraocular Pressure

Table 1: Preoperative patient data.

| | ICL Group | ArtiflexGroup | P |
|---|------------------|------------------|--------|
| Sphere (D) | | | |
| Mean ± SD | -0.41 ± 0.89 | -0.47 ± 1.09 | 0.911 |
| Range | +0.25 to -1.50 | +0.75 to -2.00 | |
| Cylinder (D) | | | |
| Mean ± SD | -0.97 ± 0.93 | -1.21 ± 0.41 | 0.007 |
| Range | 0.00 to -2.00 | -0.75 to -2.75 | |
| SE (D) | | | |
| Mean ± SD | -0.58 ± 0.79 | -1.16 ± 1.08 | 0.337 |
| Range | 0.00 to -1.50 | -0.13 to -2.75 | |
| logMAR UCVA | | | |
| Mean ± SD | 0.18 ± 0.13 | 0.35 ± 0.2 | 0.002 |
| Range | 0.40 to 0.00 | 0.70 to 0.18 | |
| logMAR BSCVA | | | |
| Mean ± SD | 0.09 ± 0.07 | 0.19 ± 0.08 | 0.0001 |
| Range | 0.18 to 0.00 | 0.30 to 0.10 | |
| ECD (cell/mm ²) (Mean ± SD) | 2685.65 ± 397.89 | 2318.43 ± 351.53 | 0.018 |
| IOP (mmHg) (Mean ± SD) | 13 ± 3.36 | 15.13 ± 2.32 | 0.006 |

UCVA: Uncorrected Visual Acuity; BSCVA: Best Spectacle-Corrected Visual Acuity; SE: Spherical Equivalent; ECD: Endothelial Cell Density; IOP: Intraocular Pressure

Table 2: Patients' results one-year after surgery.

Discussion

There are only a few reports on the comparison of anterior and posterior chamber phakic IOLs [7,11,12], Ghoreishi et al. [12] compared results of implantation of Artiflex and ICL phakic IOL in 40 eyes. Postoperatively there was no significant difference in the mean UCVA, BSCVA and CS between the two groups similar to our study. The results of our study show that implantation of phakic IOLs

for the correction of high myopia provides significant improvement in UCVA, BSCVA and CS throughout the 1-year follow-up period, similar to that reported by other authors [5,13]. In the ICL/Toric ICL group the mean log MAR UCVA and BSCVA were corrected from 1.43 and 0.43 preoperatively to 0.18 and 0.09 twelve months postoperatively and in the Artiflex group values were corrected from 1.44 and 0.35 to 0.38 to 0.19 in our study. In group 2, patients had higher preoperative SE and more myopic fundus and so, they had less UCVA and BSCVA postoperatively. A Galilean telescope is in effect created when spectacles are worn. Each diopter of spectacle overcorrection for myopia at a vertex of 12 mm causes a 2% magnification. This may state

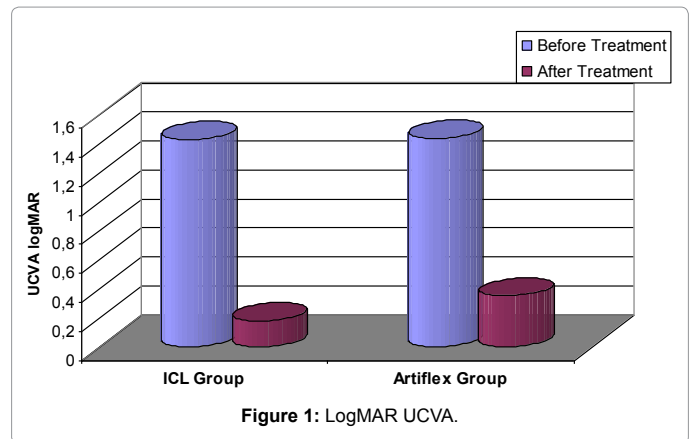


Figure 1: LogMAR UCVA.

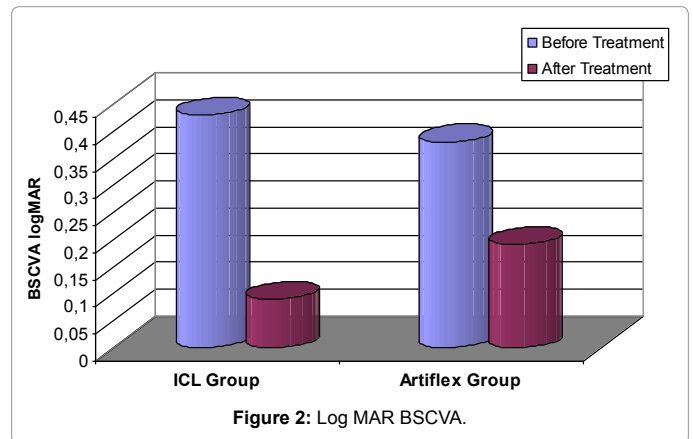


Figure 2: Log MAR BSCVA.

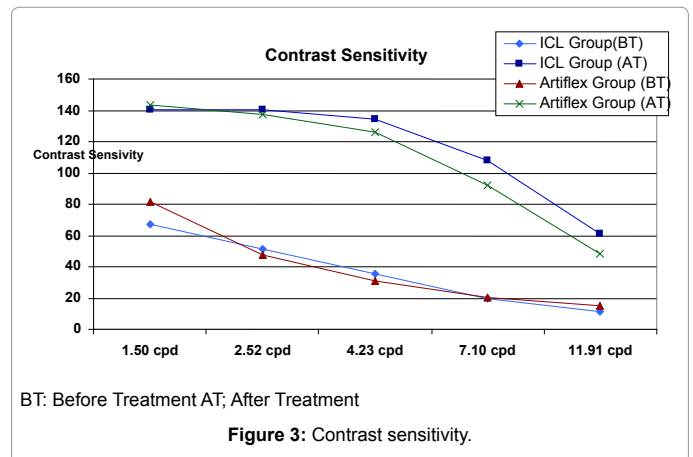


Figure 3: Contrast sensitivity.

| Spatial frequencies (cs/deg) | ICL Group | ArtiflexGroup | P |
|------------------------------|---------------|---------------|-------|
| 1.5 (Mean ± SD) | 67.09 ± 30.33 | 81.81 ± 28.4 | 0.115 |
| 2.52 (Mean ± SD) | 51.21 ± 31.71 | 47.76 ± 18.31 | 0.97 |
| 4.23 (Mean ± SD) | 35.43 ± 19.19 | 30.86 ± 14.97 | 0.385 |
| 7.10 (Mean ± SD) | 19.82 ± 10.13 | 20.57 ± 7.27 | 0.51 |
| 11.91 (Mean ± SD) | 11.36 ± 5.36 | 15 ± 5.1 | 0.073 |

cs/deg: Cycles per Degree; SD: Standart Deviation

Table 3: Preoperative mean photopic contrast sensitivity values.

| Spatial frequencies (cs/deg) | ICL Group | Artiflex Group | P |
|------------------------------|----------------|----------------|-------|
| 1.5 (Mean ± SD) | 140.15 ± 14.04 | 143.21 ± 0 | 0.295 |
| 2.52 (Mean ± SD) | 140.15 ± 14.04 | 137.62 ± 18.53 | 0.609 |
| 4.23 (Mean ± SD) | 134.02 ± 23.06 | 126.43 ± 28.88 | 0.338 |
| 7.10 (Mean ± SD) | 107.83 ± 35.38 | 90.02 ± 40.83 | 0.149 |
| 11.91 (Mean ± SD) | 61.28 ± 49.7 | 48.3 ± 22.28 | 0.873 |

cs/deg: Cycles per Degree; SD: Standart Deviation

Table 4: The mean photopic contrast sensitivity values one-year after surgery.

that implantation of pIOLs may provide improved functional vision in high myopic patients postoperatively due to possible telescopic magnification effect. In addition to this, an IOL implanted in the posterior chamber produces less image magnification than an IOL in the anterior chamber [14-16]. It supports the ICL/Toric ICL group's good visual function.

These lenses seemed not causing induced astigmatism as much as the former generation phakic IOLs do. Weaknesses of this study, we compared ICL/Toric ICL with Artiflex which is non-toric. There was no significant difference in the mean refractive astigmatism between the 2 groups ($p=0.193$; $p=0.128$) preoperatively and 1-year after surgery. This was not expected because we included 6 patients with Toric ICL in this study and we should find better results in group 1 after surgery. We think that it was mostly due to preoperative similar patients' data. In addition on this, these surgeries seemed not causing excessive induced astigmatism.

The loss of contrast sensitivity noted after LASIK for high myopia does not occur after pIOLs [17]. In our study contrast sensitivity increased in all spatial frequencies when compared with preoperative values with best spectacle correction.

One of the most frequent complications for pIOLs is endothelial cell loss. Substantial cell loss may develop following all types of intraocular surgery and it causes irreversible edema because human corneal endothelial cells have a limited ability to divide after birth. Perez-santonja et al. [18] reported that anterior chamber pIOL surgery caused higher endothelial cell loss rate than the cataract surgery. Endothelial cell loss at 1 year was 13% and at 2 year was %17.6 in their study [18]. Tehrani et al. reported that the annual cumulative endothelial cell loss was 1.9% for iris-claw lenses [1]. In Maurits et al. study, the overall endothelial cell loss in the anterior chamber pIOL group at 1 year was 4.7% [3]. In our study endothelial cell loss at 1 year was 12.2% for Artiflex group. Dejaco-Ruhseurm et al. reported that endothelial cell loss at 4 year was 12.3 % and Assetto et al. was 4% for posterior chamber pIOL [19]. Arne et al. reported endothelial cell loss of <3.8% at 1 year for ICL [20]. In our study endothelial cell loss at 1 year was 6.5% for ICL/Toric ICL group.

Cell lost is highest when the anterior chamber depth is less than 3.2 mm. In our study there was no significant difference in the mean ACD between the ICL and Artiflex groups but the mean ECD at 1 year was significantly less in the Artiflex group than the ICL group ($p=0.006$).

The reason for endothelial cell loss may be preoperative trauma due to transient contact between the implanted lens and endothelium, rubbing of eyes postoperatively, and a subclinical inflammatory condition in response to a foreign body within the AC [1]. No patient had IOP elevation, cataract or retinal detachment in both groups.

In conclusion, on the basic of the 1 year results of this study, the phakic IOLs performed well in correcting moderate to high myopia. These findings suggest that the pIOLs implantation is a good alternative to corneal refractive procedure for the treatment of high myopia. The number of patients in our study was limited, so further future studies with larger populations and longer follow-up period are required to corroborate our findings.

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The author has no financial or proprietary interest in any material or method mentioned.

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