MEDWIN PUBLISHERS
Committed to Create Value for Researchers

Open Access Journal of Ophthalmology
ISSN: 2578-465X

Study of Complications of Phakic Intraocular Lenses in Correction of Myopia

Mostafa Naderi[1], Khosrow Jadidi[2], Seyed Aliasghar Mosavi[2]* and Kianoush Kiani[1]

[1]Health Management Research Center, Baqiyatallah University of Medical Sciences, Tehran, Iran
[2]Vision Health Research Center, Semnan University of Medical Sciences, Semnan, Iran

***Corresponding author:** Seyed Aliasghar Mosavi, Vision Health Research Center, Semnan University of Medical Sciences, Semnan, Iran, Tel: +98-9120948128; Email: a.a.mosavi@gmail.

Research Article
Volume 6 Issue 1
Received Date: March 04, 2021
Published Date: March 23, 2021
DOI: 10.23880/oajo-16000214

Abstract

Objective: To evaluate the visual outcomes and complications of phakic intraocular lenses Implantation for myopia.

Method: This cross sectional study included 151 myopic eyes implanted with one of the three types of phakic intraocular lenses (Artisan 83 eyes, ICL 52 eyes, and I- Care 16 eyes). Patients were followed for an average of 33±15 months. Intraoperative and postoperative complications were recorded as short- term and long-term. All patients were recalled and examined under thorough eye examination.

Results: Three years after the surgery, safety index has changed significantly using the Artisan and ICL lenses respectively (P>0.001 and P 0.007=) and efficacy index in the three groups was 0.04 ± 0.91, 0.14± 1.61 and ± 0.42 0.15. Spherical Equivalent (SE) values decreased post operation that was statistically significant (P 001/0>) using Artisan and ICL lenses. Also, Astigmatism values dropped significantly using Artisan and I-care lenses (P 001/0> and P 03/0=) three years after surgery. Endothelial cell count reduction percentage was 6.1% and 5.2% in groups Arti san and ICL respectively, while it was 43.7% in Group ICare.

Conclusion: No significant intraoperative complication was seen among the three groups. However, sharp decline of post operatively corneal endothelial cell count was the most important complication of I- Care lens and it is suggested to prevent implantation of this type of PIOLs for anticipation of cornea decompensation.

Keywords: Phakic Intraocular Lenses; Myopia; Refractive Errors; Endophthalmitis; Corneal Edema

Abbreviations: SE: Spherical Equivalent; ACD: Anterior Chamber Depth; ICL: Implantable Collamer Lens; ECC: Endothelial Cell Count; UCVA: Uncorrected Visual Acuity; BCVA: Best Corrected Visual Acuity; IOP: Intraocular Pressure; ECD: Endothelial Cell Density; UBM: Ultrasound Biomicroscopy Images; DSAEK: Descemet Stripping Automated Endothelial Keratoplasty.

Introduction

Refractive errors, particularly myopia are seen with different prevalence in different geographical areas and races which is greatest in East Asia. The prevalence of myopia in Taiwan, China, Hong Kong, Singapore and Japan is estimated at 50-80 % among those 15 to 24 years old. This is in America, Australia and India 27-33%, 37% and 5-10 % respectively. A very small percentage of myopia is pathologic myopia. Refractive errors treatment is determined by patient's demonstration and eyesight needs. The treatment consists of glasses, contact lenses, corneal lasers (LASIK, LASEK etc.) and intraocular lenses [1].

Intraocular lenses that are implanted in the presence of Phakic Iols are a new class of lenses which has expanded

the whole surgery of refractive errors and it introduces the new options to the surgeons and their patients to correct the refractive errors. This is reversible theoretically, though damage is perceived mainly permanent by them. One of important benefits of using these lenses is the possibility of a natural fit and maintaining a natural lens that makes the vitreous stable and prevent the possibility of detached retina [2].

A wide variety of these lenses are available including angle supported ICL (Staar Surgical, Monrovia, CA, USA) and iris- fixated whose 2 common types Artisan (Ophtec, Groningen, Netherlands) and Artiflex (Ophtec, Groningen, Netherlands) are in the market [3]. ICL are effective for correcting the moderate to high anisometropia refractive errors and at the same time are considered reversible method, however, potential complications have been reported such as cataracts, corneal endothelial cell loss, uveitis, endophthalmitis, Pigmentary glaucoma and pupillary block. [4,5].

The objective of this study was to evaluate the visual outcomes and complications of phakic intraocular lenses as well as intra and postoperative safety and efficacy in correction of myopia.

Materials and Methods

In this Cross Sectional study, all patients were recalled whom underwent implantation of phakic intraocular lenses in 2004 until 2012 for any refractive error. All patients were adequately informed and signed a consent form. The study adhered to the tenets of the Declaration of Helsinki. Patients with high refractive error for any reason that had no possibility of corneal laser surgery, Refractive error change less than 0.5 diopters over the last 6 months, patients with transparent crystalline lens, Anterior chamber depth greater than or equal (according to figures obtained in orbscan: 3 mm for Artizan, and I-Care and 2.8mm for ICL, minimum density of endothelial cells 2500 cells/ 2mm for all 3 lenses and the absence of ocular pathology (disease of the cornea, glaucoma, uveitis, maculopathy) Included in our study. 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 Artisan and I Care and 2.8mm in Implantable Collamer Lens (ICL) group, Endothelial Cell Count (ECC) of less than 2000/2mm, Patients with any ocular surface disease which prevents intrtaocular surgery such as severe blepharitis, severe dry eye, conjunctivitis, and general problems preventing surgery or affecting it including diabetes, collagen vascular diseases excluded from study. All patients underwent a complete ophthalmic examination including: Uncorrected Visual Acuity (UCVA), Best Corrected Visual Acuity(BCVA), cycloplegic and manifest refraction, Intraocular Pressure (IOP), Anterior Chamber Depth (ACD) (IOLmaster, Carl Zeiss Meditec AG), Endothelial Cell Density (ECD) (Topcon-SP, Tokyo, Japan), corneal topography, slit lamp evaluation, biometry (IOL master, Carl Zeiss Meditec AG) measurement and dilated fundus evaluation. One type of studied lens was implanted according to the patient's eye conditions during surgery. Surgery was done by two experienced and skilled surgeons in this procedure (MN &KJ). Follow- up evaluation was performed on day 1,3,7, one month, three months, six months, one year and 2-3 years after the operation.

Patients were divided into three groups: Artisan, ICL and I-Care based on the type of intraocular lens. Information extracted from the records of ophthalmologic examination before surgery. Specular Microscopy (Tommy, EM-3000) was used to examine some complications associated with anterior parts of the eye and corneal endothelium. The complications occurred during surgery or immediately afterwards (such as injuries to different parts of the eye during lens implant, bleeding etc.) as complications during surgery. They were seen as short-term complications if occurred for a period of one week (such as uveitis, endophthalmitis, corneal edema etc.) and long-term complications (such as delayed-onset endophthalmitis, detached retina, cataract, etc.).

Moreover, Safety and the efficacy of this method was based on the safety and efficacy index which were measured by the current formula [6,7].

Safety index = (postoperative CDVA)/ (preoperative CDVA)

Efficacy index = (postoperative UDVA)/ (preoperative CDVA)

Statistical Analysis

The data were collected, coded and analysed by IBM SPSS Statistics for Windows) Version 20.0. Armonk, NY: IBM Corp). Mean and standard deviation and descriptive statistics were reported and for the analytical part statistical tests were taken to analyse the data. Probability values of less than 0.05 were considered significant.

Results

In total, the study was performed on 89 patients (151 eyes) that the Artisan, ICL and I-Care Groups included 51 patients (83 eyes), 30 patients (52 eyes), 8 patients (16 eyes) respectively. On average follow- up period was 33±15 months. There was no statistical difference between the studied groups in terms of age. Demographic characteristics of subjects are shown in Table 1.

Type of PIOL	Artisan[1]	ICL[2]	I-CARE[3]	P value		
Mean Age (years)	24 .42±03.4	23-2.±0364	.3±4.30	1 vs 2 0.20	1 vs 3 0.39	2 vs 3 0.43
Mean Preoperative SE(SD)	-0.12 (4.97)	-8.71 (8.72)	2.87(17.2)	Pre 1 vs post 0.44	Pre 2 vs post 0.001	Pre 3 vs post 0.67
Mean Postoperative SE (SD)	-0.87 (0.88)	-0.9(1.11)	-1(0.67)			
Meanpreoperative Ast(SD)	-2.1(1.58)	-1.66(0.6)	0	Pre 1 vs post 0.001	Pre 2 vs post 0.11	Pre 3 vs post 0.03
Mean Postoperative Ast (SD)	-1.27 (0.88)	-1.35 (0.85)	-1.50 (0.50)			
Meanpreoperative Endothelial Cell Count(ECC) (2mm)	2850(248)	2820(192)	2755(285)	Pre 1 vs post (Changes %) 6.1	Pre 2 vs post (Changes %) 5.2	Pre 3 vs post (Changes%) 43.7
Mean Endothelialcell Count (ECC) at 36 month (2mm)	2676(366)	2675(280)	1551(668)			
Efficacy Index at 36 month(SD)	0.91(0.04)	1.16(0.14)	0.42(0.16)	Pre 1 vs post 0.07	Pre 2 vs post 0.24	Pre 3 vs post 0.1
Safety Index at 36 month(SD)	0.14(0.06)	1.35(0.22)	0.5(0.16)	Pre 1 vs post 0.001	Pre 2 vs post 0.007	Pre 3 vs post 0.19

Table 1: All patients data and type of phakic intraocular lens (Piol).

Visual Acuity

The BCVA before surgery in Artisan, ICL and I-care groups was 0.64±0.13, 0.6±0.25 and 0.25±0.14 Log MAR respectively (approximately equivalent to 0.8, 0.6 and 0.7 in Snellen decimal index) that the difference was significant between Artizan, and ICL group (p=0.001). BCVA of patients after surgery in Artisan, ICL and I-care groups was 0.66±0.1, 0.72±0.17 and 0.59±0.38 log MAR respectively (approximately equivalent to 0.8 , 0.7 and 0.5 Snellen decimal index) that the difference was significant statistically between Artizan, and ICL (P=0.03). UCVA after surgery was 0.62±0.18, 0.77±0.22 and 0.64±0.46 log MAR in Artisan, ICL and I-Care groups respectively (approximately equivalent to 0.7, 0.6 and 0.4 dB in Snellen index) that was significant between Artizan and I-Care statistically (P= 0.07).

According to the results obtained in Artisan, ICL and I-Care groups 54, 65 and 0% of eyes were improved postoperative BCVA as much a line or more (in Snellen decimal chart) respectively. It was also seen that 93, 88 and 75 percent of patients were within 1 diopter of emmetropia postoperatively in three groups respectively. Also, 10.3, 11 and 50 percent of eyes had been with reduced BCVA respectively after the operation as much a line or more (in Snellen decimal chart).

Safety index has changed significantly three years after surgery statistically using the Artisan and ICL lenses respectively (0.001> P) and (p=0.007). But this change was not statistically significant using the I-Care lenses (P= 0.19). Efficacy index of all three types of lenses dropped three years after surgery. But this decline was not significant statistically (Table 1).

Refractive Errors

The mean and standard deviation values of astigmatism have declined three years after surgery that was significant using Artisan lens statistically. The mean and standard deviation SE values declined after the surgery that is significant using Artisan and ICL lens statistically (Table 1).

Corneal Complications

There was no significant complication during surgery or as short- term complications in any of the groups. Changes in endothelial cells are listed in (Table 1). There was no statistically significant difference in endothelial cell loss between two groups: Artisan and ICL (p=0.65). While it was quite significant between I-Care group and two other groups respectively (p=0.02 and p=0.02). During the study, endothelial cells decreased 6.1 and 5.2 percent, respectively in groups Artizan, and ICL, while it was decreased at a rate of 43.7 percent in the group of I-Care which in four cases led to decompensation of the cornea and I- Care lens inevitably was removed.

Complications Associated with Iris

There was no significant intraoperative complication in any of the groups. A total of 12 eyes (75%) were with ovalization in Group I-Care after surgery. This complication was not seen in the other two groups. One of the Artisan eyes (1.2%) was with detached phakic lens from the junction to the iris which was in the need to reenclavation during surgery due to severe trauma inflicted on the eye. One eye (1.2%) was experiencing the following uveitis posterior synechia in the Artisan group.

Complications Associated with Crystalline Lens

There was no significant complication during surgery or shortly after the surgery. One eye ICL (1.92%) suffered cataract in the third year after surgery that was unimportant to the end of the study period visually (visually insignificant) without the need for cataract surgery. There was no certain complication in this regard in groups Artizan, and I-Care.

Complications Associated with Inflammation and Increased Intraocular Pressure (IOP)

There was a fairly substantial uveitis in one eye (1.2%) of patients during the first week after surgery in Artisan which caused an increase in the frequency and duration of steroids. Increased intraocular pressure was seen in one eye (1.2%) of patients in Artisan and three eyes (5.77%) in ICL Group during the first week after surgery which was controlled with topical medications. The intraocular pressure was observed in Artisan group on the first day after surgery induced pupillary block, despite the patent PI. It might be due to severe coughing based on patient notation within a few hours after surgery. The problem was solved by transferring the patient to the operating room.

General Complications

6 eyes (7.23%) of patients in Artisan and 6 eyes (11.54 percent) of the ICL patients complained from glare & halo.

Discussion

In this retrospective study, three types of phakic intraocular lenses including Artisan, ICL and I-Care have been studied in patients underwent surgery for severe myopia. A total of 151 eyes were explored on average over 33 months.

In this study, efficacy index after one year of follow- up for Artisan, ICL and I-Care groups was 0.06±0.89, 0.9±1.03 and 0.1±0.82 respectively, While it increased in three years substantially after surgery in Artisan(0.04±0.91), ICL (0.14±1.16) and I-Care (0.23±0.35). Also safety index in Artizan, and ICL groups was the same in both groups; (0.06±1.14) for Artisan, (0.22±1.35) for ICL. Efficacy index and the safety index were 0.94 and 1.13 respectively in total studied population. These results were similar to those obtained on moderate to high myopia by Sanders DR, et al. [8] in patients underwent ICL phakic lens implantation in phase 1 of FDA clinical study over a 6-month follow-up period. Also, Karimiyan F, et al. [9] reported similar to the present study on 112 eyes in three Artisan, Artiflex and ICL groups over a 30-month follow-up period. Also, in study of Alfonso JF, et al. [10] the 5-year results of ICL implantation on 188 myopic cases , safety index was reported similar to our study results and no eye suffered any more than 2 lines of visual acuity loss (in Snellen chart).

In our study, postoperative BCVA improvement was as much a line or more (in Decimal Snellen chart) in Artisan, ICL and I-Care groups respectively. It was also seen that 93, 88 and 75 percent of patients in Artisan, ICL and I-Care groups were within 1 diopter from emmetropia respectively. Postoperative BCVA improved as much a line or more (in Decimal Snellen chart) in three Artisan, ICL and I-Care groups with 10.3, 11 and 50 percent respectively. All of these results were in accordance to the study by Karimiyan F, et al. [9] in Artizan, and ICL groups. Our finding in I-Care group was also similar to those obtained by Plainer S, et al. [11] in a study of I-Care lens implantation in 29 high myopic eyes (16 patients) during 51-month follow-up period. The BCVA improvement after phakic lens implantation might be explained mainly due to loss of minification effect lenses. Coullet J, et al. [5] reported 31 patients (Artisan implant in one eye and Artiflex in the other eye) during 12-month follow-up period. In their study, 58% of patients were within 1 diopter of emmetropia after implanting the Artisan, while the outcome in our study was more significant. It may be explained due to the less predictability of Artisan lens calculation accuracy.

Intraocular complication most notably cataracts may occur when implanting PIOL lens due to direct damage caused during surgery on the natural crystalline lens as well as hyphema and iris injury. However, no complication occurred during surgery in our study. One reason may be due to the fact that all surgeries were performed by two experienced surgeons in the hospital (MN &KJ). Similarly studies by Coullet J, et al. [5] and Karimiyan F, et al. [9] also did not report any complications during surgery in their study on the Artisan and ICL lens.

In one eye (1.92 percent) about three years after surgery, mild cataract; just fine subcapsular opacity and visually insignificant was found in ICL group until the end of the study period without need for cataract surgery. The cataracts formation in Artisan and I-Care Group after surgery may be explained due to the direct damage or long-term

metabolic effects of lens implant. In study of Unsitelo, et al. [12] the cataract after ICL implantation was reported 2.6% that was similar to our study. Karimiyan and his colleagues expressed 5.6% cataract formation after ICL implantation that was slightly higher than our study. Menezo JL, et al. [13] stated rate of cataract formation 17% after ICL implantation, that was attributed due to the use of V3 model of the lens because of less vaulting than the newer models (V4). It seems important to determine the exact size of the ICL lens for prevention of complication using Ultrasound Biomicroscopy Images (UBM) and merely relying on the older and normal sizes is not sufficient (such as White-to- White).

Endothelial cells were reduced in Artizan, ICL and I-Care group groups 6.5, 4.8 and 56.4 percent, respectively in our study period. In four cases it led to corneal decompensation and inevitably I-Care lens was removed. DSAEK Surgery (Descemet Stripping Automated Endothelial Keratoplasty) was performed in 4 cases to improve the eyesight and relieve the symptoms caused by the bullous keratopathy. In 12 cases, corneal endothelial cell count decreased to such an extent that the surgeons decided to remove the patients' lens before the onset of corneal decompensation. In one case, phacoemulsification and PCIOL also were carried out simultaneously with phakic lens removal. In the remaining 8 patients inevitably phakic lenses (I-Care) were removed and glasses with contact lenses were prescribed for the patient. In the study of Coullet and colleagues, the percentage of reduction of endothelial cells in Artisan lens was reported 9.4% which is similar to our study. Likewise Karimiyan and his colleagues stated the endothelial cells reduction in Artisan and ICL group 9±10 and 10±9 percent, respectively; however, the outcomes in our study seemed slightly better. In study of Plainer S, et al. [11] in 29 eyes underwent I-Care lens implantation for the correction of severe myopia, the most serious complication was sharp decline of corneal endothelial cells that was reported by 47% after 6 years and led to the removal of 8 phakic lens during 3-6 years after implantation. They concluded that I-Care lens implantation is not a safe for correction of myopia. In Ruwan A, et al. [3] study on 34 eyes for an ICL lens implantation Percentage of endothelial cells reduction was 12.9% after two years, which is more than that of our study. But the reason of the large decrease in endothelial cells is attributed to the first experience of such operations and their long-term. Because corneal endothelial cells reduction percent in a normal person is in an average of about 0.6 percent per year. It seems that the figures related to Artizan and ICL lens is fairly acceptable that show a reduction of these cells over three years.

In this study, one eye (1.2%) of Artisan group and three eyes (5.77%) of the ICL group suffered increased pressure during the first week after surgery. The problem was using topical medications that were discontinued during one month. There was no case of acute increased IOP in none of the patients of ICL group. Additionally only one Pupillary block occurred despite the patent PI (1.2 percent) in the first postoperative day in Artisan group which was controlled by retransferring the patient to the operating room and surgical fix and also prescribing the medicine. Increased intraocular pressure was not seen in any of the groups as long-term.

Also, a fairly substantial uveitis was seen after surgery in one eye (1.2%) of Artisan patients which led to an increase in the frequency and duration of steroid use. This complication led to posterior synechia without a need for additional measures to fix it. Pigment dispersion was seen in 8 eyes (9.63 percent) in Artisan phakic lens which was visually insignificant without any specific action by the end of the study period. This complication was not seen in ICL patients. Correspondingly, one eye (1.2%) in Artisan group suffered mild subluxation in a month after the surgery without a need for specific action by the end of the study period. A total of 12 eyes (75%) of patients in I-Care Group incurred to ovalization after surgery. This complication was not seen in the other two groups. Six eyes (7.23%) of the Artisan and 6 eyes (11.54 percent) of the ICL Group complained of glare & halo. The statistics were similar to those of Coullet J, et al. [5] as well as Karimiyan F, et al. [9] studies.

The power of our study is the long term result, high sample size along with independent, unsponsored study. However, our study has some limitation such as retrospective nature, randomization deficiency, and lack of preoperative higher order aberrations. In summary, our long-term results suggest that phakic IOL implantation seems as an alternative and safe procedure for moderate to severe myopia provided the thorough eye examination every year such as investigation of crystalline lens, measuring the intraocular pressure, intraocular inflammation and endothelial cells with specular microscopy.

Conflict of Interest: None of the authors has conflict of interest with this submission.

References

1. American Academy of Ophthalmology. Section 13: Refractive surgery 2015- 2016 pp: 157-172.

2. Sarver EJ, Sanders DR, Vukich JA (2003) Image quality in myopic eyes corrected with laserin situ keratomileusis and phakic intraocular lens. J Refract Surg 19(4): 397-404.

3. Silva RA, Jain A, Manche EE (2008) Prospective Long-term evaluation of the efficacy, safety and stability of the phakic intraocular lens for high myopia. Arch Ophthalmol

126(6): 775-781.

4. Kamiya K, Shimizu K, Igarashi A, Hikita F, Komatsu M (2009) Four-year follow-up of posterior chamber phakic intraocular lens implantation for moderate to high myopia. Arch Ophthalmology 127(7): 845-850.

5. Coullet J, Guell J, Fournie P, Grandjean H, Gaytan J, et al. (2006) Iris supported phakic lenses (rigid vs foldable versions) for treating moderately high myopia: Randomized paired eye comparison. Am J Ophthalmol 142(6): 909-916.

6. Fratzl P, Daxer A (1993) Structural transformation of collagen fibrils in corneal stroma during drying. An x-ray scattering study. Biophys J 64(4): 1210-1214.

7. Alio J, Salem T, Artola A, Osman A (2002) Intracorneal rings to correct corneal ectasia after laser in situ keratomileusis. J Cataract Refract Surg 28(9): 1568-1574.

8. Sannders RD (2007) Matched population comparison of the vision Implantable collamer lens and standard LASIK for myopia of -3.00 to -7.88 diopter. J Refract Surg 23(6): 537-553.

9. Karimian F, Rafii BA, Hashemian J, Hashemloo A, Jafari E, et al. (2012) Comparative study of three phakic intraocular lenses in correction of myopia. Bina J ophthalmol 17(3): 249-258.

10. Alfonso JF, Baamonde B, Vega FL, Fernandes P, Meijome JMG, et al. (2011) Posterior chamber collagen copolymer phakic intraocular lenses to correct myopia: Five year follow-up. J Cataract Refract Surg 37(5): 873-880.

11. Plainer S, Saalabian AA, Ardjomand N, Wenzl E, Wohlfart C, et al. (2011) Long term follow- up with I-care phakic IOLs. Br J Ophthalmol 95(5): 710-714.

12. Unsitalo RJ, Aine E, Sen NH, Laatikainen L (2000) Implantable contact lens for high myopia. J Cataract Refract Surg 28(1): 29-36.

13. Menezo JL, Martines PC, Cisneros A, Costa RM (2001) Posterior chamber phakic intraocular lens to correct high myopia: a comparative study between Staar and Adatomed models. J Refract Surg 17(1): 32- 42.