·Clinical Research·

Posterior chamber phakic intraocular lens implantation for high myopia

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Abstract

• **AIM: To evaluate the efficacy, safety and stability of posterior chamber phakic intraocular lens implantation for the correction of high myopia.**

• **METHODS: Retrospective case review of 82 eyes (43 patients) undergoing implantable Collamer lens (ICL) placement by a single surgeon (Xiao-Wei Gao) to correct preoperative mean spherical equivalents between -9.00 diopter (D) and -23.00D. Main outcome measures included uncorrected visual acuity (UCVA), refraction, best spectacle -corrected visual acuity (BSCVA), endothelial cell density (ECD), intraocular pressure (IOP), lens transparency, postoperative uveitis. Visante anterior segment optical coherence tomography (AS-OCT) was used to measure anterior chamber depth (ACD) and the position of ICL.**

• **RESULTS: Mean follow-up was 6.54 ±3.26 months (range 3 -12 months). Predictability of the manifest spherical equivalent (SE) refraction to within ±1.00D was achieved in 88% of eyes and ±0.50D in 72.5% of eyes. The mean postoperative manifest SE refraction was -1.85±0.72D, with 96.34% of eyes maintaining or gaining ≥1 line (s) of BSCVA. The mean 3-month postoperative ECD decreased but had no statistically difference compared with the preoperative ECD. Of the 7 eyes (8.54%) with a mild transient increase in intraocular pressure (up to 30mmHg), none required a second surgical procedure or prolonged topical medication. There was no loss of lens transparency. Pigmented precipitates were observed in 5 eyes (6.09%). The mean preoperative ACD measured with AS-OCT was 3.28 ± 0.14mm, three months after surgery, the mean ACD was 2.45 ±0.22mm. Anterior chamber depth showed a statistically significant reduction. One eye (1.22%) had ICL spontaneous rotation, 81 eyes (98.78%) of the lens remained correctly centered.**

• **CONCLUSION: The implantation of ICL is an effective surgical option for the management of high myopia. But its long time effect and safety still need more time to prove.**

• **KEYWORDS: phakic intraocular lens; lens implantation; myopia**

INTRODUCTION

Laser-assisted *in situ* keratomileusis (LASIK) has gained widespread popularity as a safe and effective surgical method for the correction of myopia, but patients with high myopia or thin corneas face some restrictions in avoiding the risk of developing keratectasia. Moreover, a large amount of laser ablation may lead to the deterioration of superior intrinsic corneal optical performance. An implantable lens consisting of a biocompatible collagen copolymer [Visian implantable Collamer lens (ICL), STAAR Surgical, Nidau, Switzerland] was developed as a posterior chamber phakic intraocular lens to rectify such disadvantages, and implantation of the ICL has been reported to be effective for the correction of moderate to high ametropia [1-3]. In addition, this surgical procedure is largely reversible and the lens is exchangeable, unlike LASIK, even when unexpected refractive changes occur after surgery. In this prospective study, we evaluated the visual and refractive results, the effects on corneal endothelium and intraocular pressure (IOP), anterior chamber depth (ACD), lens transparency, postoperative uveitis as well as the surgical complications of ICL implantation for the management of high myopia.

SUBJECTS AND METHODS

Subjects Eighty-two eyes (23 from men and 20 from women) of consecutive 43 patients who underwent ICL implantation for the treatment of high myopia between April 2010 and November 2011 were included in this retrospective

observational study. The patient age at the time of surgery was 28.6±7.6 (range 19-45) years. The preoperative manifest spherical equivalent (SE) was -15.56±4.35 (range, -9.00 to -23.00D). The preoperative manifest refractive cylinder was -1.25±0.52 (range 0.00 to -3.50D). Uncorrected visual acuity (UCVA) was 1.0 or worse. Best spectable-corrected visual acuity (BSCVA) was equal to or better than 0.4 in 74 eyes, 0.5 on 4 eyes, 0.7 on 2 eyes, 1.0 on 2 eyes. All patients were informed of the benefits and possible complications of posterior chamber phakic intraocular lens(PIOL) implantation.

Methods

Preoperative patients examination Inclusion criteria were patient age of 18 to 45, stable refraction for at least two years, lack of patient satisfaction with the correction provided by spectacles or contact lenses, ACD (measured from the endothelium to the crystalline lens) more than 3.0mm, mesopic, pupil size less than 5.0mm, endothelial cell density (ECD) more than 2 500/mm^2, normal iris and pupil configuration, no history of glaucoma and retinal detachment, retinal tear or hole. Patient with high myopia or thin corneas face some restrictions in avoiding the risk of developing keratectasia. Patients who had a simultaneous or consecutive additional refractive surgical procedure were excluded. All patients were verbally informed about the procedure, its advantages and disadvantages. A written informed consent was obtained from all patients.

Eyes were examined including UCVA, BSCVA, manifest and cycloplegic refraction to calculate the SE. UCVA and BSCVA were measured in decimal Snellen and converted to the logarithm of the minimum angle of resolution (logMAR) for statistical analysis. Before surgery, the anterior chamber depth were measured using AS-OCT (Carl Zeiss Meditec Inc, Dublin, California, USA), the horizontal white-to-white distance were measured using a scanning-silt topography system (Orbscan IIz, Bausch & Lomb, Rochester, New York, USA), the keratometric readings were measured using an autorefractometer (ARK-700A, Nidek, Gamagori, Japan), and the mean central corneal thickness was measured using an ultrasound pachymeter (model DGH-500, DGH Technologies, Exton, Pennsylvania, USA). The IOP was assessed with a noncontact tonometer (KT-500, Kowa co Ltd, Tokyo, Japan).The endothelial cell density was determined with the use of a noncontact specual microscope (SP-8800, Konan Medical Inc, Nishinomiya, Japan). In addition to the usual siltlamp biomicroscopic and funduscopic examination results.

Implantable Collamer lens power calculation Calculation of ICL power was performed by the manufacturer using a modified vertex formula. In all eyes, emmetropia was selected as the target refraction to reduce the preoperative refractive errors as much as possible. The size of the ICL was also chosen by the manufacturer on the basis of the horizontal corneal diameter, and the anterior chamber depth measured with the AS-OCT.

Implantable Collamer lens surgical procedure Insertion of ICL may change the capacity of posterior chamber and increase residence of aqueous circulation, leading to postoperative papillary block. To avoid its happening, two peripheral laser iridotomies 90° apart were carried out at least 2 weeks before surgery. In all patients, pupils were dilated with 1% tropicamide, 2.5% phenylephrine, and 1% cyclogyl 1h preoperatively. Topical anesthesia was applied half an hour before surgery with 4% lidocaine. As long as good papillary dilation and ocular anesthesia were obtained, the operation began. Staar PIOLs were placed in the lens insertion cartridge under direct visualization with the operating microscope. A microsurgical sponge of 1.0mm in diameter was placed behind PIOLs for its protection. A lid speculum was placed; a 3.2mm temporal clear corneal incision was performed with a diamond knife; and sodium hyaluronate (OcuCoat, Storz, Bausch & Lomb surgical, St. Louis, MO, USA) was injected into the anterior chamber. The injector tip was then placed on the incision, not entering the anterior chamber, and the lens were slowly injected anterior to the iris plane, ensuring proper orientation. Verification of proper lens orientation was aided by the positioning hole on the haptics' anterior surface. An intraocular hook was used to insert the temporal haptics beneath the iris to achieve gentle posterior pressure. If temporal or nasal haptic were not correctly placed, the hook was inserted through the superior paracentesis. Centration was ensured before pupillar constriction caused by acetylcholine injection into anterior chamber. Remaining viscoelastic was removed with gentle irrigation and aspiration with the Staar phacoemulsification system. After surgery, topical tobramycin-dexamethasone was given.

Follow –up Follow-up visits were done at week 1 and months 1, 3, 6, 12 postoperatively. All eyes were examined at each postoperative visit. During this period, the assessed outcome parameters included the last visit UCVA and BSCVA, refraction, ECD, IOP, silt-lamp examination for lens transparency and inflammation. AS-OCT was used to observe ACD and the position of ICL.

Statistical Analysis All data were entered into a spreadsheet and statistical analyses were performed using SPSS for Windows software version 11.0. Preoperative and postoperative mean outcome measurements were expressed as the arithmetical mean±standard error. Statistical comparisons were compared using U-test. A two-tailed probability of 5% or less was considered statistically significant.

Table 1   Preoperative and postoperative visual acuities in logMAR units

	≤1.0	0.5-0.7	0.3-0.4	0.1-0.2	-0.1-0
UCVA preoperation	82	0	0	0	0
BSCVA preoperation	2	6	10	27	37
UCVA 1 month postoperation	1	3	8	24	46
UCVA 3 months postoperation	1	2	7	24	48

RESULTS

Successful implantation was achieved in all patients. No complications occurred during the surgical procedures. Mean follow-up was 6.54±3.26 months (range 3-12 months).

Visual Acuity Preoperative and operative patient visual acuity condition data are given in Table 1. Preoperative UCVA was 1.0 or worse. BSCVA was equal to or better than 0.4 in 74 eyes, 0.5 on 4 eyes, 0.7 on 2 eyes, 1.0 on 2 eyes. Postoperative UCVA was equal to or better than 0.4 in 78 eyes, 0.5 on 2 eyes, 0.7 on 1 eyes , 1.0 on 1 eyes at one month after operation (Table 1). The mean preoperative logMAR UCVA of 1.36±0.41 (range 1-2) was improved to 0.28±0.27 (range -0.1 to 1, $P<0.01$) after three months. UCVA was 20/40 or better in 90.2% and 92.7% of eyes after 1 month, and 3 months, respectively.

Spherical Equivalent Refraction Preoperatively, the mean spherical refraction was -15.56±4.35D (range, -9.00 to -23.0D), the mean cylindrical refraction was -1.25±0.52D (range, 0.00 to -3.50D) and the mean the SE was -16.85±4.72D (range, -9.5 to -23.50D). Postoperatively, the mean spherical refraction was -1.04±0.65D (range, -1.5 to -0.5D), the mean cylindrical refraction was -0.12±0.35D (range, 0.00 to -1.25D) at the three months, respectively. Predictability of the manifest SE refraction to within ±1.00D was achieved in 88% of eyes and ±0.50D in 72.5% of eyes. The mean postoperative manifest SE refraction was -1.85±0.72D, with 96.34% of eyes maintaining or gaining ≥1 line(s) of best spectacle-corrected visual acuity (BSCVA).

Endothelial Cell Density The mean preoperative ECD was 2 726±250/mm² (range, 2 672 to 3 200/mm²). Three months after surgery, the mean ECD was 2 654±186/mm² (range, 2 560 to 3 182/mm²). The mean endothelial cell loss after three months was 156±86/mm². The mean 3-month postoperative ECD decreased but had no statistically difference compared with the preoperative ECD ($P>0.05$).

Anterior Chamber Depth and Intraocular Pressure The mean preoperative ACD measured with AS-OCT was 3.28±0.14mm (range, 3.15mm to 3.46mm). Three months after surgery, the mean ACD was 2.45±0.22mm (range, 2.15mm to 2.70mm). Anterior chamber depth showed a statistically significant reduction ($P<0.01$). Mean preoperative IOP was 14.2±2.7mmHg, and mean postoperative IOP was 16.46±4.1mmHg over all follow-up investigations. IOP was found to be increased up to 30mmHg in 7 eyes (8.54%) shortly after surgery, after treatment in three to four days the intraocular pressure become normal. None required a second surgical procedure or prolonged topical medication.

Crystal Lens and Implantable Collamer lens The mean refractive power of ICL was -17.18±3.57D (range, -11.5 to -23.0D). Non-pigmented deposits on the ICL surface were observed in seventy-seven eyes (93.90%) and pigmented deposits were found in five eyes (6.09%), but no pigmentary glaucoma. These eyes were treated with topical corticosteroid agents, but pigment precipitates persisted in five eyes. These eyes, however, did not have a loss of visual acuity. There was no loss of lens transparency. One month after surgery, 1 eye (1.22%) had ICL spontaneous rotation, 81 eyes (98.78%) of the lens remained correctly centered. Three months after surgery, the central vault of the ICL (distance from posterior surface of ICL to the crystalline lens) measured with AS-OCT was 0.46±0.28mm. For each eye, the ICL was in contact with the iris, but it was never in contact with the crystalline lens.

DISCUSSION

Phakic IOLs are able to correct high levels of myopia and hyperopia, and provide immediate improvement in visual acuity while preserving the accommodation. The implantation of ICL has been shown to be an effective surgical option for the treatment of refractive errors, offering an optical quality claimed to be superior to that of corneal refractive surgeries [4].The efficacy and safety of the ICL has been demonstrated in several multicenter studies [5,6]. It may be that ICL implantation through a 3.2-mm corneal incision, regardless of the amount of myopic correction, has a negligible effect on refractive outcome and that this surgical technique is less subject to the wound-healing responses of the cornea. In this study, we evaluated the effectiveness, predictability, and potential risks of the implantation of ICL for the management of high myopia.

Efficacy and predictability of the ICL have been previously reported. In their study comprising 210 phakic eyes, Sanders et al [7] reported a significant improvement of BSCVA with 96.8% of patients achieving 20/20 or better, 76.4% gaining 1 or more lines while 18.9% gaining 2 or more lines. When

considering predictability, in the Kamiya *et al* [8] studied, 79.0% of the eyes were within ±0.5D of the intended correction and 93.0% were within ±1.0D after 4 years. Similarly, in the Food and Drug Administration study, 67.5% of the eyes were within ±0.5D of the intended correction and 88.2% of the eyes were within ±1.0D after 3 years [9]. In 1996, Lee and Lee [10] reported the first clinical study describing the performance of ICL for the correction of myopia in phakic eyes. Their results demonstrated that this lens is a predictable, stable, and efficient option for the correction of myopia. In their study, UCVA was improved in all eyes at the sixth month and 76% of the eyes gained 1 or 2 lines of BSCVA. Successful visual outcomes of ICL implantation were also reported 6 months later, in the Asian multicenter study in which 85% of the eyes were within ±0.5D of the desired correction and 96.0% of the eyes were within ±1.0D after 6 months [11]. In the present study, we concluded that the implantation of ICL corrected high myopia with a high degree of predictability and stability, and provided improvement in both UCVA and BSCVA after a 3-12 months follow-up period. Predictability of the manifest SE refraction to within ±1.00D was achieved in 88% of eyes and ±0.50D in 72.5% of eyes. The mean postoperative manifest SE refraction was -1.85±0.72D, with 96.34% of eyes maintaining or gaining ≥1 line(s) of BSCVA.

Previous reports of posterior chamber phakic IOL surgery report an incidence of lens opacity from 1.5% to 25% [12]. Maeng *et al* [13] reported that cataract developed in 8 (30.8%) of 26 eyes (6 of 20 patients) a mean of 18.7 months ±10.1 (SD) postoperatively. Alfonso *et al* [14] demonstrated that three of 188 eyes (1.6%) developed late anterior subcapsular cataract that was clinically significant in 1 case, leading to ICL removal and phacoemulsification. Fernandes *et al* [15] reviewed the postoperative complications of ICL implantation. They reported that cataract was the major postoperative complication reported: 136 (5.2%) in 2592 eyes. Of those, 43.4% (*n*=59) were reported within 1 year, 15.4% (*n*=21) between 1 and 3 years, and 35.3% (*n*=48) ≥3 years after ICL implantation. Twenty-one (15.4%) cataracts were reported as surgically induced, 46 (33.8%) eyes had poor vault (<200μm), and cataract surgery was carried out in 27.9% (*n*=38) of eyes. In our series, there was no loss of lens transparency within 3-12 months follow-up. Furthermore, three months after surgery, the central vault of the ICL (distance from posterior surface of ICL to the crystalline lens) measured with AS-OCT was 0.46±0.28mm. For each eye, the ICL was in contact with the iris, but it was never in contact with the crystalline lens. Longer follow-up is needed to properly analyze long-term effects of the ICL on the ocular structures. Several factors can play a role in the opacification of the crystalline lens, surgical trauma, postoperative inflammation, use of topical steroids, and contact between the phakic IOL and the crystalline lens. Of these, one can postulate that phakic posterior chamber IOL implantation in eyes with early nuclear changes might promote the progression of these changes into the development of a clinically significant nuclear cataract. The thickness of the crystalline lens increases as the eye ages, and this may lead to transient or permanent contact. It can be hypothesized that implantation of phakic IOLs in patients in their 40s or 50s may increase the trend to develop cataracts earlier than in nonmyopic eyes.

Although multiple factors influence the complication profile of ICL, the majority of complications are attributable to the design and position of the ICL. ICL have been associated with several surgical complications such as elevation of IOP, cataracts, pigment deposits, pupil ovalization and chronic anterior segment inflammation [16]. Also, myopes, in particular, are prone to the development of different types of chronic open-angle glaucoma. Trindade *et al* [17] studied the relative position of the posterior chamber phakic IOL using ultrasound biomicroscopy. They reported that IOL-iris touch, IOL-crystalline lens touch, and anterior chamber shallowing raise concerns of pigmentary dispersion, cataractogenesis, and narrow angle glaucoma following posterior chamber phakic intraocular lens implantation. Alfonso *et al* [14] reported that 1.6% (3 of 188 eyes) with a mild transient increase in intraocular pressure (up to 27mmHg), none required a second surgical procedure or prolonged topical medication. Some of the variation may be due to the definition of cataract or opacity and the follow-up period, as well as surgical technique. In this study, pigmented precipitates were observed in 5 eyes (6.09%). Mean preoperative IOP showed an elevation of 14.2±2.7mmHg to 16.46 ±4.1mmHg. IOP was found to be increased up to 30mmHg in 7 eyes (8.54%) shortly after surgery, after treatment in three to four days the intraocular pressure became normal. None required a second surgical procedure or prolonged topical medication.

In this study, we conclude that the implantation of the ICL is an effective surgical option for the management of high myopia. In addition, no vision-threatening complications occurred throughout the follow-up period. These findings suggest that ICL implantation may be a good alternative for the treatment of high myopia. More prolonged careful observation for longer time is necessary to assess late-onset complications of this surgical technique.

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