

Posterior chamber phakic intraocular lens for the correction of high myopic anisometropic amblyopia in adults

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Abstract

• **This study aims to evaluate the clinical results of posterior chamber implantable collamer lens (ICL) implantation in adults with high myopic anisometropic amblyopia. Thirteen patients aged 27.04±7.24y (range 19.2 to 42.5) were studied. ICL implantation was performed in 13 amblyopic eyes. The mean myopic anisometropia was significantly dropped from -10.70±3.02 D preoperatively to +0.09±1.67 D at 1mo postoperatively. The logMAR CDVA at 3d, 1, 3 and mean 9mo postoperatively improved by a mean of 1.69, 2.50, 3.01 and 3.00 lines and gained more than 2 lines accounted for 23.08% (3 eyes), 41.67% (5 eyes), 63.63% (7 eyes) and 55.56% (5 eyes), respectively. The contrast sensitivity of amblyopic eyes was significantly increased after surgery. Four patients partially recovered near stereopsis (400" to 100"). There was no severe complications were observed. ICL implantation alone can improve vision, contrast sensitivity, and partial restoration of binocular vision in adult patients with high myopic anisometropia.**

• **KEYWORDS:** phakic intraocular lens; myopic anisometropic; amblyopia; refractive surgery

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INTRODUCTION

Amblyopia is a neurodevelopmental ocular disease manifested as monocular and binocular impairments, including reduction of vision, contrast sensitivity, or

even loss of stereoscopic vision. It is mainly caused by anisometropia, strabismus, or both. Spectacles or contact lenses are the traditional treatments of eliminating refractive errors for anisometropic amblyopia. Cornea refractive surgeries including photorefractive keratectomy, laser *in situ* keratomileusis (LASIK), laser-assisted subepithelial keratectomy, femtosecond laser-assisted *in situ* keratomileusis (FS-LASIK) or small-incision lenticule extraction have been reported as efficacious and safe alternatives to correct high myopic anisometropic amblyopia in children who have failed with spectacles or contact lenses to correct refractive errors^[1-3]. High myopia over -12 diopters (D) or a thin cornea (residual stromal bed thickness <280 μm) was supposed as contraindications for corneal refractive surgeries. Due to the advantages of reversible, less traumatic, a rapid recovery, and avoiding corneal-related complications, posterior chamber phakic implantable collamer lens (ICL) implantation has become the preferred refractive surgical approach for the patients who were not suitable for corneal refractive surgeries^[4-5]. Several previous studies^[6] also suggested that ICL may be a better surgical option for correcting high myopia in adult patients because of optical advantages, fewer ocular higher order aberrations, better contrast sensitivity compared with LASIK. Previous studies also showed that ICL implantation can be a promising alternative therapy for high myopic anisometropic amblyopia in pediatric patients who have failed with conventional treatments and were not suitable for corneal refraction surgeries^[7-8].

Nowadays, amblyopia treatments are not merely restricted to childhood, which is regarded as the critical visual developmental period. A few studies in the literature reported the effectiveness of refractive correction alone by corneal refractive surgeries^[9-11], or angle-supported phakic intraocular lens (PIOL)^[12-13] and ICL^[14] in adult patients with anisometropic amblyopia. Therefore, this study was proposed to further observe the ICL implantation for adults with high myopic anisometropia amblyopia.

SUBJECTS AND METHODS

Thirteen patients (8 men and 5 women) diagnosed with high myopic amblyopia at Zhongshan Ophthalmic Center of Sun Yat-sen University between December 2013 and February 2015 were evaluated. Inclusion criteria were as follows: age at least 18y; between two eyes with refractive errors difference at

Table 1 Preoperative demographics of adult patients with high myopic amblyopia

Patient No./ Gender	Age at surgery (y)	Eye	Refraction (D)	Ocular alignment	Surgery	LogMAR (Snellen)	
						UDVA	CDVA
1/M	28.0	OD	-6.25+1.25×180	Ortho	FS-LASIK	1.00 (20/200)	0.00 (20/20)
		OS	-14.75+1.00×16		ICL	1.70 (20/1000)	0.20 (20/32)
2/M	19.7	OD	-7.25+2.25×15	Ortho	FS-LASIK	0.90 (20/160)	0.00 (20/20)
		OS	-18.00+1.00×150		ICL	2.00 (20/2000)	0.70 (20/100)
3/M	19.2	OD	-7.50+2.75×180	Ortho	ICL	1.10 (20/250)	0.10 (20/25)
		OS	-13.00+3.50×170		ICL	1.7 (20/1000)	0.60 (20/80)
4/F	19.5	OD	-17.25+0.50×150	Ortho	ICL	2.00 (20/2000)	0.10 (20/25)
		OS	-8.75+0.50×150		ICL	1.00 (20/200)	0.00 (20/20)
5/M	21.7	OD	-14.50+1.00×150	Ortho	ICL	1.22 (20/250)	0.30 (20/40)
		OS	-7.75+1.00×180		ICL	0.60 (20/80)	0.00 (20/20)
6/M	37.2	OD	-13.00	Exo	ICL	1.7 (20/1000)	0.20 (20/32)
		OS	-0.50+0.50×75		Without	0.15 (20/28)	0.00 (20/20)
7/F	32.8	OD	-12.00+1.00×170	Exo	ICL	1.7 (20/1000)	0.9 (20/160)
		OS	-0.75		Without	0.30 (20/40)	0.00 (20/20)
8/M	42.5	OD	+1.00×170	Exo	Without	0.15 (20/28)	0.00 (20/20)
		OS	-11.25		ICL	1.52 (20/667)	0.24 (20/33)
9/M	23.6	OD	-13.50+2.00×180	Ortho	ICL	1.7 (20/1000)	0.84 (20/136)
		OS	-2.50+3.00×10		Without	1.30 (20/400)	0.00 (20/20)
10/M	30.9	OD	-17.00+2.00×100	Exo	ICL	1.52 (20/667)	0.50 (20/63)
		OS	-0.50+1.75×100		Without	0.15 (20/28)	-0.08 (20/17)
11/F	23.3	OD	-16.75+0.75×17	Ortho	ICL	1.7 (20/1000)	0.70 (20/100)
		OS	-6.75+0.75×75		FS-LASIK	1.30 (20/400)	0.00 (20/20)
12/F	24.2	OD	-19.25+2.25×60	Ortho	ICL	1.7 (20/1000)	0.8 (20/125)
		OS	-7.25+1.25×150		SMILE	1.0 (20/200)	0.0 (20/20)
13/F	28.9	OD	-5.50+0.50×95	Ortho	ICL	1.7 (20/1000)	0.8 (20/125)
		OS	-19.00+2.25×20		SMILE	1.0 (20/200)	0.0 (20/20)

D: Diopters; UDVA: Uncorrected distance visual acuity; CDVA: Corrected distance visual acuity; Ortho: Orthophoria; Exo: Exotropia; Without: Without surgery; ICL: Implantable collamer lens; FS-LASIK: Femtosecond laser-assisted *in situ* keratomileusis; SMILE: Small-incision lenticule extraction.

least 5.00 D; corrected distance visual acuity (CDVA) below 20/25 (Snellen) in the eye with high refractive errors or the difference of binocular CDVA was no less than two lines; fulfill the indications for ICL implantation. Table 1 shows the preoperative patient demographics. The mean age of the 13 patients at the time of ICL implantation was 27.04±7.24y (range: 19.2 to 42.5). All the study procedures were conducted in accordance with the tenets of the World Medical Association's Declaration of Helsinki. Ethical approval was obtained from the Ethics Committee of Zhongshan Ophthalmic Center (ethical approval number: 2014MEKY001).

Preoperative ocular examinations included slit lamp and fundus, alternate cover test, cycloplegic refraction, noncontact tonometry, OrbscanIIz, and corneal endothelial cell photography; these were conducted on all patients. The size of ICL was determined with a STAAR sizing calculation formula that based on the measurement of anterior chamber depth and horizontal corneal diameter (white to white distance) by Orbscan II Topographer. Early Treatment of Diabetic

Retinopathy Study was converted to logMAR notation for uncorrected distance visual acuity (UDVA) and CDVA test. Furthermore, contrast sensitivity and the near stereopsis (Randot Preschool Stereoacuity Test) were also evaluated preoperatively. Contrast sensitivity of both amblyopic eyes and fellow eyes was assessed at 0.5, 2 and 8 cycles per degree (cpd), using previously described Psykinematix psychophysics software (KyberVision, Quebec, Canada) converging on 79.4% accuracy^[15-16].

Thirteen high myopic amblyopic eyes and three fellow eyes were treated with ICL surgery (ICL; model V4, Staar Surgical Inc., USA) by the same experienced surgeon (Yu KM). Postoperatively, tobramycin 0.3% dexamethasone 0.1% eyedrops (Tobradex) were administered 4 times a day for 1wk and then 2 times a day for 1wk. Slit-lamp examination, intraocular pressure (IOP), refraction, UDVA, CDVA, contrast sensitivity and near stereopsis, objective vaulting were evaluated at each follow up time except 1d and 1wk. Where possible, endothelial cell counts, fundus evaluations and

Table 2 Refraction changes over time in adult patients with high anisometropic amblyopia after refractive surgeries

Time (n)	Spherical equivalent (D)		Anisometropia (D)
	Amblyopic eye	Fellow eye	
Preop. (13)	-15.97±2.89 (-11.25, -20.38)	-5.27±3.57 (+0.50, -9.00)	-10.70±3.02 (-5.88, -16.63)
Postop. 1mo (12)	-0.75±0.74 (+0.75, -2.00) ^a	-0.84±1.40 (+1.00, -4.63) ^a	+0.09±1.67 (-1.88, +4.75) ^a
Postop. 3mo (11)	-0.95±0.82 (+0.50, -2.50) ^a	-0.92±1.58 (+0.63, -5.13) ^a	-0.01±1.93 (-1.88, +5.25) ^a
Postop. 9mo (9)	-0.89±0.80 (+0.38, -2.38) ^a	-1.15±1.84 (+0.63, -5.75) ^a	+0.26±2.06 (-1.88, +2.09) ^a
<i>P</i> ^b	0.146	0.149	0.025

Preop.: Preoperative; Postop.: Postoperative; D: Diopters. ^a*P*<0.05 compared with preop.; ^b*P* represent difference among postop. follow up time.

other examinations were performed. The objective vaulting was assessed using a WaveLight Oculyzer anterior segment analysis system (Alcon, Fort Worth, Texas, USA).

RESULTS

Patients completed postoperative follow ups in this study at 3d, 1, 3mo and the last follow up time [mean: 9.33±2.87 (range 6 to 14)mo] accounted for 100% (13/13), 92% (12/13), 85% (11/13), and 69% (9/13), respectively.

Refraction The achieved spherical equivalent (SE) at 1mo postoperatively was within ±0.50 D and ±1.00 D of the attempted power, accounting for 69% (9 eyes) and 100% (13 eyes) of patients respectively. Table 2 shows the mean SE of amblyopic eyes, the mean SE of fellow eyes, and that the SE anisometropia were significantly reduced at 1, 3 and approximately 9mo postoperatively (all *P*<0.05). The SE refraction of both in amblyopic eyes and fellow eyes was not significantly changed during about 9mo after surgery (all *P*>0.05 respectively). However, the SE anisometropia changes was statistically significantly different during about 9mo postoperative follow up (*F*=4.881, *P*=0.025).

Visual Acuity There was a significant improvement for both UDVA and CDVA of the amblyopic eye at 3d, 1, 3 and about 9mo after surgery compared with preoperative (*P*<0.05 for all) shown in Figure 1A. Both UDVA and CDVA of the amblyopic eye after ICL implantation were significantly increased during about 9mo follow up postoperatively (*P*<0.05 for all). Figure 1B shows the logMAR CDVA was improved mean 1.69±1.55 (0-5) lines, 2.50±1.51 (0-5) lines, 3.01±1.22 (1-5) lines, 3.00±1.50 (1-6) lines at 3d, 1, 3 and about 9mo postoperatively, and gained more than 2 lines accounted for 23.08% (3 eyes), 41.67% (5 eyes), 63.63% (7 eyes) and 55.56% (5 eyes), respectively. No amblyopic eyes lost visual acuity after surgery.

Contrast Sensitivity Table 3 shows the changes in contrast sensitivity over time for both eyes in patients after refractive surgeries for anisometropia correction. The contrast sensitivity of 0.5, 2, 8 cpd at 3d and 3mo, 2 cpd and 8 cpd at 1mo and 2 cpd at about 9mo in amblyopic eyes was significantly increased after surgery (all *P*<0.05). The contrast sensitivity of 8 cpd at 3mo and 0.5 cpd at about 9mo in dominated eyes was significantly improved postoperatively (all *P*<0.05). The

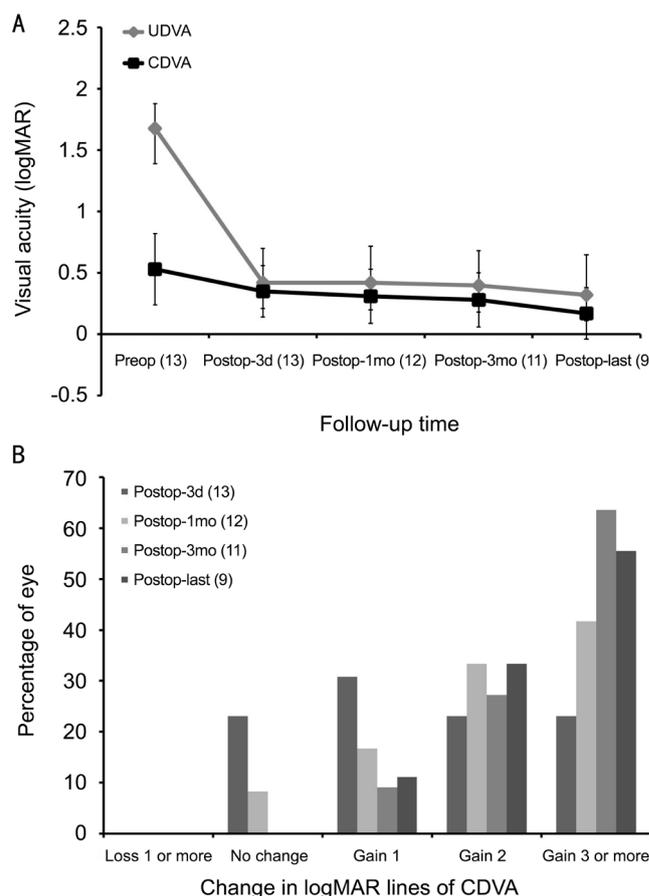


Figure 1 Visual acuity changes in the operated eyes A: Changes of logMAR UDVA and CDVA over time in amblyopic eyes after ICL implantation; B: Changes in lines of logMAR CDVA in amblyopic eyes postoperatively.

contrast sensitivity of 8 cpd in amblyopic eyes and 0.5 cpd in fellow eyes was significantly increased with the follow-up time (all *P*<0.05), but other spatial frequencies were not significantly changed (*P*>0.05 for all).

Stereopsis Only one patient with 400” near stereopsis preoperatively, and 4 patients (30.8%) recovered to 400” to 100” at approximately 9mo follow up postoperatively.

Intraocular Pressure The IOP for the amblyopic eye was significantly changed from 15.60±3.79 (8, 21) mm Hg preoperatively to 16.38±5.20 (7, 24) mm Hg at 3d, 13.75±4.43 (9, 22) mm Hg at 1mo, 12.73±3.52 (5, 17) mm Hg at 3mo, 15.38±3.38 (9, 22) mm Hg at about 9mo after surgery, respectively (*F*=3.069, *P*=0.032).

Table 3 Changes in contrast sensitivity over time in patients with high anisotropic amblyopia after refractive surgeries

Time (n)	Amblyopic eye (space frequency)			Fellow eye (space frequency)		
	0.5 cpd	2 cpd	8 cpd	0.5 cpd	2 cpd	8 cpd
Preop. (13)	56.12±17.25	41.70±33.02	4.86±7.50	116.04±33.48	173.34±69.46	45.49±34.05
Postop. 3d (13)	75.50±31.22 ^a	74.81±46.52 ^a	12.09±13.42 ^a	117.64±50.90	184.75±99.55	57.01±49.16
Postop. 1mo (11)	61.52±14.74	63.14±32.33 ^a	12.14±14.59 ^a	112.33±28.64	170.18±60.88	45.87±38.38
Postop. 3mo (10)	71.68±18.72 ^a	90.93±69.97 ^a	13.81±12.17 ^a	129.91±37.20	199.34±79.89	63.33±32.20 ^a
Postop. 9 mo (9)	74.66±22.44	91.73±39.43 ^a	16.40±10.64	139.19±47.77 ^a	222.36±115.61	50.20±33.51
P ^b	0.313	0.063	0.017	0.004	0.167	0.204

Preop.: Preoperative; Postop.: Postoperative; cpd: Cycle per degree. ^aP<0.05 compared with preop. significantly difference; ^bP represent difference among postop. follow up time.

Vaulting The mean vaulting was significantly changed from 0.52±0.17 (range, 0.20 to 0.77) mm at 3d, to 0.48±0.16 (range, 0.23 to 0.71) mm at 1mo, 0.46±0.16 (range, 0.20 to 0.68) mm at 3mo and 0.40±0.12 (range, 0.23 to 0.60) mm at about 9mo after surgery ($F=3.935$, $P=0.030$).

Endothelial Cell Count The mean endothelial cell count as not significantly changed from 2760.17±276.80 (range, 2189.80 to 3217.00) cells/mm² preoperatively to 2799.95±328.83 (range, 2177.80 to 3209.20) cells/mm² at approximately 9mo postoperatively ($t=0.661$, $P=0.525$).

Complications Two patients had transient IOP elevation, and no other intraoperative or postoperative complications were observed.

DISCUSSION

Refractive correction with spectacles, contact lenses or corneal surgeries were reported as effective in adult patients with anisotropic amblyopia^[9,17]. Agca *et al*^[9] reported that 14 eyes in 33 adults with myopic anisotropic amblyopia improved two lines or more of CDVA at 6mo after LASIK. Oruçoğlu-Orucov *et al*^[10] also stated that 5 out of 30 myopic eyes in adult with mild to moderate amblyopia gained 2 to 4 lines of CDVA after laser refractive surgery. Unilateral lens extraction was also reported can improve vision for high anisotropic myopia in children and adolescents, however, the incidence of retinal detachments was 3 fold higher than phakic IOL implantation^[18]. We previously observed 11 children with unilateral high myopic amblyopia^[7]. The logMAR CDVA of the amblyopic eye was improved by a mean of 2.64 lines at about 8mo after ICL surgery. Alió *et al*^[12] implanted angle-supported PIOL in 59 eyes of 48 patients with anisotropic amblyopia, and 91.5% eyes gained one or more lines of visual acuity. Kwon *et al*^[13] reported the CDVA of 12 eyes with high myopic amblyopia improved an average of 3.92±1.24 lines after angle-supported PIOL implantation. Shi *et al*^[14] also reported the CDVA improved mean 2 lines after ICL implanted for myopic anisotropic amblyopia in 11 adults. In our study, the SE of 13 amblyopic eyes was as high as -15.97±2.89 D that were not suitable for corneal refractive surgeries. The logMAR CDVA increased by a mean of 3.00 lines at 3 and

9mo postoperatively, without anyone lost visual acuity. The contrast sensitivity was also significantly increased after ICL implantation. The decimal CDVA of four cases (30.77%) recovered to over 0.8 reaching the cure standard of amblyopia, and the near stereopsis for these patients also recovered to 100'' to 400''. Our results agree with the literatures that simple refractive errors correction can improve the visual acuity and contrast sensitivity and partially recover near stereopsis of adult patients with high anisotropic amblyopia. We speculated the reasons for the good optical treatment results after ICL implantation might as follow: firstly, the CDVA of the cured amblyopic eyes in our study was not so bad before surgery; secondly, ICL implantation is superior for the treatment of unilateral myopic anisotropic than spectacle correction for it might eliminate the binocular retinal image size differences and be much closer to the physiological conditions. However, whether the adult patients with residual amblyopia after elimination of anisotropic by refractive surgeries can benefit from amblyopia therapy needs further study.

Potential complications including cataract formation, pupillary-block glaucoma, and dislocation were previously reported in adults after ICL implantation^[5]. A continuous reduction of central vault in agreement with previous research was observed in our results^[19-20]. The vaulting was ranged from 0.23 to 0.60 mm at 9mo after surgery, and no adverse events were observed. An excellent vaulting was defined as 0.25 to 0.75 mm. Excessive and insufficient vaulting were the risk factors of complications such as pupillary-block glaucoma or cataract formation^[21]. Temporary mild elevated of IOP was observed and soon resolved. Residues of hyaluronic acid material in anterior chamber, a side effect of topical corticosteroids, and measurement errors of non-contact nometer might be the reasons for transient high IOP. Although endothelial cell count was not significantly lost, and severe postoperative complications were not observed. The patients need to be followed regularly to evaluate the vault and endothelial cell count to avoid severe complications. Recently, the newly ICL V4c with a central hole (STAAR Surgical AG) is widely used to replace the V4 to correct moderate to high myopia in adults

which can provide similar results to conventional ICL^[22-23]. It does not require iridotomy or iridectomy and may also reduce the risk of pupillary block and cataract formation. This newly developed hole ICL implantation appears to be a good option for anisometropia with amblyopia in adults.

Our preliminary results show that ICL implantation can improve visual acuity, contrast sensitivity and partially recover near stereopsis in adult amblyopic patients with high myopic anisometropia. However, there were only a small number of patients with short-term follow up evaluated in our study. Longer time and more patients are still needed to observe the security and effectiveness of ICL implantation for adult anisometric amblyopia.

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