·Clinical Research·

AcrySof phakic angle-supported intraocular lens for the correction of high to extremely high myopia: one-year follow-up results

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Abstract

• AIM: To assess the safety, efficacy and predictability of the AcrySof phakic angle-supported intraocular lens (IOL) (Alcon Inc., U.S.A.) for correction of high-to-extremely high myopia in adults.

• METHODS: In this prospective study performed in Tianjin Medical University Eye Center & College of Optometry, Tianjin, China, 25 eyes of 13 patients were implanted with AcrySof phakic angle-supported IOLs and followed for 1 year postoperatively. Preoperative manifest refractive sphere was (-12.08± 2.44) diopters (D) and cylinder was (-1.35± 0.62)D. Visual acuity, predictability and stability of manifest refraction spherical equivalent (MRSE), adverse events, and endothelial cell density were analyzed during 1-year of follow-up.

• RESULTS: After 1 year of follow-up, no eyes lost ≥ 1 line (best spectacle-corrected visual acuity)BSCVA; an uncorrected visual acuity (UCVA) of 20/20 or better was achieved in 60% of eyes; 100% had an UCVA of 20/40 or better; a BSCVA of 20/30 or better was achieved by 100% of eyes; 84% had a BSCVA of 20/20 or better. The overall mean percentage change in endothelial cell density 1 year after surgery was (-0.27± 3.60)%. Two eyes (8%) had increased intraocular pressure (IOP) on the day of surgery. No pupil ovalization, pupillary block, or retinal detachment events were observed.

• CONCLUSION: After 1 year of follow-up, the implantation of AcrySof phakic angle-supported IOL is proved to be safe, effective and predictable with minimal complications in patients with high-to-extremely high myopia. Due to the limitation of visiting time, long-term of clinical investigation is necessary to verify the safety and efficacy of this IOL.

• KEYWORDS: phakic eye; lens, intraocular; high myopia; foldable; angle-supported

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INTRODUCTION

Although LASIK has been shown to be a very effective procedure for the correction of low to moderate myopia, high to extremely high myopia (>-9.00 diopters[D]) still remains challenging because of many of these patients having refractive errors and corneal thickness outside the range of treatment with LASIK. In addition, LASIK does come with some risks and disadvantages such as over-corrected or under-corrected, regression of refractive error, visual aberrations, dry eye symptoms, flap-related complications and extreme changes in corneal shape postoperatively. As a way of compensation, phakic intraocular lenses (IOLs) of various design and material have been placed in the anterior (or posterior) chamber or fixed to the iris to correct their refractive errors.

It has been demonstrated phakic IOLs have excellent refractive results, but the safety of this kind of surgery is always concerned by oculists [1,2]. A high frequency of pupil ovalization and IOL rotation has been associated with an early investigational angle-supported anterior chamber phakic IOLs [3]. The AcrySof phakic angle-supported IOL (Alcon Inc., USA) is the latest generation of angle-supported phakic IOLs, which is made of foldable hydrophobic acrylic, permitting a small corneal incision size (2.6mm) to perform the IOL implantation. Haptics are designed to permit compression within the angle for IOL stability and without excessive force that would result in pupil ovalization or angle tissue damage. The IOL is vaulted to provide optimal central clearance between the IOL and the cornea and the natural crystalline lens. There are four model designations of IOLs with different diameter can be chosen for varying anterior chamber dimensions.

This article mainly describes the 1-year results (the safety, efficacy, predictability, and complications) of the AcrySof phakic angle-supported IOL for the correction of high to extremely high myopia in adults.

Table 1 AcrySof phakic angle-supported IOL sizing and selection guidance

Model number	Optic size (mm)	Optic type	Length(mm)	Anterior chamber diameter(mm)	Diopter range (D)
L12500	6.0	Meniscus	12.5	11.25-11.75	-6.0 to -16.5
L13000	6.0	Meniscus	13.0	11.76-12.25	-6.0 to -16.5
L13500	6.0	Meniscus	13.5	12.26-12.75	-6.0 to -16.5
L14000	6.0	Meniscus	14.0	12.76-13.25	-6.0 to -16.5

MATERIALS AND METHODS

Subjects Twenty-five eyes of 13 patients were implanted with AcrySof phakic angle-supported IOLs with 1 year of follow-up from January 2010 to February 2011. Eligible patients were 21 years or older(all patients in this study were between 21 and 48 years of age) with good general and ocular health and high to extremely high myopia (range, -16.5 to -6.0 D) in the intended operative eyes; preoperative best spectacle-corrected visual acuity (BSCVA) of 0.30 (logMAR) or better and stable refraction (≤0.50D change in manifest refraction spherical equivalent [MRSE] yearly); who no longer desire to wear glasses for functional and occupational requirements or vision demands. Patients were excluded from this study if they had any of following conditions: anterior chamber depth (ACD) <3.2mm (including corneal thickness); irregular or abnormal corneal and intraocular anatomy; scotopic pupil diameter >7mm; astigmatism >2.0D; nonqualifying preoperative endothelial cell density (i.e., <2800/mm^2, age 18-25years; <2600 cell/mm^2, age 26-35years; <2200/mm^2, age 36-45 years; <2000/mm^2, age ≥46 years; U.S. A. Food and Drug Administration, Draft August 1, 2000).

Methods

AcrySof phakic angle-supported IOL The AcrySof phakic angle-supported IOL is a single-piece, foldable, soft acrylic lens and is intended for implantation in the anterior chamber angle (Figure 1). There are four model designations of IOLs with different diameter can be chosen for varying anterior chamber dimensions (Table 1). All models have a 6.0 mm meniscus optic and were available in half-diopter increments from -16.5 to -6. 0D.

Preoperative ocular examinations Preoperative ocular examinations included uncorrected visual acuity (UCVA), BSCVA, uncorrected near visual acuity at best distance, slit-lamp examination, tonometry (Goldmann applanation method), gonioscopic examination, dilated fundus examination (indirect ophthalmoscopy), scotopic pupil size (Wavescan, Visx Inc., USA), manifest refraction and cycloplegic refraction, manual keratometry (HAAG-STREIT BERN Inc., Z2983, Swiss). Axial length was measured with IOL-Master (Zeiss Inc., Oberkochen, Germany), ACD was measured with IOL-Master and Pentacam (Oculus Inc., 70700, Germany), and pachymetry was measured with Pentacam. For corneal endothelial cell density (ECD) analysis (Topcon Inc., SP-3000P, Japan), endothelial images were taken at the corneal center and the other four peripheral regions (superior, inferior, nasal and temporal), every region was taken 3 times, and at least 200 contiguous cells were marked on the image to obtain an analysis of at least 100 cells. At last, the cell counts of the whole regions were averaged to calculate the mean ECD.

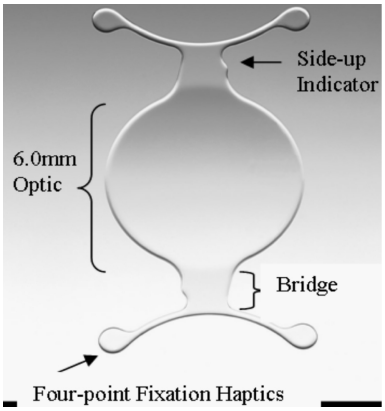

Figure 1 AcrySof phakic angle-supported IOL.

For the purpose of lens size selection, the anterior chamber diameter was measured preoperatively as the width of the cornea from the nasal limbus to the temporal limbus (white-to-white measurement). This was measured with calipers and IOL-Master.

Lens power calculation The lens power was calculated by using the modified van der Heijde formula (refined by Holladay). The presumptive "target" residual refractive error of -0.25D and a spherical equivalent (SE) of the subjective manifest refraction at a 12mm vertex were adopted.

Surgical technique and postoperative treatment All the 25 surgeries were performed by one experienced surgeon. Iridectomy or iridotomy was not performed preoperatively and intraoperatively. Before surgery, the pupil was constricted (1% pilocarpine, 4 times preoperatively) to prevent potential contact with the crystalline lens. After topical anesthesia, a corneal tunnel incision of 2.6mm was performed temporally. To maintain the anterior chamber, 1% sodium hyaluronate (Provisc, Alcon Inc., USA) was injected tangentially into the angle, away from the pupil. Then the AcrySof phakic IOL was implanted into the anterior chamber by using the Monarch Ⅲ IOL injector and P cartridge (Figure 2). After that, the ophthalmic viscoelastic

device (OVD) was removed thoroughly from the anterior chamber via injection of intraocular irrigating solution to displace the OVD through the incision. Finally, IOL position and integrity were confirmed before incision closure.

After the surgery, 50mg Methazolamide tablets was given to the patient to prevent elevation of intraocular pressure (IOP), and patients were instructed not to rub the eyes and to avoid direct eye trauma. Postoperative treatment also included antibiotic and steroidal eye drops (*e.g.*, 0.25% Levofloxacin and 1% prednisolone acetate) for 4 weeks.

Postoperative examinations Postoperative examinations mainly included UCVA, BSCVA, uncorrected near visual acuity at best distance, manifest refraction, slit-lamp examination, tonometry, fundus examination, ACD and ECD analysis. In addition, the minimum distance from the IOL optic anterior surface to corneal endothelium (vertical distance from IOL optic edge to the corneal surface) was measured with Pentacam. The IOL stability in the anterior chamber was assessed at each postoperative visit via slit-lamp examination, using the centerline of the IOL (a line along the optic diameter extending across both haptic ramps). Intraocualr lens position was recorded in four 15-degree increment categories (*e.g.*, 1-15, 15-30, 30-45, and 45-60 degrees). Patients were examined on the first postoperative day and 1 week, 1 month, 3 months, 6 months after surgery. The first time of IOP examination was 2 hours later after surgery.

Statistical Analysis The study results were calculated and summarized descriptively (*e.g.*, %, mean, standard deviation, range and so on). The overall mean change in ECD was calculated as the percent change in mean values from the preoperative visit to 1 year after surgery. Intraocular lens position was estimated as a supportive safety outcome.

RESULTS

Demographics and patients characteristics Patients had a mean age of (33.15 ±9.28) years (standard deviation) ranging from 21 to 48 years; 62% were female and 38% were male. The mean preoperative MRSE in the operative eyes was (-12.08±2.44)D ranging from -16.5 to -8.75D. The mean preoperative astigmatism in the operative eye was (-1.35 ±0.62)D ranging from -2.0 to 0D. The mean lens power of implanted IOLs was (-12.58±2.45)D (range, -16.5 to -9.0D). A preoperative BSCVA of 20/40 or better was achieved by 100% of eyes, and 60% had 20/20 or better.

Safety After 1 month, 3 months, 6 months, and 1 year postoperatively, 100% of eyes achieved a BSCVA of 20/32 or better, and 80%, 88%, 92%, and 92% achieved 20/20 or better, respectively. After 1 month, 3 months, 6 months, and 1 year postoperatively, no eyes lost 1 or more lines of BSCVA; 24% , 20% , 28% , and 28% gained 1 line of BSCVA; 4%, 8%, 8%, and 4% gained 2 line of BSCVA, 0%, 4%, 4%, and 4% gained more than 2 line of BSCVA,

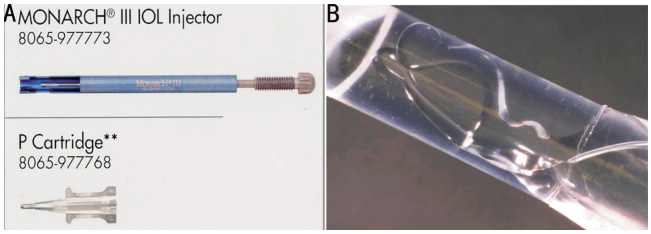

Figure 2 Monarch Ⅲ intraocular lens delivery system A: Monarch Ⅲ intraocular lens injector and P cartridge; B:Actual status of AcrySof phakic IOL in P cartridge.

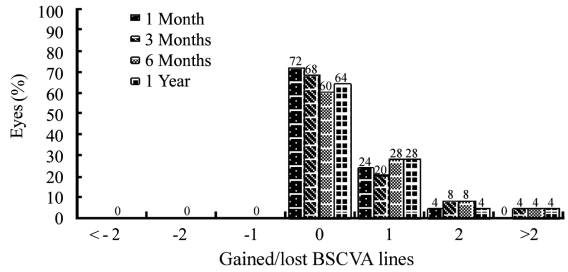

Figure 3 Percentage of eyes gained and lost BSCVA lines 1 month, 3 months, 6 months, and 1 year after AcrySof phakic angle-supported IOL implantation.

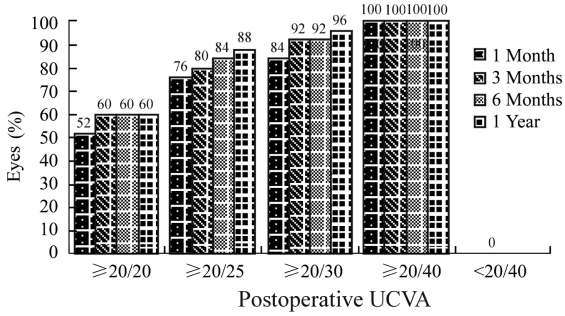

Figure 4 Percentage of eyes with postoperative UCVA 1 month, 3 months, 6 months, and 1 year after AcrySof phakic angle-supported IOL implantation.

respectively (Figure 3). The safety index (ratio of mean postoperative BSCVA / mean preoperative BSCVA) was 1.07(1.02/0.96), 1.11(1.06/0.96), 1.13(1.08/0.96), and 1.13 (1.08/0.96), at 1 month, 3 months, 6 months, and 1 year after surgery, respectively.

Efficacy After 1 month, 3 months, 6 months and 1 year postoperatively, 100% of eyes achieved a UCVA of 20/40 or better; 52%, 60%, 60%, and 60% of eyes achieved a UCVA of 20/20 or better, respectively (Figure 4). The efficacy index (ratio of mean postoperative UCVA/ mean preoperative BSCVA) was 0.94, 1.0, 1.04, and 1.04 at 1 month, 3 months, 6 months and 1 year after surgery, respectively.

Predictability and Stability

Targeted refractive error correction The deviation of the achieved spherical equivalent (SE) correction from the targeted refractive SE was calculated. After 1 month, 3months, 6 months, and 1 year, the deviation from the targeted refractive error was within ±0.5D in76%,80%, 84%, and 84% of eyes, respectively, and within ±1.0D in 96% ,

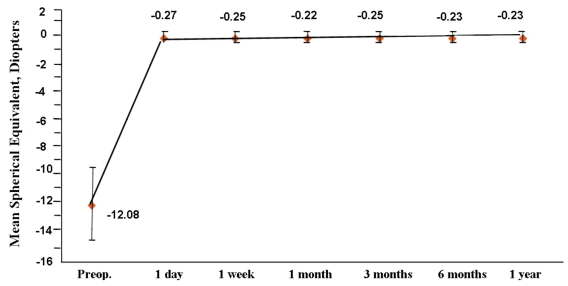

Figure 5 Mean manifest refractive spherical equivalent from before surgery to 1 year after implantation with the AcrySof phakic angle-supported IOL.

Table 2 The mean ECD change from preoperation to one year after surgery

Mean Change in Endothelial Cell Density Category, %	Eyes *n*(%)	Overall Mean Change,%
Loss≥10	1(4%)	
Loss<10 to≥5	2(8%)	
Loss<5 to gain<5	19(76%)	
Gain≥5 to <10	2(8%)	
Gain≥10	1(4%)	
Total	25(100%)	-0.27±3.6%

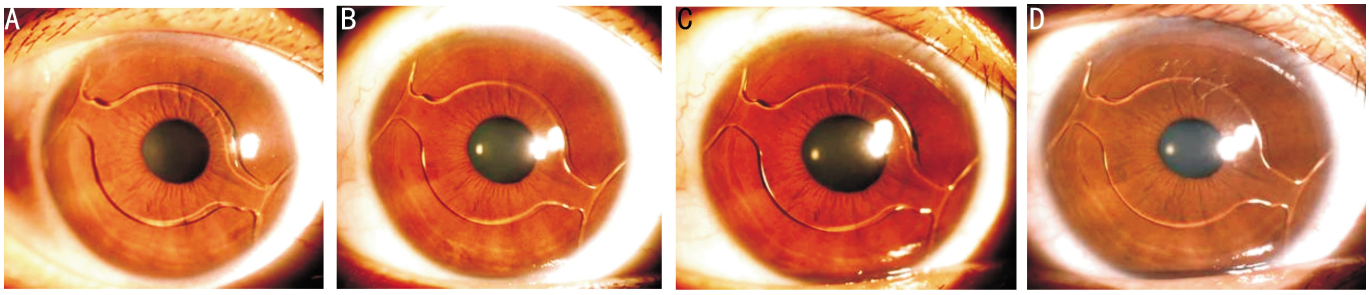

Figure 6 Stability of AcrySof phakic IOL A: 1 month after surgery; B: 3 months after surgery; C: 6 months after surgery; D: 1 year after surgery.

96%, 100%, and 100% of eyes, respectively. All eyes were within ±2.0D of the targeted refractive SE at 1 year after surgery.

Refractive stability The mean preoperative MRSE was (-12.08±2.44)D. The refractive error at 1 day after surgery was (-0.27±0.38)D and remained stable until 1 year after surgery (-0.23±0.45D, Figure 5).

Surgically induced astigmatism The mean preoperative manifest subjective refractive cylinder was (-1.35±0.62)D. At 1 year after surgery, the mean cylinder was (-1.46±0.56)D, there was no statistical difference between them.

Endothelial cell density Endothelial cell density was measured before surgery and at 1 month, 3 months, 6 months, and 1 year after surgery. The mean preoperative ECD was 2767±214/mm^2; the mean postoperative ECD at 1 month, 3 months, 6 months and 1 year were 2680±190/mm^2, 2725 ±252/mm^2, 2767 ±235/mm^2, and 2764 ±252/mm^2, respectively. One year after surgery, the mean ECD change ranged from a loss of <5% to a gain of <5% (76%, n=19) (Table 2).

Intraocular lens position Intraocular lens position was estimated in two ways: (1) incidence of rotation >15 degrees from baseline at any visit through the 1 year visit; (2) change of the minimum distance between the IOL optic anterior surface and corneal endothelium from baseline at any visit through the 1 year visit. It showed that the whole eyes had ≤15 degrees IOL rotation from baseline to any visit and from visit to visit through 1 year after surgery (Figure 6). The mean minimum distance between the IOL optic anterior surface and corneal endothelium at 1 month, 3 months, 6 months, and 1 year were (1.41±0.08)mm, (1.40±0.07)mm, (1.41±0.07)mm, and (1.40±0.07)mm, respectively. There were no statistical differences among them.

Intraocular pressure The mean preoperative IOP was (14.80 ±2.22)mmHg, the mean postoperative IOP were (14.76±2.22)mmHg, (15.04±1.99)mmHg, (14.88±226)mmHg, (14.92±2.02)mmHg at 1 month, 3 months, 6 months, and 1 year respectively, there were no statistical differences among them.

Complications and secondary interventions There were no serious intraoperative and postoperative complications occurred. Two eyes (8%) had increased IOP soon after surgery because of retained OVD, and the IOP returned to normal by anterior chamber paracentesis on the day of surgery. On subsequent days after surgery, the IOP of all eyes maintained normal. Mild glare (4%, n=1) and halos (12%, n=3) mainly occurred in 1 month after surgery, associated with big pupil diameter (>6mm) in scotopic light conditions or decentration of the pupil. As time goes on, the glare and halos were significantly alleviated and brought no negative impact on patients' daily life and work. During 1 year of follow-up, no other adverse events occurred.

Patient satisfaction The patients were asked to express their level of satisfaction about the AcrySof phakic angle-supported IOL in photopic, mesopic, and scotopic light conditions by giving a score between 1 (very unsatisfied) and 10 (very satisfied). The mean satisfaction 1 year after surgery was very high, with a rating of 9.76

(range, 8-10), 9.44 (range, 7-10), and 9.16 (range, 6-10) for photopic, mesopic, and scotopic light conditions, respectively.

DISCUSSION

Safety, Efficacy, Predictability and Stability During 1-year of follow-up after surgery, the AcrySof phakic angle-supported IOL has proven itself for its favorable results in terms of BSCVA, UCVA, predictability and stability of MRSE, endothelial cell density, stability of IOL, and complications. In this group of 25 eyes, there were no serious intraoperative or postoperative complications occurred. Several notable adverse events previously associated with phakic IOLs were not observed in this study, such as papillary block, pupil ovalization, secondary glaucoma, and IOL rotation. In addition, 1-year postoperative MRSE values demonstrated strong predictability. Visual acuity observations were consistent with published reports of phakic IOLs [4-6]; UCVA and BSCVA results were excellent. The added value of the AcrySof phakic angle-supported IOL is that it can be inserted through a small incision (2.6mm), the incision is smaller than that of other phakic IOLs'. This study results showed that there were no surgically induced astigmatism. It seems that this kind of phakic IOL can compete with laser treatments in terms of strong predictability, efficacy. Furthermore, implantation of this phakic IOL could also avoid regression of refractive power, that was more often in laser treatment group because of change in the corneal thickness by the laser. Although the study results did not raise safety concerns, ongoing follow-up is essential.

Endothelial Cell Density Endothelial cell density is a subject that much attention is being focused on it. Loss of endothelial cells from increasing age, trauma, disease, or corneal surgery can reduce the density of endothelial cells and can affect the ability of the endothelium to maintain its primary function [7]. One of the complications that has been associated with anterior chamber phakic IOLs is postoperative cell loss via potential mechanical contact between the IOL and corneal endothelium. In this study, the mean minimum distance between the IOL optic and corneal endothelium from visit to visit through 1 year after surgery is 1.40mm, which ensure that there is no mechanical contact between the IOL optic and corneal endothelium, except for four-point fixation haptics touching with the angle.

Compared with other anterior chamber angle-supported phakic IOLs, the AcrySof phakic IOL had superior 1-year mean changes in ECD (ZB5M and ZB5MF IOLs, -5.53%[8]; Baikoff Model ZB5M IOL, -4.3 to -5.3%[9]; Worst-Fechner IOL, -13%[10]). The 1-year mean percentage change in ECD of the AcrySof phakic IOL (-0.27%) was also better than the 1-year mean percentage change reported for the currently marketed iris-fixated polymethyl methacrylate Verisyse/ Artisan IOL (Advanced Medical Optics, Inc., Santa Ana, CA, and Ophtec BV, Groningen, The Netherlands) (-9.39 to +0.5% in various studies) [11,12] and the 1-year mean percentage change of the iris-fixated anterior chamber VeriFlex/ArtiFlex 5-mm and 6-mm IOLs (Advanced Medical Optics, Inc.) (-8.4% and -4.06%, respectively)[5].

The maintenance of endothelial cell density in 25 eyes observed 1 year after surgery was reassuring but merits ongoing evaluation. All eyes will continue to be evaluated in the long-term follow-up, and the estimated 0.6% physiologic age-related annual decrease [13] should be considered. In the future, ongoing surgical experience with this kind of phakic IOL may lead to refinements in surgical technique, lessening early ECD loss. Gains in ECD were possibly related to common measurement or analysis variability and the effects of corneal remodeling in response to wound healing. Other studies have reported similar postoperative cellular activity[11,12].

Anterior Chamber Biometry Measurement A key important factor is the accurate phakic IOL size chosen for different eye, which would be determined by accurate anterior chamber biometry measurement and would contribute to phakic IOL stability in anterior chamber. Options of anterior chamber biometry measurement include ultrasound biomicroscopy, Scheimpflug camera, anterior segment optical coherence tomography, IOL-master and so on. In this study, calipers and IOL-Master were used to estimate the anterior chamber diameter. It showed that there were no apparent IOL rotation occurred from baseline to each visit and from visit to visit through 1 year after surgery. While anterior chamber biometry estimation remains challenging, because the internal diameter of the anterior chamber varies with the horizontal or vertical axis and undergoes constant modifications as the result of accommodation and aging [14]. A method with acceptable biometric accuracy and availability has not been firmly established. Additional study of the suitability of such methods for clinical use in anterior chamber measurement for phakic IOL sizing is needed.

Surgical Considerations Some surgical considerations were regarded as essential. Accurate IOL power calculation was necessary to ensure target refractive results after surgery. In this study, the lens power was calculated by using the modified Vander Heijde formula (refined by Holladay), and it showed that all eyes were within ±2.0D of the targeted refractive error at 1 year after surgery, the result was better than or similar to other phakic IOLs[3,4]. Correct implantation of the IOL with the anterior optic surface facing upward is also very important, because the IOL is vaulted forward, if the IOL is implanted upside-down, the central clearance between the IOL and the natural crystalline lens will be decreased, which will increase the incidence of iatrogenic

cataract. Since there is safe clearance between the IOL and the pupil, iridectomy or iridotomy is unnecessary. In this study, there was no pupillary block occurred in 1-year of follow-up after surgery. Intraocular pressure elevation occurred in 2 of 25 eyes (8%) soon after surgery because of retained OVD in the anterior chamber, so it was very important to remove thorough OVD after IOL implantation. One percent sodium hyaluronate (Provisc, Alcon Inc., USA) was applied in this study, because this kind of OVD could inflate and maintain the anterior chamber very well and could be removed easily after IOL implantation. In addition, the OVD should be injected tangentially into the angle, away from the pupil to avoid it enter into posterior chamber.

In conclusion, the short-term clinical study shows that the AcrySof phakic angle-supported IOL has excellent results in safety, efficacy, predictability and stability when good patient selection, a correct surgical technique, and sufficient postoperative care are taken into account. The AcrySof phakic IOL is the first flexible IOL in the series of angle-supported IOLs having been used, so further follow-up is needed to investigate the long-term effects of the IOL on the corneal endothelium, iris, anterior chamber angle, and natural crystalline lens. On the basis of these early observations of excellent refractive correction and predictability with safety, the AcrySof phakic angle-supported IOL represents a promising future option for the correction of high myopia and extremely high myopia.

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