

Long-term results of phakic anterior chamber intraocular lens implantation in myopic eyes

*Serpil Akar, MD,
Mustafa Dogan, MD, Yasar Kucuksumer, MD,
Vedat Kaya, MD, Sukru Bayraktar, MD,
Birsen Gokyigit, MD, Omer F. Yilmaz, MD.*

Correction of high myopia remains to be a challenge as there are various treatment modalities. Angle supported anterior chamber phakic intraocular lenses (IOL) have several potential advantages including excellent and stable refractive results, fast visual recovery, preservation of accommodation in young patients, relatively familiar surgical technique for the average anterior segment surgeon, and potential reversibility. However, IOL implantation in phakic eyes raises some concern on the long-term potential risks to delicate anterior segment structures.¹ Angle supported phakic IOLs have been used for more than 20 years for the correction of high myopia. In 1990, the ZB5M (Chiron-Domilens, Lyon, France), which had a small vaulting angle to avoid excessive proximity to the corneal endothelium, a thinner optic, and greater flexibility of the haptics was first introduced.² The stability of the refractive outcome and good endothelial cell survival have been reported in some retrospective studies.^{1,2} The objective of this prospective, single center study was to evaluate the visual and refractive stability, and the potential long-term risks associated with ZB5M anterior chamber phakic IOL implantation.

The stability of refraction and complications was evaluated after a minimum follow-up of 144 months. Thirty-eight phakic myopic eyes of 26 patients that had anterior chamber phakic IOL implantation between July 1990 and October 1996 were included in this study. Inclusion criteria were preoperative myopic spherical equivalent (SE) refraction of at least 7 diopters (D), corneal astigmatism of less than 3 D, best corrected visual acuity (BCVA [Snellen word]) of at least 0.1 (20/200), a normal anterior segment with an anterior chamber depth of at least 3.4 mm, intraocular pressure (IOP) less than 21 mm Hg, wide open anterior chamber angle with minimal, or no pigmentation. A written informed consent was obtained from all patients in accordance with the Helsinki declaration. Exclusion criteria were any previous refractive procedure or corneal surgery, progressive myopia, corneal pathology, evidence of any lens' opacity or developing cataract, pseudoexfoliation, or pigmentary dispersion, glaucoma, history of uveitis, intraocular inflammation, macular pathology or retinal

detachment, and previous trauma. Only a small number of these patients had history of contact lens wear less than 5 years prior to anterior chamber phakic IOL implantation. No institutional review board approval was obtained for the study. The anterior chamber phakic IOL used in the study was model ZB5M (Chiron-Domilens, Lyon, France), which was a single piece biconcave lens made up of polymethyl methacrylate. It had an effective optical diameter of 4.0 mm (total optic diameter 5.0 mm with refined edges; the haptics on each side consisted of proximal and distal loops, which were open and flexible connecting the 2 footplates.) Three different overall diameters were available; 12.5, 13.0, and 13.5 mm. The lens was anteriorly angulated 20 degrees. It is available in 1.0 D increments from minus 7-20 D.¹ The dioptric power of the anterior chamber phakic IOL power was selected using a formula based on average keratometry, anterior chamber depth, and the spherical equivalent of the cycloplegic refraction. The postoperative mean refraction target was emmetropia. The overall lens diameter was selected by adding 1.0 mm to the horizontal white-to-white distance.¹

Surgery was performed under general anesthesia. A clear corneal incision of 5-6 mm was performed in the upper quadrant, pupillary constriction was achieved by intracameral carbachol 0.01 % injection and anterior chamber was filled with sodium hyaluronate for protection of the endothelium and the lens surface. The anterior chamber phakic IOL was inserted using forceps. A peripheral iridectomy was then performed. The position of the anterior chamber phakic IOL was verified, viscoelastic substance was washed out, and the incision was closed with interrupted 10-0 nylon sutures.³ Postoperatively, dexamethasone 0.1%, neomycin, and polymyxin B were given every 4 hours for the first 15 days, and then tapered over the next week, and stopped at the end of one month. Postoperative manifest refraction, unaided visual acuity (UCVA), BCVA, and IOP were measured at the first week, then at the first, third, and sixth months and first year, then annually. Snellen acuities were converted to logMAR and statistical analysis and comparisons were carried out using LogMAR acuity. Mean logMAR acuity were then re-converted to Snellen. Complications and subjective symptoms were also evaluated. The mean follow up was 150 ± 9.6 (standard deviation [range: 144-160 months]).

As we had no specular microscope available in our institution at the beginning of the study, no evaluation of endothelial cell density (ECD) could be obtained prior to anterior chamber phakic IOL implantation. We evaluated ECD 144 months after the implantation. The

specular microscopic images of the central portion of each cornea were taken using the specular microscope (KONAN Cellcheck SP-7000, Carolina Optics, Inc, Raleigh, NC, USA). Six images of corneal endothelium count in average were taken and recorded. These images were then saved in the IMAGE-net version 2.1 (Topcon Inc, Berkshire, UK). Endothelial cell count, cell area, coefficient of variation (CV) in the cell area were measured and compared with the parameters obtained from healthy subjects of the same age group.⁴ The study population included 12 (46.2%) men and 14 (53.8%) women, and the mean age was 25.6 ± 6.5 (range: 19-37) years. The ZB5M was implanted in one eye in 14 patients, and both eyes in 12 patients. The average anterior chamber phakic IOL power was -14.9 ± 3.9 D (range: -10.0 to -25.00). The average preoperative SE refraction was -17.17 ± 4.03 D. The average SE were; -1.83 ± 2.66 (range: -8.75 to +1.75) D, and -2.63 ± 2.90 (range: -8.75 to +0.50) D at the first and 12th year post-operative visits. The slight increase of myopia was not found to be statistically significant (2-way ANOVA; $p=0.285$), indicating stability in refractive outcome (Figure 1). Post-operative SE refraction was within ± 0.50 D in 10 eyes (26.3%) at the first year, and in 8 eyes (21.1%) at the twelfth year. It was within ± 1.0 D in 22 eyes (57.9%) at the first year, and 20 eyes (52.6%) at the twelfth year visits. Our results were consistent with the previous studies.^{1,2} De Souza et al¹ reported in their 5-year study that 26.9% of cases were within ± 0.5 D, and 57.7% of cases within ± 1.0 D. Javaloy et al² reported that the SE refraction was within ± 1.0 D in 39.3% of the eyes at 12 years postoperatively.

The average UCVA increased from 0.04 ± 0.02 (20/500 to 0.34 ± 0.15 (20/59) post-operative first year, and 0.31 ± 0.15 (20/64) at post-operative twelfth year.

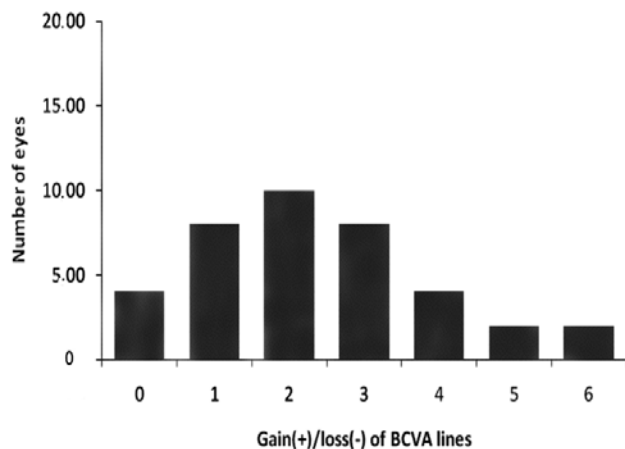


Figure 1 - Changes in best corrected visual acuity (BCVA) at postoperative twelfth year.

A total of 47.4% of eyes at the first year, and 44.7% of eyes at the twelfth year visits were able to have better UCVA than 0.5 (20/40). Postoperative UCVA were stable during follow-up (2-way ANOVA; $p=0.658$). Our results were similar to a 5-year study, which reported that 50% eyes had UCVA of at least 0.5 (20/40).¹ The average BCVA increased from 0.31 ± 0.17 (20/64) to 0.52 ± 0.16 (20/38) at postoperative first year, and 0.54 ± 0.19 (20/37) at postoperative twelfth year. A total of 36.8% of the studied eyes before surgery, 68.4% of eyes at the first year, and 65.8% of eyes at the twelfth year visits were able to have better BCVA than 0.5 (20/40). Our results are slightly higher than Javaloy et al,¹ who reported that 36.02% at the first year, and 34.69% of eyes were able to see at least 0.5 (20/40) at the year visits.² Postoperative BCVA in our study was better than preoperative values (2-way ANOVA; $p=0.001$) and stable during follow-up (2-way ANOVA; $p=0.658$). Figure 1 shows gaining Snellen lines of visual acuity at postoperative twelfth year.

The mean ECD at 144 months after surgery was 1900 ± 337 (range: 1466-2341) cells/mm², and the mean ECD of healthy eyes in subjects between 20-30 years old is 2407 ± 399 cells/mm². There was a statistically significant difference between these 2 values (paired student t test; $p=0.002$). The postoperative ECD was 26.7% less than the ECD of the normal population in the same age group. The mean cell area 12 years (144 months) after anterior chamber phakic IOL implantation was 541 ± 96 (range: 427-682) μm^2 . The mean cell area of the normal population in same age group was 428 ± 75 μm^2 . The average increase in cell dimension was not found to be statistically significant (paired student t test; $p=0.008$). The mean CV of cell area after anterior chamber phakic IOL implantation was $46.9 \pm 9.4\%$, and $20.4 \pm 5.5\%$ in the normal population. The difference was statistically significant (paired student t test; $p=0.0001$).

Despite the excellent refractive results, it was obvious that the endothelial cell loss found with this type of anterior chamber phakic IOL made it a potentially dangerous procedure in long-term. However, the exact mechanisms of endothelial cell loss is not clear. It has been suggested to be related to the intermittent contact between the optic edge and the endothelium when the patient rubbed his/ her eyes.^{1,2} A constant greater loss of ECD has been found for the ZB5M IOL models analyzed in the Javaloy et al study.² Javaloy et al² reported a 10.69% surgically induced fall in the ECD in the first year, and 1.78% average rate every year after that.² Furthermore, we determined an endothelial cell loss of 30.31% at 12 years. None of our patients had prolonged contact lens use prior to anterior chamber

phakic (ACP)-IOL implantation so we suggest that endothelial cell alterations due to contact lens use did not play a significant role in the apparent postoperative endothelial cell damage. Our results led us to a mechanism of a chronic and ongoing endothelial cell loss, or stressed endothelium. The absence of a definitive physio-pathological model of endothelial injury after angle-supported phakic IOL implantation and the large number of eyes implanted, especially in young patients should oblige surgeons to perform periodic endothelial cell analysis in those patients.² It also pointed out the importance of regular follow-up and preventive phakic IOL explantation as soon as significant endothelial cell loss was detected.

The IOP did not change significantly following ACP-IOL implantation (2-way ANOVA; $p=0.077$) however, anti-glaucomatous treatment with eye drops was initiated in 3 eyes. There was pupil ovalization in 16 eyes (42.1%). Javaloy et al² reported that the cumulative percentage of pupil ovalization was 34.7% of eyes after 12 years. There was no significant relationship between this phenomenon and the diameter of the implanted ACP-IOL (χ^2 test=1.36, $p=0.356$). Pupil ovalization was not associated with elevation of IOP. A significant correlation was not found between pupil ovalization and endothelial cell impairment (Friedman's test; $p=0.65$). Significant decentration and haloes were noted in 4 (10.5%) of the 38 eyes. The situation and possible consequences (explanation) were thoroughly discussed with those patients. Three of these eyes had extreme pupil ovalization with sector iris atrophy. The IOLs were exchanged in those eyes due to extreme day and night glare that was unbearable for the patients. In one eye, repositioning was performed as the patient refused exchange. Corneal edema, chronic iridocyclitis, hyphema, or cystoid macular edema were not encountered in any of the subjects. Now, more advanced imaging techniques, such as optical coherence tomography (OCT) for anterior segment imaging, or high-frequency ultrasound provide more accurate white-to-white measurement for better IOL size determination.⁵ More flexible biomaterials with appropriate sizes might offer better alternatives for pupil ovalization and phakic IOL decentration.

The risk of retinal detachment after ACP-IOL implantation should be not underestimated.² Some authors reported cataract formation after angle supported phakic IOL implantation.^{1,2} Cataract formation and retinal risks in eyes that received ACP-IOLs to correct severe myopia was analyzed in a previous study from our institution.⁵

In conclusion, although ACP-IOL (model ZB5M) implantation provided good visual acuity, refractive results and stability over a long period of time, serious complications were also encountered. Constant and ongoing loss in the endothelial cells and deterioration in morphology requires periodic ECD evaluation. Pupil ovalization which increases over time is a common complication after ACP-IOL implantation, and in some cases, IOL exchange may be required. We suggest that close follow-up of patients implanted with this phakic IOL and future implantations should be avoided.

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From the Anterior Segment Department, Beyoglu Education and Research Eye Hospital, Istanbul, Turkey. Address correspondence and reprints request to: Dr. Serpil Akar, Anterior Segment Department, Beyoglu Education and Research Eye Hospital, Acibadem cad, Yurtsever sok, Alsancak sitesi, E Blok, Da:19 Acibadem/Kadikoy, Istanbul, Turkey. Tel. +902 (16) 3274787. Fax. +902 (12) 2450947. E-mail: akarserpil@yahoo.com

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