

Short and long-term outcomes of angle supported phakic intraocular lens implantation in high myopic eyes

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Abstract

• This cohort study included 36 eyes of 21 patients with high myopia treated with angle supported phakic intraocular lens (pIOL). Endothelial cell density (ECD) at baseline, 6mo and 3y were 3017±296, 2775±265 and 2558±299 cells/mm² respectively. ECD loss at 6mo was 7.2% and annual ECD loss was 3% over 36mo. Corrected distance visual acuity at 36mo was 0.4 logMAR or better in 32 (88.9%) eyes. Intraocular pressure did not change ($P=0.9$). No eyes developed cataract, retinal detachment or pupillary distortion. Angle supported pIOL gives good visual outcome. Endothelial cell loss should be monitored.

• **KEYWORDS:** phakic intraocular lens; high myopia; refractive surgery

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INTRODUCTION

Phakic intraocular lens (pIOL) is an alternative for excimer laser ablation in treatment of myopia^[1]. Unfortunately long-term damage to the corneal endothelium are noted^[2]. They are angle-supported pIOLs, iris fixated pIOLs and posterior chamber pIOLs^[3]. Outcomes of angle supported pIOL in an Arab population, are limited^[4-5]. We present short and long term outcomes of pIOL for high myopia in relation to the corneal status, intraocular pressure (IOP) and distance visual acuity after 6, 12, 24 and 36mo in Dhahran, Saudi Arabia.

SUBJECTS AND METHODS

The institutional research committee approved this retrospective cohort. Patients with high myopia (-6 to -14 D) that underwent angle supported pIOL implantation between 2009 and 2014 at the Dhahran Eye Specialist Hospital or the Magrabi Hospital, Dhahran were included. Patients with an anterior chamber depth (ACD) <3.2 mm or had previous ophthalmic surgery, a mesopic pupil of 7.00 mm or larger, astigmatism >2.00 D, cataract and endothelial cell count <2500 cells/mm² were excluded. We assumed that endothelial cell density (ECD) loss after pIOL implantation would be 15% over the 12 postoperative months and 25% at 36mo postoperatively compared to conventional ophthalmic surgery where ECD is likely to be less than 5%^[6-7]. To achieve 95% confidence interval (CI) and 80% power for this cohort study with 1:1 ratio, at least 31 eyes were required in each arm.

Corrected distance visual acuity (CDVA) was measured using a Snellen vision chart. The anterior segment was evaluated with a slit lamp biomicroscope (Topcon Corp., USA). IOP was measured using a Goldmann applanation tonometer. With Pentacam HR (Oculus GmBh, Wetzlar, Germany), corneal thickness, keratometry (K_1 , K_2), mean K and ACD were noted. ECD was measured with a specular microscope (Topcon SP-2000P, USA)^[8].

Preoperatively, the pupil was constricted with 2% topical pilocarpine to protect the crystalline lens from contact of pIOL. The final intraocular lens (IOL) size was determined by confirming the white-to-white (WTW) measurement with callipers. Through a temporal corneal tunnel incision, the angle fixated Cachet pIOL^[6] was folded and inserted with a Monarch II IOL Delivery system (Alcon Laboratories, Inc., Fort Worth, TX, USA). Topical antibiotic and steroids were given for 1wk. The outcome variables were: 1) decline in ECD; 2) IOP at follow up and CDVA; 3) complications. Postoperative follow up was conducted at 6, 12, 24 and 36mo.

Statistical Package for Social Studies (SPSS 16; IBM Corp., Armonk, NY, USA) was used for analysis. For IOP, ECD and CDVA, the mean and standard deviations were calculated. Outcomes of same eye at different follow-ups were compared using the paired *t*-test. The decline in ECD to 66% from baseline was plotted to study survival of the endothelium by time following angle supported phakic IOL implantation.

RESULTS AND DISCUSSION

We studied 36 eyes of 21 patients. The median age was 27y (20-37y). The mean central corneal thickness (CCT) was 552±36 µm. The median spherical equivalent was -10.5 D (25% quartile -11 D). The mean K₁ and K₂ were 42.2±1.3 and 44.2±1.0 D respectively. The ECD at the different visits are presented in Table 1. There was acute loss of ECD in the 6mo following surgery and steady loss of ECD over the remaining period. An ECD loss of 33% is likely to occur 10y after angle supported pIOL implantation. The CDVA preoperatively and postoperatively is presented in Table 1.

Eyes with preoperative CDVA of 0.11±0.08 logMAR improved to 0.4 logMAR or better in 32 (88.9%) eyes and 0.00 logMAR in 15 (41.7%) eyes after 36mo. The CDVA improved by two or more lines in 17 (47.2%) eyes. CDVA at 36mo improved by one line in another 15 (41.7%) eyes and remained the same in 4 (11.1%) eyes. The IOP preoperatively was 16.3±2.1 mm Hg. At 6, 12, 24 and 36mo follow-up, IOP was 16.1±1.9, 16.1±2.3, 15.5±1.5 and 16.1±2.0 mm Hg respectively. Change in IOP ($P=0.9$) was not significant. There were no cases of an oval pupil, pupillary block, cataract or retinal detachment. The correlation of CDVA to endothelial loss was not significant at 6mo (Spearman $P=0.6$), 12mo ($P=0.3$), 24mo ($P=0.5$) and 36mo ($P=0.09$). Correlation of CDVA to preoperative ECD (Spearman $P=0.6$), 12mo ($P=0.2$), 24mo ($P=0.25$), 36mo ($P=0.17$) was not significant. Visual outcomes after angle supported pIOL were promising, without increasing IOP but had slow progressive endothelial damage. Glaucoma, cataract, distortion of pupil and retinal detachment were not found. While reviewing the safety of pIOL, we noted that 8% acute ECD loss. This could be due to intraoperative manipulation and disturbances in hydrodynamics of aqueous humour in the anterior chamber. This was less than the 10% estimate as per ISO standard 11 979^[9]. Approximately a third of ECD is projected to be lost in a decade.

As the anterior chamber pIOLs is close to the cornea, cells have higher risk of damage^[10]. Excessive endothelial cell loss was reported for cachet and early anterior chamber pIOLs. Effect of pIOL implantation on ECD could be due to surgery also in addition to the physiologic decrease in ECD occurs with aging^[11]. ECD loss in different studies could be due to variations in study designs, tools and method used for endothelial cell counts^[12]. A clinical trial of anterior chamber angle-supported pIOL reported ECD losses from 4.2% to 15.3% after 3y^[5]. The 3-year decline in ECD in our study is lower than in studies using other types of pIOL.

The visual acuity at one year were similar to those of a European study^[6]. US Food and Drug Administration clinical trials of the Artisan/Verisyse iris-fixated pIOL reported CDVA of 20/20 in 31% of patients and 20/40 or better in 84% of patients after 3y^[13]. The viability, safety and complications

Table 1 ECD and CDVA preoperatively and at different follow up visits after angle supported pIOL implantation for high myopia

Time of evaluation	ECD (cells/mm ²)		CDVA (logMAR) mean±SD
	Mean±SD	Difference of mean	
Before surgery	3017±296		0.11±0.08
After pIOL			
6mo	2775±267	241 (169-313)	0.05±0.08
12mo	2719±276	279 (217-376)	0.04±0.08
24mo	2640±295	377 (283-471)	0.04±0.08
36mo	2558±299	458 (360-557)	0.04±0.08

ECD: Endothelial cell density; CDVA: Corrected distance visual acuity; pIOL: Phakic intraocular lens. $P<0.001$ both for difference of mean of ECD and CDVA.

of pIOLs implanted for such a long duration requires further study. Visual acuity improvement was likely due to the magnification effects. This could also be due to exclusion of patients with more than 2D astigmatism. There was no variation of IOP postoperatively. Kohnen *et al*^[6] reported transient increase in IOP over first 4wk. Angle supported pIOLs are less likely to obstruct the flow of aqueous.

There was no case of postoperative retinal detachment and lens changes. The risk of retinal detachment should be carefully assessed prior to pIOL surgery as high myopes are at higher risk of developing retinal detachments^[14-15]. Comprehensive retinal evaluation and prophylactic treatment of highly myopic eyes with retinal degeneration prior to pIOL implantation are recommended. Improvements in techniques over time have minimized the risk of lens opacity due to pIOL.

This was a one-armed cohort study, and comparison of outcomes with other types of pIOL should be judicious. Myopia is often associated with astigmatism, and we included patients with astigmatism of less than 2.00 D only. The implantation of angle supported pIOL resulted in promising outcomes for the correction of high myopia with mild astigmatism. However, chronic endothelial cell loss should be monitored.

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Angle supported phakic IOL

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