Short-Term Evaluation of the AcrySof Angle-Supported Phakic Intraocular Lens: Visual Performance, Intraocular Pressure and Endothelial Cell Counts

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Abstract

Objectives: The aim of this study was to evaluate the visual performance, intraocular pressure and the endothelial cell density changes after implantation of the AcrySof angle-supported pIOL for the correction of moderate to high myopia.

Patients and Methods: This study comprised patients with moderate to high myopia ranging from –6.0 D to –16.50 D who had implantation of the AcrySof angle supported pIOL. Outcome measures included uncorrected visual acuity (UCVA), best spectacle corrected visual acuity (BSCVA), safety, predictability and endothelial cell density (ECD).

Results: Of the 32 eyes that were enrolled in the statistics the UCVA was 0.3 LogMAR (20/40, 6/12) or better in 62.5% and 0.2 LogMAR (20/32, 6/9) or better in 25% of the eyes. The BSCVA was 0.3 LogMAR (20/40, 6/12) or better in 88% and 0.2 LogMAR (20/32, 6/9) or better in 72% of the eyes. The mean percentage loss of the corneal endothelium at 1-month post operative was 5% and at 6 months was 0.1%.

Conclusion: The AcrySof angle-supported pIOL provided favorable refractive correction, predictability and acceptable safety in patients with moderate to high myopia.

Key Words: Myopia – AcrySof – Phakic IOL – Endothelial cell counts.

Introduction

KERATOREFRACTIVE surgeries, such as photorefractive keratectomy and LASIK have limitations when used for the correction of high refractive errors [1]. Intra-ocular refractive procedures offer many potential advantages over keratorefractive surgeries, mainly a broader range of treatable ametropia, faster visual recovery, more stable refraction and better visual quality [2].

Two basic intraocular refractive procedures exist: Phakic intraocular lens (pIOL) implantation and refractive lens exchange. However, Refractive lens exchange may increase the risk of retinal detachment and is generally not considered in myopic pre-presbyopic patients who can still accommodate [8]. Phakic intraocular lenses may be classified according to the site of implantation within the eye: Anterior chamber or posterior chamber [4].

The AcrySof phakic angle supported IOL (Alcon Laboratories, Inc., Fort Worth, TX, USA) is made of foldable hydrophobic acrylate, permitting small corneal incision size (~3.0mm). The haptics are designed to permit compression within the angle for the IOL stability without creating excessive force that could cause angle tissue damage or pupil ovalization. The IOL is vaulted to provide optimal central clearing distance between the IOL, the cornea and the crystalline lens [5].

Aim of work:

The aim of this study was to evaluate the visual performance, intraocular pressure and the endothelial cell density changes after implantation of the AcrySof angle-supported pIOL for the correction of moderate to high myopia.

Material and Methods

The study included 20 adult patients (32 myopic eyes), with good general, ocular and mental health, suffering from stable moderate to high myopia (ranging between –6.0 to –16.0 diopters of myopia) in the intended operated eyes.

The patients were selected from the outpatient clinic of Kasr Al Aini Hospital Cairo University between June 2010 and May 2011.
Inclusion criteria:

Patients had to be motivated to be spectacle independent and should have had realistic expectations and willingness to participate in an evaluating trial for a relatively new pIOL. Patients should also have had tried other methods of correction of myopia before surgery and proved intolerant to either glasses cosmetically or to contact lenses.

- Best spectacle corrected visual acuity of 6/12 or better.
- Myopia more than 10.0 D.
- Myopia of less than –10.0 D when keratorefractive procedures are not suitable e.g. corneas thinner than 500um.
- Anterior chamber depth of 2.8mm or more measured from the corneal endothelium to the anterior lens capsule using the pentacam as required by the manufacturer.
- A pupil (under mesopic light conditions) smaller than 6.0mm in diameter using the pentacam.
- ECD using specular microscopy meeting the criteria proposed by the manufacturer of the Phakic IOL.

Endothelial Cell Density Requirements

<table>
<thead>
<tr>
<th>Age</th>
<th>Minimum cell density (cells/mm²)</th>
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<tbody>
<tr>
<td>21-25</td>
<td>2800</td>
</tr>
<tr>
<td>26-35</td>
<td>2600</td>
</tr>
<tr>
<td>36-45</td>
<td>2200</td>
</tr>
<tr>
<td>46</td>
<td>2000</td>
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</table>

Exclusion criteria:

- Astigmatism >2.0D.
- Abnormal cornea such as corneal opacity or corneal dystrophy.
- Abnormal pupil, fixed pupil or pupil greater than 7.0mm in mesopic light.
- Anterior segment pathology such as any form of cataract, pseudoexfoliation, pigment dispersion and severe iris atrophy.
- History and/or any clinical signs of previous attack of uveitis.
- Glaucoma or any Intraocular pressure (IOP) greater than 21 mm Hg.
- Posterior segment pathology.
- Patient has undergone any previous intraocular surgery.

Preoperative evaluation:

After a full review of the patient’s medical and ophthalmic history, all patients received complete ophthalmological examination including:

- Measurement of best spectacle corrected visual acuity (BSVCA) using Snellen’s visual acuity chart.
- Patients were manually refracted to their best correction using trial lenses and cycloplegic refraction.
- Slit lamp examination of the anterior segment.
- IOP measurement using Goldmann’s applanation tonometry.
- Gonioscopy of the anterior chamber angle using Goldmann’s three mirror goniolens to exclude angle recession, angle trauma or anatomic anomalies.
- Fundus examination by indirect ophthalmoscopy and fundus biomicroscopy using the 90D lens.
- Scheimpflug imaging was performed preoperatively using the pentacam (WaveLight, Erlangen, Germany) to assess the distance between the corneal endothelium and the anterior surface of the crystalline lens, which represented the measured anterior chamber depth.
- The specular microscope Tomey EM-3000 (Tomey corporation. Nagoya, Japan) was used to determine the endothelial cell density.
- The IOL Master (Carl Zeiss AG, Oberkochen, Germany) was used to determine:
  - Anterior chamber depth.
  - Width of the cornea from the nasal to the temporal limbus (white to white measurement).
- For purposes of lens size, power selection and eligibility determination, all the previous data was then entered into an online calculator, www.acrysofcachetcaculator.com. The chosen power of the pIOL was always the closest to emmetropia.

Surgical technique:

Before surgery, the pupil was constricted (pilocarpine 2% was recommended) to prevent potential contact with the crystalline lens. Surgeons administered the anesthesia of their choice (e.g., topical, retrobulbar, peribulbar, or general anesthesia). The anterior chamber was accessed with a corneal tunnel incision of approximately 2.6mm oriented temporally, superiorly, or along the steepest axis.
To inflate and maintain the chamber, sodium hyaluronate 1% (Provisc, Alcon Laboratories, Inc.) was injected tangentially into the angle, away from the pupil. This cohesive ophthalmic viscoelastic device (OVD) was used to achieve ease of OVD removal after IOL implantation. The AcrySof phakic IOL was loaded into the Monarch III IOL Delivery System with its anterior optic surface facing upward and was then folded and slowly delivered with the cartridge positioned at midpupil to provide delivery in the area of maximum corneal depth. After pausing for the leading haptics to unfold, delivery was continued; when the leading haptics reached the distal angle, the cartridge was withdrawn as delivery continued, to avoid increased compression in the distal angle. Trailing haptics were left just outside the incision and then tucked one at a time into the anterior chamber angle so that the lens was positioned with all 4 haptics in the anterior chamber. The cohesive OVD was cautiously removed with passive removal that consisted of irrigation via injection of intraocular irrigating solution to displace the OVD through the incision. Acetazolamide was given at the conclusion of surgery to control intraocular pressure. The operative eye was protected with an eye shield, and subjects were instructed not to rub the eye and to avoid direct eye trauma. Postoperative treatment included an ocular antibiotic and steroid regimen.

Post operative follow-up:

Patients were examined on the first postoperative day and one week after surgery. Subsequent examinations were done at 1, 3 and 6 months.

Each visit candidates went through the following:
- Measurement of uncorrected visual acuity (UCVA) using Snellen’s visual acuity chart.
- Manual refraction to their best correction using trial lenses and cycloplegic refraction.
- Measurement of best spectacle corrected visual acuity measured using Snellen’s visual acuity chart.
- Slit lamp examination for the detection of any cataractous changes, acute/chronic inflammation or IOL deposits.
- Measurement of IOP using Goldmann’s applanation tonometry.

Starting the third month onward the specular microscope was used to assess the same preoperative parameters for comparison.

Results

Thirty-two eyes of 20 patients were included in the statistical analysis. By the time of this analysis 33 eyes had received the angle-supported pIOL. One eye was implanted with the L12500 model, 18 eyes were implanted with the L13000, 12 eyes with the L13500 and 2 eyes with the L14000. All the eyes had completed the 6-month postoperative visit.

One patient was discontinued from the study due to intractable unilocular diplopia in the first postoperative week. This resulted in IOL explantation.

Patients recruited in this study had a mean age of 26.91±4.92 (standard deviation) ranging from 21 to 43 years old; 65.6% were females and 34.4% were males.

The mean preoperative mean refractive spherical equivalent (MRSE) of the operated eyes was −11.30 D ±3.37 ranging from −18.0 D to −6.0 D. The mean lens power of implanted IOLs was −12.14 D ±3.03 ranging from −16.5D to −7.0 D.

<table>
<thead>
<tr>
<th>BSCVA preoperatively</th>
<th>0.3 LogMAR or better</th>
<th>0.2 LogMAR or better</th>
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<tbody>
<tr>
<td>Number of patients</td>
<td>62.5%</td>
<td>28.1%</td>
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</table>

Preoperative BSCVA in LogMAR.

Postoperatively the BSCVA significantly improved from the pre-operative figures \( p < 0.05 \).

<table>
<thead>
<tr>
<th>BSCVA Postoperatively</th>
<th>0.3 LogMAR or better</th>
<th>0.2 LogMAR or better</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>88%</td>
<td>72%</td>
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</table>

Postoperative BSCVA in LogMAR.

Safety:

Six months postoperatively no subjects had lost 2 or more lines of BSCVA. Three eyes had no change in lines of BSCVA, 29 eyes out of 32 had gained 1 BSCVA line, and 10 out of 32 eyes gained 2 BSCVA lines.

The safety index (Ratio of the mean postoperative BSCVA/mean preoperative BSCVA) was 1.32 (0.66/0.5). Indicating improved BSCVA after surgery.

Predictability and stability:

The 6th month postoperative mean MRSE was −0.59 D ±0.4 ranging from −1.50 D to +0.25 D. The residual refractive error was within ±0.50 D of the targeted refractive error in 21 out of 32 eyes (65.6%) and within ±1.0 D in 30 eyes (93.75%). The residual refractive error was −1.25 in 2 of the operated eyes.
Short-Term Evaluation of the AcrySof Angle-Supported Phakic Intraocular Lens

Multiple views of the AcrySof angle-supported phakic IOLs.

Intraocular pressure:

The intraocular pressure was significantly stable over time from the date of surgery until the 6th month post operative visit.

The mean IOP pre-implantation was 14.31 mmHg, 13.41 mmHg at day 1, 15.44 mmHg at 1 week, 15.47 mmHg at 1 month, 14.48 mmHg at 3 months and 13.88 mmHg at 6 months. All the previous measurement differences were statistically insignificant.

Endothelial cell counts:

Data from the 32 operated eyes met the pre-specified criteria for statistical analysis of the endothelial cell density.

Acute endothelial cell density changes (surgical loss):

The mean percentage change in the ECD from the preoperative visit (2777±218 cells/mm²) to the 1-month postoperative visit (2640±241 cells/mm²) was 13.7. This approximates to 5%, being within the acceptable range of loss postoperatively.

Chronic endothelial cell density changes:

The mean percentage change in the ECD from the first month postoperative visit to the sixth month postoperative was 3. This is approximately 0.1%, which was statistically insignificant.

Discussion

Six months after surgery, the AcrySof phakic angle-supported IOL demonstrated favorable and efficient results in all its primary outcomes. This includes UCVA, BSCVA, safety, predictability, IOP and endothelial cell density.

Patients who had a mean preoperative MRSE of −11.98 D ±3.3 had Clinically significant improvements at the 6th month postoperative visit with an UCVA of 0.3 LogMAR (20/40, 6/12) or better in 62.5% of patients. BSCVA of 0.2 LogMAR (20/30, 6/9) or better was achieved by 72% of patients and 0.3 LogMAR (20/40, 6/12) or better by 88% of patients.

UCVA and BSCVA in this study were very favorable post implantation and were consistent with the published reports of phakic IOLs.

The visual acuity results in the current study are consistent with those achieved by Kohnen et al., during the 1-year interim analysis of their multicenter European study. An UCVA of 20/20 or better was achieved by 57.8%; 99.4% had 20/40 or better. A BSCVA of 20/32 or better was achieved by 100% [6].

The results of the current study are also consistent with Knorz et al., at 3 years, in the only three-
year study about the AcrySof angle supported phakic intraocular lens. The authors found that, of the 104 patients who reached the 3-year visit, the UCVA was 20/40 or better in 101 (97.1%) and 20/20 or better in 48 (46.2%). The BSCVA was 20/32 or better in 103 (99.0%) \[7\].

Mastropasqua et al., in the latest study about the AcrySof angle-supported pIOL found that the mean UCVA was 0.3 LogMAR (20/40) or better in 100% of patients. BSCVA was 0.2 LogMAR (20/20) or better in 78% of patients and 0.3 Log-MAR (20/40) or better in 100% of patients \[8\].

Safety:

In this study no patients lost 2 lines of BSCVA, (9.3%) 3 patients had no change in lines of BSCVA, (59.3%) 19 patients gained 1 line of BSCVA and (31.25%) 10 patients gained 2 or more lines of BSCVA. The safety index (ratio of the mean post-operative BSCVA of 0.66/mean preoperative BSCVA of 0.5) was 1.32.

These results were equivalent to Kohnen’s one year’s trial in which no subjects lost 2 or more lines of BSCVA. Many subjects (44.7%) had no change in lines of BSCVA, 31.1% gained 1 BSCVA line, and 23.0% gained 2 BSCVA lines or more. the safety index (ratio of mean post-operative BSCVA of 1.15/mean preoperative BSCVA of 0.92) was 1.25 \[6\].

Knorz et al., found that no patient lost 2 lines of BSCVA, approximately one third of the 104 patients [40 (38.5%)] had no change in lines of BSCVA and a similar number [42 (40.4%)] gained 1 line of BSCVA. Another 20% gained 2 lines of BSCVA or more \[7\].

The safety index in Knorz’s study (ratio of mean 3-year postoperative BSCVA of 1.15/mean preoperative BSCVA of 0.95) was 1.21, indicating improved BSCVA after surgery \[7\].

In the U.S. clinical investigation of the Artisan myopia lens for the correction of high myopia in phakic eyes by Alexander et al., 72% gained 1 or more lines and 22% gained 2 or more lines regardless of the degree of the astigmatism. Refractive outcomes were convincing and complications were minimal. Two eyes lost 2 lines of BSCVA \[9\].

As for the ICL, treatment of high myopia study group confirmed that at 3 years after ICL implantation, 3 eyes (0.8%) decreased by 2 lines, in contrast to 40 eyes (10.8%) that improved by a similar amount \[10\].

Predictability:

In this study, predictability outcomes of the AcrySof lens were also satisfying and very much similar to other published literature. We found that 65.6% and 93.75% of patients achieved a residual refractive error of ±0.50D and ±1.0D respectively, of the targeted postoperative refractive error.

Knorz et al.’s predictability outcome was 78.9% within the 0.50D and 91.3% within the 1.0D \[7\].

Kohnen et al.’s results were similar: 72.7% and 95.7% within the 0.50D and the 1.0D respectively \[6\].

The FDA study for Artisan 71.7% within the 0.50D and 91.7% within 1.0D respectively \[11,12\].

Similarly The ICL study group reported 67.5% of eyes being within 0.50D and 88.8% within 1.0D of attempted correction \[10\].

Endothelium:

The maintenance of endothelial cell density of 32 operated eyes observed 6 months after implantation with this angle-supported pIOL was reassuring, but merits ongoing evaluation.

All the subjects operated upon will continue to be evaluated in an annual follow-up. However, interpretation of mean percentage change in endothelial cell density should consider the estimated 0.6% physiological related annual loss \[13\].

Apparent gains in endothelial cell number were reported in different studies and were probably due to analysis variability and effects of corneal remodeling in response to the corneal wound healing \[14,15\].

The 6th month mean percentage change in endothelial cell density of the AcrySof phakic IOL was 4.93% in this study. This was consistent with the European multicenter study that concluded a –4.77%±8.4% and the three year interim results that found a (−4.08%) at 6 months \[6\].

Compared with other angle-supported phakic IOLs, the AcrySof phakic IOL had a better mean percentage endothelial cell loss \[6,7\].

Silva et al., in 2008, evaluating the Artisan found a decrease of −7.18% of the mean ECD at 1 year \[16\]. Allemann et al., in 2000 evaluating the NuVita, found a decrease of −12% at the second year \[17\]. Also, Maloney et al., in 2002, evaluating the Artisan found that 20% of the eyes lost more...
than 10% of the endothelial cells after 6 months while 25% of patients gained 10% or more of the endothelial cells [18]. Leccisotti & Fields, in 2005, evaluating the ZSAL-4 found a decrease of ~6.2% at the 12th month visit [19]. Similarly, Alio et al., in 2007, evaluating the Kelman Duet concluded with a loss of ~5.4% at 1 year [20].

Plainer et al., in 2011, evaluating the I-CARE found no statistically significant decrease in endothelial cell count within the first year, but a significant decrease could be seen after the second postoperative year. The average endothelial cell count change was 1850±693 cells/mm² after 5 years, which was statistically significant [21].

Intraocular pressure:

In our study, the IOP was stable over time after implantation of the pIOLs, with exception of the 4 eyes that had a postoperative spike most probably due to residual OVD and 2 eyes that responded to steroids.

This was consistent with the results of Kohnen et al., where 6 subjects had an increased IOP requiring treatment at >1 month after surgery for the following reasons: Four patients were steroid responders, one case was related to surgery and one of unknown reason. They also had 5 eyes with an elevated IOP on the day of surgery due to retained viscoelastic [6].

Knorz et al., had an increase IOP of more than 10mmHg from the preoperative baseline as a result of residual OVD from the surgical procedure in 2.8% of the patients [7].

Conclusion:

We conclude from this study that AcrySof angle-supported pIOL implantation for the correction of moderate to high myopia, being a sutureless surgery, is a promising option achieving rapid visual rehabilitation.

The studied IOL has proved to provide good refractive correction and predictability together with several other advantages including a small incision that is inherently astigmatically neutral, a smooth operative procedure negating the need for a surgical iridectomy and easy reversibility when indicated.

The endothelial cell findings suggest that with appropriate patient selection, most importantly adequate anterior chamber depth and preoperative endothelial cell count, the safety concerns encountered with the previous angle-supported phakic IOLs that were withdrawn from the market, could be overcome. However, long-term safety data will have to be evaluated to draw future definite conclusions.

References


