AcrySof Phakic IOL for Correction of Moderate-to-High Myopia: 1 Year Results

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PURPOSE: To evaluate the efficacy, predictability and safety of myopic phakic angle-supported intraocular lens for correction of moderate to high myopia.

METHODS: In a prospective non comparative interventional case series, outcomes in 42 eyes, with a preoperative mean spherical equivalent of -11.00 diopters (D) ± 2.79, were analyzed 12 months after the implantation of the AcrySof Cachet. They comprised uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), slit-lamp examination, refraction, endothelial cell count, IOL rotation and position.

RESULTS: The mean UCVA and BCVA after AcrySof Cachet implantation were 0.80±0.25 and 0.92±0.18, respectively (efficacy index: 0.94). No eyes lost ≥1 lines, 16 eyes did not change after surgery, 11 eyes gained 1 line and 15 eyes gained ≥ 1 lines of visual acuity. (safety index: 1.08). All eyes were within ±1.00D of the desired refraction and 83.3% within ±0.50D. The mean postoperative spherical equivalent was -0.24±0.36D. The mean percentage change in central endothelial cell density from the preoperative visit to 1 year post-surgery was -6.16±4.29%. The mean value of misalignment was 3.97±2.91 degrees. OCT Visante showed a mean central lens-endothelium value of 2.09±0.26 mm, a central lens-anterior crystalline lens capsule value of 0.91±0.18 mm and a lens edge-endothelium of 1.16±0.31 mm. No pupil ovalization, pupillary block, or retinal detachment events were observed.

CONCLUSIONS: The AcrySof phakic angle-supported lens implantation was a safe, effective, and predictable procedure for the correction of moderate and high myopia.

KEYWORDS: phakic IOL, myopia, anterior chamber IOL.

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INTRODUCTION

The implantation of a phakic intraocular lens (IOL) for the correction of moderate or high myopia has theoretical advantages in comparison with corneal procedures and clear lens extraction, such as precision and stability not dependent on the corneal healing process, a wider range of correction, magnification of the intraocular image, and preservation of accommodation. However, these lenses have also been associated with safety concerns such as uveitis, endophthalmitis, glaucoma, corneal damage, cataract, and pupil ovalization.

A new anterior chamber angle-supported phakic IOL, the AcrySof Cachet (Alcon Laboratories, Inc.), is single piece and composed of hydrophobic acrylate. Models of varying diameter are designed to fit within a variety of anterior chamber dimensions. Because it is foldable it can be inserted through a small corneal incision size (about 2.6 mm 3.0 mm) using the Monarch II IOL Delivery System («B» or «C» «P» cartridge). The haptics are designed to permit compression within the angle for IOL stability, without creating excessive force that could cause angle tissue damage or pupil ovalization. A previous multicenter clinical study has confirmed the good predictability, safety and efficacy of this

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The AcrySof phakic IOL is a single-piece, foldable, soft acrylic lens with a chemically bonded ultraviolet chromophore (acrylate/methacrylate co-polymer) and is intended for implantation in the anterior chamber angle. This study included 4 IOL models (L12500, L13000, L13500 and L14000), each with a different overall length (12.5, 13.0, 13.5 and 14mm, respectively). All models have a 6.0-mm meniscus optic and were available in half-diopter increments from –6.0 to –16.5 D. In this study, the overall size of the IOL was determined using white-to-white OCT Visante (Zeiss-Meditec, Germany) measurements plus 0.5 mm. The IOL power was calculated using a formula originally derived by van der Heijde and refined by Holladay.

All surgeries in this study were performed by two experienced surgeons (R.R.M, F.P.) Iridectomy or iridotomy at the time of surgery was not performed in any case. Before surgery, the pupil was constricted (pilocarpine 2%) to prevent potential contact with the crystalline lens. Topical or peribulbar anesthesia was administered. A paracentesis was created about 2 clock hours on the left side of the incision. An initial posterior limbal tunnel incision of about 2.75 mm oriented temporally, superiorly, or along the steepest axis was created to access to the anterior chamber. Sodium hyaluronate 1% (Provisc) was injected and the pIOL was loaded into a Monarch II IOL delivery system (Alcon Labs, Inc.) with the anterior optic surface facing upward. The IOL was inserted into the anterior chamber through the posterior limbal tunnel incision. After the leading haptics unfolded and were gently guided into the distal angle, the cartridge was withdrawn to avoid increased compression in the distal angle. Postoperative treatment included an ocular antibiotic and steroid regimen (prednisolone acetate ophthalmic suspension 1% [Pred Forte, Allergan, Inc., Irvine, CA]) or tobramycin 0.3%/ dexamethasone 0.1% [Tobra-dex, Alcon Laboratories, Inc.]) for 1 to 4 weeks. The tenets of the Declaration of Helsinki were followed in this research. Informed consent was obtained from all patients after the nature and possible consequences of the study were explained. Institutional Review Board approval was obtained. The targeted refraction was emmetropia in all cases.

Follow-up was 12 months postoperatively. They comprised uncorrected visual acuity (UCVA), BCVA, slit-lamp examination, refraction, endothelial cell count, rotational stability and fundoscopy. OCT Visante was also used to analyze distances between endothelium and crystalline lens to the IOL: central lens-endothelium (D1), central lens and anterior crystalline lens capsule (D2) and lens edge and endothelium (D3). All examinations were performed at 12 months after implantation by one ophthalmic technician who was unaware of the objective of the study. Data analysis was performed using SPSS for Windows version 12.0 (SPSS Inc., Chi-

<table>
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<tr>
<th>Table 1: Demographic Characteristics of Participants</th>
<th>AcrySof Cachet IOL</th>
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<tbody>
<tr>
<td>Number of eyes</td>
<td>42</td>
</tr>
<tr>
<td>Age (years) (range)</td>
<td>37.52 ± 4.65 (31 to 51)</td>
</tr>
<tr>
<td>Gender (Male/Female)</td>
<td>4/17</td>
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<tr>
<td>IOL Power (D) (range)</td>
<td>–11.36 ± 2.41 (–7 to –16.5)</td>
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<tr>
<td>Anterior Chamber Depth (mm) (range)</td>
<td>3.86 ± 0.41 (3.2 to 4.17)</td>
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<tr>
<td>Endothelial Cell Count (cell/mm²) (range)</td>
<td>2905.47 ± 519.22 (2183 to 4326)</td>
</tr>
<tr>
<td>Spherical equivalent (D) (range)</td>
<td>–11.00 ± 2.79 (–6.25 to –18)</td>
</tr>
<tr>
<td>Best corrected visual acuity (Snellen) (range)</td>
<td>0.85 ± 0.14 (0.66 to 1)</td>
</tr>
<tr>
<td>White to white (mm) (range)</td>
<td>12.36 ± 0.52 (11.2 to 13.57)</td>
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<tr>
<td>Means ± standard deviation, IOP= intraocular pressure.</td>
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cago, IL). Normality was checked by the Shapiro-Wilk test, and the monovariate $t$-test was used for analysis. Differences were considered to be statistically significant when the $P$ value was $<0.05$ (i.e., at the 1% level).

**RESULTS**

No complications occurred during the surgery. No eye needed explantation or repositioning of the lens. Decentration of the lens optic was not observed and no patients reported halos and glare under daylight conditions. Figure 1 shows postoperative images of the implanted AcrySof phakic IOL.

**Visual Acuity**

The mean Snellen UCVA and BCVA after IOL implantation was 0.80±0.25 and 0.92±0.18, respectively (fig. 2). The overall efficacy index (mean postoperative UCVA/mean preoperative BCVA) at 12 months was 0.94. No eyes lost 1 or more than 1 lines, 16 eyes did not change after surgery, 11 eyes gained 1 line and 15 eyes gained ≥1 line of visual acuity (fig. 3). The safety index (ratio of postoperative and preoperative BCVA) at 12 months was 1.08. The BCVA after IOL implantation was statistically significantly better than the BCVA before surgery ($P=0.003$).

**Refractive Errors**

The deviation of the achieved spherical equivalent refractive error from the calculated spherical equivalent refractive error was calculated. Figure 4 shows the attempted versus achieved plot for spherical equivalent. All eyes were within ±1.00 D of the desired refraction and 83.3% within ±0.50 D (35 eyes). The mean postoperative spherical equivalent was $-0.24±0.36$ D at 12 months [sphere: $0.07±0.54$ D and cylinder $-0.70±0.67$]. There was a significant reduction in spherical equivalent after implantation ($P<0.0001$).

**Endothelial Cell Count and IOL Rotation**

Postoperative endothelial cell count was $2789.39±488.75$ cell/mm², ranging from 2000 to 3894 cell/mm², at 1 year of follow-up. Mean cell loss...
was 184.86±138.48 cell/mm² and the overall mean percentage change in central endothelial cell density from the preoperative visit to 1 year after surgery was –6.16±4.29% (range from 0 to –13.58%). For most eyes, the mean reduction change was ≤5% (23 eyes). Including intraoperative cell lost.

The mean of the absolute value of misalignment based upon slit-lamp examination was 3.97±2.91 degrees, ranging from 0 to 10 degrees. The greater percentage of eyes (32 eyes) showed a rotation ≤5 degrees, with a lower percentage between 6-10 degrees (20 eyes). In relation to the OCT Visante measurements, we have obtained the following mean values 2.09±0.26 mm (from 1.55 to 2.57), 0.91±0.18 mm (from 0.37 to 1.35) and 1.16±0.31 mm (from 0.57 to 1.65), for D1, D2 and D3, respectively. Figure 5 shows an example of this measurement at 1 year post-surgery.

DISCUSSION

In this prospective study of 42 eyes we have evaluated the visual and refractive outcomes of the AcrySof Cachet IOL after 1-year post-surgery. Our study shows that AcrySof Cachet IOL implantation is an effective procedure for the correction of moderate and high myopia. Previous published series of AcrySof Cachet IOL implantation showed similar outcomes\textsuperscript{15,16}.

The postoperative visual acuity outcomes in our study were good, the mean Snellen UCVA and BCVA was 0.80±0.25 and 0.92±0.18, respectively, with an efficacy index of 0.94. The three-year multicenter study\textsuperscript{16}, that analyzed 360 patients implanted with the AcrySof Cachet (mean spherical equivalent: −10.41±2.31 D), showed a significant improvement in UCVA with 20/20 or better in 48 [46.2%] of 104 patients and 20/40 or better in 101 patients [97.1%]. The BCVA was 20/32 or better in 103 [99.0%] of the 104 patients and 20/20 or better in 84 patients [80.8%]. Our results, on a sample of 42 patients with a similar mean spherical equivalent of −11.00±2.79 D, agree completely with these. The outcomes for the 1-year interim analysis on 337 eyes were also similar\textsuperscript{15}.

In relation to the safety, we found that no eyes lost 1 o more than 1 lines, 16 eyes did not change after surgery, 11 eyes gained 1 line and 15 eyes gained ≥1 line of visual acuity, with a safety index of 1.08. In the three-year multicenter study\textsuperscript{16}, no patient lost more than 2 lines, 2 patients had a decrease (1 line and 2 lines) in BCVA, 40 patients (38.5%) had no change, 42 (40.4%) gained 1 line, 15 patients (14.4%) gained 2 lines and 5 patients (4.8%) gained more than 2 lines of BCVA. These data were similar to data collected throughout the postoperative period from 6 months to 2 years\textsuperscript{15,16}. The 3-year postoperative safety index was 1.21, indicating improved BCVA after surgery.

Our results also showed that predictability was good, with all eyes within ±1.00 D of the desired refraction and 83.3% within ±0.50 D (35 eyes). The mean postoperative spherical equivalent was –0.24±0.36 D. Our results broadly agree with the three-year multicenter study\textsuperscript{16}, which found a residual refractive error within ±0.50 D in 82 patients (78.8%), within ±1.00 D in 95 patients (91.3%) and a mean postoperative spherical equivalent of −0.24±0.55 (range −2.00 to 1.63 D).

As we have introduced, the main concerns previously identified with phakic IOL implantation are related to safety, with risks including cataract formation, endothelial cell loss, pupillary block, retinal detachment, and pupil ovalization\textsuperscript{1-13}. No postoperative adverse events (i.e. pupil ovalization, pupillary block, or retinal detachment) were reported in our series. The overall mean percentage change in central endothelial cell density from the preoperative visit to 1 year after...
surgery was \(-6.16\pm4.29\%\) (range from 0 to \(-13.58\%\)). The annualized percentage loss in the three-year multicenter study\(^{16}\) from 6 months to 3 years was 0.41% and 1.11%, respectively. Specifically, at 1 year\(^{17}\) the percentage change in endothelial cell density was \(-4.77\pm8.04\%\), which is similar to that reported in our series with the same follow-up. It is necessary to note that the decrease of endothelial density is proportional to the surgical time and manipulation\(^2\). In our study we have obtained statistically significant changes at 1 year follow-up (P<0.0001), but in any case the endothelial cell count has been critical. In relation to other anterior chamber angle-supported phakic IOLs, the AcrySof phakic IOL had superior or similar 1-year mean changes in endothelial cell density (Worst-Fechner IOL\(-13\%\); ZB5M and ZB5MF IOLs, \(-5.53\%\); Baikoff Model ZB5M IOL, \(-4.3\%\) to \(-5.3\%)\(^{14,9}\). Iris-fixated VeriFlex/ArtiFlex IOLs with \(-9.39\%\) to \(-0.5\%\) and 1-year mean percentage change of the VeriFlex/ArtiFlex IOLs with \(-8.4\%\) and \(-4.06\%\), respectively, showed larger values\(^2,5,10,22,23\).

Mean value of rotation was 3.97\(\pm\)2.91 degrees (from 0 to 10 degrees), with the greater percentage of eyes (32 eyes) with \(\leq5\) degrees. We need to note that variances in a subject’s head tilt on slit-lamp examination may have confounded IOL position results. However, IOL rotation was low and not associated with visual, refractive or other event sequelae. Recent reports using Scheimpflug imaging (3 years)\(^{24}\) and anterior segment optical coherence tomography (3 months)\(^{25}\) showed adequate central clearance distances to the corneal endothelium and the natural crystalline lens over 3 years and excellent intraocular behavior after pupil dilation. Accurate phakic IOL sizing is necessary for IOL stability considering that internal diameter of the anterior chamber varies with the horizontal or vertical axis and undergoes constant modifications as the result of accommodation and aging.

In relation to the lens position into the anterior chamber, our results showed good distance for D1 (2.09\(\pm\)0.26 mm), D2 (0.91\(\pm\)0.18 mm) and D3 (1.16\(\pm\)0.31 mm). Baumeister et al.\(^{26}\) using Scheimpflug photography analyzed the NuVita angle-supported lens (Bausch & Lomb, USA) showing that the mean endothelium-IOL (D1) and IOL-crystalline lens (D2) distance 1 year after implantation was 2.04\(\pm\)0.16 mm and 0.80\(\pm\)0.14 mm, respectively. The outcomes for Kohnen and Klaproth\(^{24}\) using the same technology with the AcrySof Cachet 3 years post-surgery were 2.15\(\pm\)0.29 mm (D1) and 0.86\(\pm\)0.22 mm (D2). Our results, at 1 year, broadly agree with those recently reported by Kohnen and Klaproth\(^{24}\). These authors also reported slight differences with time post-surgery, showing the good stability of the lens when implanted in the anterior chamber and maintained adequate central clearance distances to the corneal endothelium and to the natural crystalline lens.

In conclusion, the present results with 1-year of follow-up, show that the AcrySof Cachet IOL is a good option for moderate to high myopia correction. The analysis revealed good and predictable refractive correction being a safe procedure. Longer follow-up with larger sample of patients is necessary to further assess the possible adverse events of this IOL.

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