Analysis of Accommodative Performance of a New Accompomodative Intraocular Lens

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ABSTRACT

PURPOSE: To compare objective and subjective accommodation and visual acuities with a new accommodative intraocular lens (IOL) (Lumina; AkkoLens Clinical BV, Rijswijk, The Netherlands) with a monofocal IOL and young phakic eyes.

METHODS: In this prospective, randomized controlled clinical investigation, patients aged 51 to 85 years with symptomatic cataract were enrolled in the study. A total of 25 eyes were implanted with the accommodative IOL and 18 eyes received the monofocal Acrysof SA60AT IOL (Alcon Laboratories, Inc., Fort Worth, TX). Each group included 4 bilateral patients. An additional 20 phakic eyes of young patients aged 19 to 29 years were used to assess the restoration of accommodation. Subjective and objective accommodative amplitudes were evaluated by defocus curves and the WAM-5500 open-field Auto Ref/Keratometer (Grand Seiko, Tokyo, Japan), respectively.

RESULTS: The 1-year postoperative examination showed significantly better visual acuities with the accommodative IOL compared to the monofocal IOL, over a defocus range of -0.50 to -5.00 diopters (D) (P < 10^-6), and revealed more than 50% of the visual acuities of the young phakic eyes at up to -3.50 D defocus. The depth of focus of the accommodative group exceeded that of the monofocal group by 2.52 ± 0.03 D in a visual acuity range of 0.3 to 0.8 (decimal) (20/63 to 20/25 Snellen). Compared with the monofocal IOL, the accommodative IOL resulted in a similar uncorrected distance visual acuity of 0.99 ± 0.12 (20/20 Snellen) (P > .79) and a significantly better uncorrected near visual acuity of 0.91 ± 0.11 (20/22 Snellen) (P < 2.7 × 10^-6). A significant correlation of 0.51 (P < 1.3 × 10^-3) was found between the objective and subjective accommodative amplitudes with the accommodative IOL.

CONCLUSIONS: Eyes implanted with the accommodative IOL showed similar amounts of objective and subjective accommodation.

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Satisfactory vision for both reading and far distances in presbyopic or pseudophakic eyes implanted with intraocular lenses (IOLs) can be achieved by extending the depth of focus of the eye (ie, by pseudoaccommodation).1,2 The extended depth of focus can be achieved by multifocal IOLs,3-5 corneal inlays,6 and IOLs employing the pinhole effect.7 However, such devices do not change the refractive power of the eye in response to the accommodative stimulus and usually cause side effects, including reduced visual acuity, loss of contrast sensitivity, and unwanted photic phenomena (eg, glare and halos under low light conditions).3-6 In the past few years, attempts have been made to reinstate the eye’s accommodation by accommodating IOLs.8 Such IOLs aim to provide a continuous focusing of the eye, and therefore are expected to be devoid of the disadvantages of the extended depth of focus approach. However, clinical investigations followed by a comprehensive analysis of the accommodative outcomes are needed to prove the real efficacy of an accommodating IOL.9,10 The current International Organization for Standards (ISO) and American National Standards Institute (ANSI) norms for IOLs stipulate the procedures for assessing accommodative amplitudes of the eyes implanted with the accommodating IOLs and emphasize the importance of objective measurements.11

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Drs. Simonov, van Lawick, and Rombach are employees of AkkoLens and Dr. Simonov has patents involving the Lumina lens. The remaining authors have no financial or proprietary interest in the materials presented herein.

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We previously reported the effective restoration of accommodation by the Lumina IOL (AkkoLens Clinical BV, Rijswijk, The Netherlands) in patients with cataract and found that the mean postoperative objective accommodation exceeded 1.00 diopter (D). However, the accommodative IOL’s accommodation was evaluated only in terms of averages. The individual objective and subjective accommodative contributions of each eye and the mutual dependency of these contributions were not studied systematically.

An analysis of the accommodative performance of the accommodative IOL is presented. We investigated the individual objective accommodative performance and the subjective near vision performance of eyes implanted with this lens and compared them with control pseudophakic eyes implanted with monofocal IOLs, and benchmarked the accommodative IOL’s near vision performance versus normal phakic eyes of young patients.

**PATIENTS AND METHODS**

This prospective, randomized controlled investigation included only eyes with clinical cataract with no other ocular comorbidity or previous ocular treatments and with an expected positive effect of the surgery on the visual outcome. All cataractous eyes underwent standard cataract surgery and were systematically followed up for at least 12 months postoperatively. The clinical investigation protocol and procedures complied with the tenets of the Declaration of Helsinki of 1975, as revised in 1983, and were approved by the competent national authorities and ethical committees of the clinical sites. Informed consent was obtained from all patients.

A study group including 25 eyes of patients aged 51 to 85 years received the accommodative IOL (accommodative group). Four patients were implanted bilaterally and the other patients were implanted unilaterally. The accommodative IOL and its working principle have been described elsewhere. In brief, as shown in Figure A (available in the online version of this article), the lens consists of two free-form optical elements and implements the variable-focus principle of Alvarez with additional correction of dynamic aberrations. The accommodative IOL is positioned at the sulcus plane in front of the capsular bag (Figure B, available in the online version of this article). When the ciliary muscle contracts, the lens elements move in opposite directions, perpendicular to the optical axis, hence changing the optical power of the accommodative IOL.

Eighteen eyes of patients aged 53 to 79 years were implanted with a standard monofocal IOL with anterior asymmetric biconvex optics (Acrysof SA60AT; Alcon Laboratories, Inc., Fort Worth, TX) (monofocal group). Four patients were implanted bilaterally. This group served as a non-specific comparison condition to verify the test method used in the clinical investigation for measuring objective accommodation. An additional control group of 20 eyes of normal young phakic patients aged 19 to 29 years (control group) was enrolled in the study for comparison purposes.

**PREOPERATIVE AND POSTOPERATIVE MEASUREMENTS**

The accommodative, monofocal, and control groups underwent preoperative evaluations required by the ISO norm for the clinical investigation of ophthalmic implants. These included measurements of refraction, keratometry, uncorrected (UDVA) and corrected (CDVA) distance visual acuities, slit-lamp examination, tonometry, and fundus examination. The distance visual acuity was measured under photopic conditions, at 4 m or more, by using standard Snellen charts and by a computerized LCD chart system (CC-100XP; Topcon Corporation, Tokyo, Japan). Table 1 summarizes the main baseline characteristics of the groups.

In addition to these preoperative measurements, several postoperative evaluations were made, including measurements of near visual acuity, the average

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**Table 1**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Accommodative IOL</th>
<th>Monofocal IOL</th>
<th>P</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>70.7 ± 8.4 (51 to 85)</td>
<td>68.8 ± 8.1 (53 to 79)</td>
<td>.42</td>
<td>22.9 ± 2.8 (19 to 29)</td>
</tr>
<tr>
<td>Sphere (D)</td>
<td>-1.39 ± 2.30 (-7.50 to +1.25)</td>
<td>0.00 ± 3.00 (-5.00 to 3.00)</td>
<td>.15</td>
<td>-0.95 ± 1.40 (-3.30 to 0.73)</td>
</tr>
<tr>
<td>Cylinder (D)</td>
<td>-1.00 ± 0.32 (-1.50 to -0.50)</td>
<td>-0.75 ± 0.35 (-1.00 to -0.50)</td>
<td>.44</td>
<td>-0.53 ± 0.35 (-1.14 to -0.03)</td>
</tr>
<tr>
<td>UDVA (decimal)</td>
<td>0.23 ± 0.17 (&lt; .04 to 0.5)</td>
<td>0.25 ± 0.20 (0.02 to 0.6)</td>
<td>.97</td>
<td>0.8 ± 0.5 (&lt; 0.04 to 1.5)</td>
</tr>
<tr>
<td>CDVA (decimal)</td>
<td>0.49 ± 0.19 (0.1 to 0.8)</td>
<td>0.46 ± 0.26 (0.1 to 0.8)</td>
<td>.77</td>
<td>1.29 ± 0.14 (1.15 to 1.5)</td>
</tr>
<tr>
<td>Mean keratometry (D)</td>
<td>43.56 ± 1.42 (40.91 to 45.80)</td>
<td>43.79 ± 2.40 (40.62 to 48.25)</td>
<td>.61</td>
<td>–</td>
</tr>
<tr>
<td>Axial length (mm)</td>
<td>23.88 ± 0.76 (22.46 to 25.44)</td>
<td>23.03 ± 0.78 (21.98 to 24.02)</td>
<td>.008</td>
<td>–</td>
</tr>
</tbody>
</table>

*Values are presented as mean ± standard deviation (range).*

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subjective and objective accommodation. In this study, we report the measurements of accommodative amplitudes performed between 330 and 420 days postoperatively (as per individual Case Report Form 5 of the ISO norm).

**Subjective and Objective Accommodation**

Subjective accommodation was assessed by defocus curves in all three groups. Each defocus curve was obtained monocularly using the corrected distance refraction and under controlled low ambient light conditions resulting in mesopic pupil diameters. The visual acuity was measured as a function of defocus imposed by spectacle lenses with a dioptric power ranging from +2.00 to -5.00 D in steps of 0.50 D.

Measurements of objective accommodation were performed with the WAM-5500 open-field Auto Ref/Keratometer (Grand Seiko, Tokyo, Japan). During the evaluations, the device was operated in high-speed mode, allowing more than five measurements of refraction and pupil diameter per second, under the control of custom C++ software acquired data directly from the WAM-5500 serial port. During the measurements, the spherical equivalent of the eye was measured monocularly while the patient was looking at a slowly approaching target through an open-field, semi-transparent screen. A starting value of -0.17 D was set for the far point positioned 5.8 m away from the patient’s eye. This value was further subtracted when determining the accommodative amplitude of the eye.

The patients in both IOL groups were examined with corrected distance refraction by appropriate spectacles. Contact lenses were provided to correct distance vision of the eyes from the control group.

**Statistical Analysis**

The R software for statistical computing (#R version 3.2.4, JMP; SAS Inc., Cary, NC) and OriginPro (version 8; OriginLab Corporation, Northampton, MA) software were employed for the statistical analysis. In all cases, we examined the normality of the data samples with the Kolmogorov–Smirnov or Shapiro–Wilk tests. The parametric analysis (providing higher statistical power) of both paired and unpaired data was done using the Student’s *t* test. We performed the Wilcoxon–Mann–Whitney rank sum test for assessing the statistical difference between the samples when the parametric analysis was not applicable (ie, when the normality assumption was not met). The Rho de Spearman non-linear rank correlation *U* test was applied to determine the correlation between data samples. A *P* value of less than .05 was considered statistically significant.

**RESULTS**

**Defocus Curves and Depth of Focus**

Figure 1 shows the mean defocus curves of all three groups. The accommodative group yielded a significantly higher visual acuity over a defocus range of -0.50 to -5.00 D (*P* < 10⁻⁵) with no significant difference at zero defocus (*P* = .46) compared to the monofocal group. In turn, the control group revealed significantly better visual acuities compared to both the accommodative and monofocal groups in a defocus range of -0.50 to -5.00 D (*P* < 2.5 × 10⁻⁷) and at zero defocus (*P* < 6.5 × 10⁻⁶).

To benchmark the accommodative performance of the accommodative group against the control group, the mean defocus curves were also calculated as percentages of the mean visual acuity values of the control group. Figure C (available in the online version of this article) depicts the mean relative defocus curves of the accommodative and monofocal groups as percentages of the corresponding visual acuities obtained in the control group. It can be seen from the plot that the accommodative eyes showed more than 50% of the visual acuities of the control eyes at a defocus of up to -3.50 D, whereas the same visual acuities were observed in the monofocal group only at a defocus not exceeding -1.00 D.

By analyzing the individual defocus curves of the eyes, the average dependencies of the depth of focus (depth of focus) on the visual acuity were determined. We defined the depth of focus as the width of the defocus curve (in diopters) at a chosen level of visual acuity. Linear interpolation was additionally applied to obtain data between the measured visual acuity points, discretized with an interval of 0.50 D. Figure D (available in the online version of this article) represents the mean depth of focus for the accommodative and monofocal eyes. We did not include depth of focus data for
the control eyes because these eyes revealed large depth of focus values exceeding the available defocus range.

As can be seen from the plots in Figure D (available in the online version of this article), the accommodative group showed a systematic and almost constant value outperformance of $2.52 \pm 0.03$ D in the depth of focus for visual acuities ranging from 0.3 to 0.8 (decimal units) (20/63 to 20/25 Snellen); hereafter, the notation mean ± standard deviation is used for the results. In a wider visual acuity range from 0.2 to 1.0 (20/100 to 20/20 Snellen), the accommodative group confirmed a significantly greater depth of focus compared to the monofocal group ($P < 4.8 \times 10^{-4}$).

**UDVA**

The uncorrected distance (UDVA) and near (UNVA) visual acuities were measured for all three groups (Figure E, available in the online version of this article). Figure F (available in the online version of this article) summarizes the mean values and standard deviations of these measurements. There was no significant statistical difference in UDVA values between the accommodative group at $0.99 \pm 0.12$ (decimal units) (20/20 Snellen) and the monofocal group at $0.98 \pm 0.29$ (20/20 Snellen) ($P > .79$). However, the control eyes resulted in a significantly higher mean UDVA of $1.29 \pm 0.14$ (20/16 Snellen) compared to the accommodative eyes ($P < 1.7 \times 10^{-7}$). The mean UNVA of the accommodative group ($0.91 \pm 0.11$; 20/22 Snellen) was statistically higher than that of the monofocal group ($0.44 \pm 0.20$; 20/46 Snellen [$P < 2.7 \times 10^{-4}$]), but significantly lower than the UNVA found in the control group ($1.00 \pm 0.00$; 20/20 Snellen [$P < 2.1 \times 10^{-4}$]).

**OBJECTIVE ACCOMMODATION AND PUPIL SIZE**

The objective accommodation was measured for all eyes by the WAM-5500 open-field autorefractor as described above. Figure 2 shows the mean accommodative amplitude for the stimulus distances of 50 (-2.00 D), 40 (-2.50 D), and 33 (-3.00 D) cm, respectively. The corresponding objective accommodative amplitudes of the accommodative eyes were: $-0.70 \pm 0.39$, $-0.93 \pm 0.47$, and $-1.07 \pm 0.45$ D, respectively. Thus, the mean objective accommodative amplitude of the accommodative eyes exceeded 1.00 D at a stimulus distance of 33 cm (-3.00 D). The monofocal eyes resulted in $-0.08 \pm 0.14$, $-0.07 \pm 0.10$, and $-0.05 \pm 0.07$ D accommodative amplitudes for the same stimulus distances. The highest mean accommodative amplitudes of $-1.13 \pm 0.35$, $-1.54 \pm 0.41$, and $-1.95 \pm 0.47$ D, respectively, were obtained in the control eyes. As seen from the plots in Figure 2, the accommodative group yielded significantly larger accommodative amplitudes at all stimuli ($P < 7.6 \times 10^{-7}$). The control group was, in turn, superior to the accommodative group at all accommodative stimuli ($P < 5.4 \times 10^{-4}$).

The pupil size of the accommodative eyes changed weakly from $4.37 \pm 0.83$ to $4.12 \pm 0.91$, $3.82 \pm 1.21$, and $4.12 \pm 0.89$ mm when the stimulus distance decreased from 5.8 m to 50, 40, and 33 cm, respectively. These variations in size were not statistically significant ($P > .26$) enough to cause changes in the mean depth of focus of the accommodative eyes.

The corresponding pupil sizes of the monofocal group were $3.82 \pm 1.22$, $3.83 \pm 1.15$, $3.85 \pm 1.05$, and $3.93 \pm 1.07$ mm, respectively, for the above stimuli. Although the pupil sizes of the monofocal group were not statistically smaller compared to the accommodative eyes ($P > .42$), this difference could eventually facilitate a greater (by approximately 0.15 D) depth of focus in individual monofocal eyes.

In the control group for the above stimulus distances, we obtained pupil sizes of $5.65 \pm 0.88$, $5.55 \pm 0.75$, $5.45 \pm 0.78$, and $5.35 \pm 0.64$ mm, respectively, showing no statistical difference ($P > .16$). The obtained sizes, systematically larger than those in the accommodative ($P < 1.8 \times 10^{-4}$) and monofocal ($P < 0.8 \times 10^{-5}$) groups, can be explained by the difference in the mean age of the patients.

**OBJECTIVE VS SUBJECTIVE ACCOMMODATION**

Using the control group as a baseline measure for accommodative performance, we compared the objective and subjective accommodative amplitudes of the accommodative and monofocal eyes. The bar plots in Figure 3 represent the mean relative subjective and objective accommodations of the accommodative and monofocal eyes at a defocus stimuli of 50 (-2.00 D), 40 (-2.50 D), and 33 (-3.00 D) cm, respectively. The results are expressed in the percentages of the corresponding...
measurements performed with the control group. As seen from the bar plots in Figure 3, the accommodative amplitudes of the accommodative eyes remained superior to the monofocal eyes at all defocus stimuli. The amplitudes of objective accommodation exceeded the corresponding subjective values in the accommodative (P < 1.1 × 10⁻⁸) and monofocal (P < 1.3 × 10⁻⁶) groups.

We analyzed the correlation between the objective and subjective measurements of accommodative amplitudes in all three groups. Our approach was to access the non-linear correlation between the visual acuity values, determined in the measurements of defocus curves, and the refractive changes caused by accommodative stimuli in the WAM-5500 open-field autorefractor measurements. The defocus parameter in subjective measurements and the defocus stimulus in objective measurements were considered as one implicit variable in the analysis.

A high and statistically significant correlation of \( r = 0.51 \) (P < 1.3 × 10⁻⁷) between the objective and subjective measurements of accommodative amplitudes was found in the accommodative group. The monofocal group, in turn, revealed a low and statistically insignificant correlation coefficient of \( r = 0.17 \) (P > .18) between the results of objective and subjective measurements. A statistically significant but slightly lower (compared to the accommodative group) correlation coefficient of \( r = 0.37 \) (P < 8 × 10⁻⁴) was found in the control group. This moderate correlation can be explained by almost constant high visual acuities in the control group for a defocus stimulus ranging from far (-0.17 D) to 33 cm (-3.00 D) and increasing visual acuity steps in the acuity chart for high visual acuities, leading to lower accuracy of visual acuity determination.

**DISCUSSION**

The current study continues a previous report from our research group on the accommodative IOL. Emphasis was placed on the accommodative performance of the accommodative IOL as stipulated by the current ISO and ANSI regulations. Objective and subjective contributions of individual eyes were assessed. An additional comparison with the eyes of control patients was made to benchmark the restoration of accommodation by the accommodative IOL.

This increased depth of focus of the accommodative IOL correlated significantly with the objective changes in the refraction of the eyes measured by the WAM-5500 open-field autorefractor. This finding indicates that the accommodative IOL outperforms the monofocal IOL in terms of visual acuity over a wide range of distances and accommodative demand. On the contrary, we found low and statistically insignificant correlations between the objective and subjective measurements of accommodation with the monofocal IOL. The accommodative IOL provided more than 50% of the visual acuities of the control eyes over a wide range of defocus. In comparison with the monofocal eyes, the accommodative eyes revealed significantly higher uncorrected distance and near visual acuities with the mean values approaching those visual acuities of the control group.

This is the first study showing that the amplitude of objective accommodation correlates well with the amplitude of subjective accommodation with the accommodative IOL. A significant accommodative response of the accommodative eyes, confirmed by the above results and analysis, suggests that the accommodative IOL is a truly accommodating lens allowing effective restoration of near and distance visual functions after cataract surgery.

**AUTHOR CONTRIBUTIONS**

Study concept and design (JLA, ANS, DR, MCR); data collection (JLA, DR, AA, YA); analysis and interpretation of data (JLA, ANS, DR, WV, MCR); writing the manuscript (JLA, ANS, DR, AA, YA, MCR); critical revision of the manuscript (JLA, DR, WV, MCR); statistical expertise (ANS); administrative, technical, or material support (JLA, ANS); supervision (JLA)

**REFERENCES**


Figure A. The Lumina lens (AkkoLens Clinical BV, Rijswijk, The Netherlands) consists of two varifocal optics that slide one onto the other to create a continuous change in the focality in the retina. Both optics are joined by the same haptic, which adequately supports the ciliary sulcus and lies over the ciliary body.

Figure B. Clinical optical coherence tomography aspect of an implanted Lumina lens (AkkoLens Clinical BV, Rijswijk, The Netherlands) in the (A) anterior and (B) central portion. The two varifocal optics are clearly visible beyond the limits of the pupillary edge. Haptics are located in the sulcus with the posterior part being supported by the ciliary body. (C) Ultrasound biomicroscopy.
Figure C. Defocus curves of the accommodative (blue) and monofocal (red) groups. D = diopters

Figure D. Mean depth of focus of the accommodative (blue) and monofocal (red) intraocular lenses. D = diopters
Figure E. Standard graphs for visual outcomes. UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity; D = diopters.

Figure F. Mean uncorrected distance (UDVA) and uncorrected near (UNVA) visual acuity of the accommodative, monofocal, and control (young) groups.