Short-term results with the Synchrony lens implant for correction of presbyopia following cataract surgery

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OBJECTIVE: To evaluate the efficacy and safety of the Synchrony® dual-optic lens, for the correction of presbyopia following cataract surgery.

SETTING: Fundación Oftalmológica del Mediterráneo, Valencia, Spain.

METHOD: Prospective, non-comparative study of 18 patients (36 eyes) in whom a Synchrony® dual-optic lens was implanted bilaterally following cataract surgery. All patients were studied preoperatively, and 1, 3 and 6 months postoperatively. The following measurements were taken: Uncorrected visual acuity (UCVA) and best corrected visual acuity (BCVA) for distance, intermediate and near vision, and the objective amplitude of accommodation using the OQAS™ system.

RESULTS: The mean age of the group studied was: 74 ± 6 years. Of the 18 patients, 8 were men and 10 women. The mean postoperative distance BCVA improved significantly, from 0.27 ± 0.17 logMAR, (0.53 on the decimal scale) to 0.06 ± 0.21 logMAR (0.96) six months after surgery (p > 0.05). The mean addition required for near vision (reading at 40 cm) was 1.87 D after 1 month, 1.66 D after 3 months and 1.5 D after 6 months. The following postoperative objective amplitude of accommodation values were found: 2.25 ± 1.00, 2.17 ± 0.77 and 2.25 ± 0.83 D, after 1, 3 and 6 months, respectively.

CONCLUSIONS: The Synchrony® dual-optic lens is a promising option for the treatment of presbyopia in patients following cataract surgery, due to its special design. However, new designs are required to improve this capability.

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Presbyopia is the most common visual dysfunction, as it occurs in almost the entire population after the age of 40. It is classically defined as the difficulty in focusing on close objects due to age-related loss of the ability of the lens to accommodate. This ability enables the human lens to change its dioptric power, depending on whether it needs to focus on close, distant or medium-distance objects.

The physiological changes that take place in the lens with aging are: increased hardness, increased light scattering in the zones of discontinuity, loss of accommodative capacity, changes in the spherical aberration and refraction index, increase in lens thickness and an increase in the curvature of its anterior and posterior surfaces.

The great development of cataract surgery, by phacoemulsification of the lens through microincisions and its replacement with an intraocular lens (IOL), has led to an increase in the number of lenses on the market that attempt to achieve the best uncorrected acuity possible at all distances. However, it is no longer sufficient to simply settle for replacing the natural lens with a static one. The new intraocular lenses need to fulfil one of the most sophisticated characteristics of lens physiology: accommodation. This has resulted in the appearance of IOL that have movement within the capsular bag to be able to focus images at all distances, just as the young lens does in physiological conditions.
These types of lenses are called “accommodating lenses”, and are based on the anterior movement of the IOL optic in response to contraction of the ciliary muscle\textsuperscript{12-15}. The interest in accommodating IOL stems from the studies performed by Cumming\textsuperscript{16}, who began researching the axial movement of the silicone haptics of these plate lenses, using A-scan ultrasound biometry. In his experiments, he pharmacologically induced contraction and relaxation of the ciliary muscle using pilocarpine and cyclopentolate, respectively. At the beginning of 1990, Cumming began to design accommodating intraocular lenses. Various models of single-optic accommodating IOLs appeared on the market, based on this axial movement of the optic. Single-optic accommodating lenses have the disadvantage of moving less than 1 mm forward during accommodation, as was determined by ultrasound biomicroscopy\textsuperscript{17}. On observing these limitations, Hara et al.\textsuperscript{18} proposed a design composed of a pair of inflexible polymethylmethacrylate optics, 6 mm in diameter, linked by four peripheral, closed polyvinylidene fluoride flexible loops that separated the optics by about 3.0 mm\textsuperscript{18,19}. These dual-optic lenses were probably the predecessors of the current Synchrony\textsuperscript{®} dual-optic lens (Visiogen, Abbott Medical Optics, AMO, Santa Ana, California, U.S.A.). This is an innovative design with dual-optics, single-piece, foldable, composed of very flexible modified silicone\textsuperscript{20}. It has a 5.5 mm anterior optic with positive dioptic power (+32 D) which is connected via haptics to a 6.0 mm negatively-powered posterior optic. These haptics have movement similar to a spring. The lens has a total length of 9.5 mm and a width of 9.8 mm (Figure 1).

Its mechanism of action is based on a lens complex consisting of two optics joined by a spring system which, at rest outside the confines of the capsular bag, produces an outward force with which it separates the optics by about 3.7 mm. When implanted within the capsular bag, the tension compresses the optics, reducing the separation between both, i.e. the resting ciliary body maintains zonular tension that is transmitted to the bag, producing outward circumferential movement of the equator, axial shortening of the capsular bag and compression of the lens system, which will result in the storage of strain energy in the connecting haptics of both optics. Elements have been incorporated into this lens system in order to control the minimal separation.

With accommodative effort, the zonule relaxes, releasing the tension on the capsular bag, thus allowing release of the strain energy stored in the interoptic articulations, and resulting in anterior displacement of the anterior optic (Figure 2). This innovative dual-optic lens design could have a promising future for treating presbyopia after cataract surgery\textsuperscript{21-23}.

PATIENTS AND METHODS

This prospective, non-comparative study included 36 eyes of 18 patients who had implantation of a Synchrony\textsuperscript{®} dual-optic accommodating IOL (Visiogen Abbott Medical Optics, AMO, Santa Ana, California, U.S.A.) following cataract surgery. All patients had a bilateral implant performed. The study was conducted according to the Declaration of Helsinki for research in humans. Of the 18 patients, 8 were men and 10 women. The mean age of the group studied was: 74 ± 6 years. Prior to the indication for surgery, the presence of associated ocular pathology was discarded, including: age-related macular degeneration, diabetic retinopathy, glaucoma, history of trauma, pseudoexfoliation, etc., or any other pathology that could affect the refractive results. The presence of corneal astigmatism greater than 1.5 diopters (D) and an anterior chamber less than 3 mm were ruled out for implantation of this lens.
Exclusion criteria:
- Abnormalities in the endothelial count or quality (ruled out in patients with fewer than 2000 cells/mm²).
- Patients who had received ocular treatment of any type 1 month before surgery.
- Patients taking medication that could cause drowsiness (antihistamines, etc.) or with a history of drug or alcohol addiction.
- Patients with poor pupil dilatation with mydriasis and cycloplegia.
- Diabetic patients with or without previous retinopathy.

All patients were studied before the surgery at the first preoperative visit, and 1, 3 and 6 months after surgery. The following measurements were taken:
- Uncorrected visual acuity (UCVA) and best corrected visual acuity (BCVA) in logMAR units. The visual acuity was measured at different distances: distance (4.80 m), intermediate (2 m, 70 cm) and near (40 cm). The intermediate visual acuity distances were chosen as they simulate the usual distances for watching television (2 m) or working in front of a computer (70 cm). The visual acuity was measured monocularly at all visits, although after 3 months it was also measured binocularly. The optotypes used to test the VA were ETDRS distance and near charts.
- Corneal topography (Oculus Pentacam® HR) to evaluate possible changes in the corneal cylinder due to potential structural changes after surgery.
- Addition necessary for each observation distance, required by each patient, to obtain the BCVA.
- Measurement of the objective amplitude of accommodation using the OQASTM (Visiometrics-System).
- For the lens calculation (performed by the manufacturer from the data provided), ocular biometry was carried out using the IOL-Master (Carl Zeiss Meditec) version 5.0 and the OcuScan® (Ophthalmic Ultrasound System for A-scan by Alcon Laboratories). The lens calculation should be as accurate as current technology allows. Here we present a pilot study of the first patients to undergo surgery, where the difficulty in the initial lens calculation caused them to become slightly myopic.

Surgical technique

We implanted Synchrony® dual-optic accommodating-pseudo-accommodating intraocular lens (Visiogen, Irvine, California) bilaterally in all patients included in the study. This is a foldable silicone IOL, dual-optic, with spherical design but in a single piece. Both optics are connected by spring-type haptics. The power of the anterior optic is fixed at 32 D, but the posterior varies depending on the personalised dioptic power of each patient. This lens is not toric, i.e. it is not designed to compensate for preoperative astigmatism.

Centred circular capsulorhexis not greater than 5 mm was performed in all cases (Figure 3A), so that once the lens had been inserted into the capsular bag (Figure 3B and 3C), the anterior optic remained below the rim of the circular capsulorhexis (Figure 3D).

After phacoemulsification had been performed using the Infinity System platform (Platform Alcon®, Alcon Infinity System. Inc. Fort Worth Texas, USA) through a main limbal incision of 2.2 mm, the lens was implanted in the capsular bag using an injector, after uncomplicated surgery. One of the greatest advantages of this lens is that it is preloaded in a very smooth-handling cartridge that allows the lens to be inserted into the bag through an incision of between 3.8 and 4.00 mm, depending on the lens power of each patient. All patients received the same postoperative regimen of antibiotic and corticoid eye drops for 4 weeks at a dose of 4 times daily initially and then in tapered doses (Tobramycin + Dexamethasone) (Tobradex® Ophthalmic Suspension, Alcon Cusi, Barcelona, Spain).

Statistical analysis

Data were analyzed using SPSS. Normal distribution of variables was assessed using the Kolmogorov-Smirnov test. Repeated-measures analysis of variance (ANOVA) was used to gauge any statistically significant difference within the different situations. Post-hoc multiple comparison testing was performed using the Scheffé F test. Differences were considered...
to be statistically significant when the p value was < 0.05. The results shown below are expressed as mean ± standard deviation (SD).

RESULTS

Visual Acuity

The mean postoperative distance BCVA improved significantly from 0.27 ± 0.17 logMAR (0.53 on the decimal scale) to 0.06 ± 0.21 logMAR (0.96) six months after surgery (p > 0.05).

Figure 4 shows the mean BCVA values over time for the four distances analysed (distance, intermediate-TV, intermediate-computer and near), both monocular (Figure 4A) and binocular (Figure 4B). We did not find any statistically significant differences between the 3 month and 6 month visits for the far and intermediate distances in monocular vision; however, we did find statistically significant differences between the 1 month visit and all the other visits for all distances. Although we observed a decrease in BCVA at the 40 cm distance, this behaviour was not statistically significant (p = 0.68).

In binocular vision (Figure 4B, binocular AV only evaluated at 3 and 6 months postoperatively), the slight improvement observed at all distances was not significant (p = 0.34 for distance vision, p = 0.62 for intermediate 2 m, p = 0.38 for intermediate 70 cm and p = 0.79 for near vision –40 cm–).

Figure 5 shows the mean values over time for the UCVA in monocular (Figure 5A) and binocular vision (Figure 5B) for the four distances measured. In all cases, the VA improved when the patient was optically compensated. The lowest UCVA was 0.35 logMAR, obtained in monocular vision at the 1 month visit. We observed a slight improvement in the mean UCVA values over time in all cases; this improvement was significant for the 70 cm distance between the 1 month visit and the other visits (p = 0.009 and p = 0.0002, respectively), and for the 2 m distance between the 1 month and 6 month visits (p = 0.03).
Table 1. Mean spherical equivalent (in diopters) for each visit and distance measured. At the first preoperative visit, only the BCVA was measured for distance vision.

<table>
<thead>
<tr>
<th>Distance</th>
<th>Preoperative</th>
<th>1 month</th>
<th>3 months</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.80 m</td>
<td>−0.66 ± 2.6</td>
<td>−0.94 ± 1.00</td>
<td>−0.86 ± 1.14</td>
<td>−0.84 ± 1.12</td>
</tr>
<tr>
<td>2 m</td>
<td>N/A</td>
<td>−0.68 ± 0.79*</td>
<td>−0.75 ± 1.12</td>
<td>−0.52 ± 0.98*</td>
</tr>
<tr>
<td>70 cm</td>
<td>N/A</td>
<td>−0.14 ± 0.79</td>
<td>−0.36 ± 1.05</td>
<td>−0.22 ± 1.12</td>
</tr>
<tr>
<td>40 cm</td>
<td>N/A</td>
<td>+0.85 ± 0.93</td>
<td>+0.59 ± 1.33</td>
<td>+0.54 ± 1.30</td>
</tr>
</tbody>
</table>

In all cases, the patients’ VA was better if they were optically compensated. The lowest mean UCVA obtained was 0.35 logMAR (0.45), which was found at monocular level 1 month post-surgery. A slight improvement was observed in the UCVA over time in all cases, but this was only significant for the 70 cm distance between the 1 month visit and the other visits (p = 0.009 and p = 0.0002, respectively), and for the 2 m distance between the 1 month and 6 month visits (p = 0.03).

The mean spherical equivalent (manifest refraction) 6 months after the cataract surgery was slightly myopic, −0.84 ± 1.12 D (table 1). Table 1 shows the mean evolution over time of the spherical equivalent of the optic compensation necessary for the four observation distances analysed. Although changes were observed in the spherical equivalent over time, these were only statistically significant at the 2 m distance at the 1 month and 6 month visits.

Table 2. Objective amplitude of accommodation (D) obtained with the OQAS™.

<table>
<thead>
<tr>
<th></th>
<th>1 month</th>
<th>3 months</th>
<th>6 months</th>
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<tbody>
<tr>
<td></td>
<td>2.25 ± 1.00</td>
<td>2.17 ± 0.77</td>
<td>2.25 ± 0.83</td>
</tr>
</tbody>
</table>

Figure 6 shows the mean addition necessary for each observation distance required by each patient to obtain the BCVA. The mean addition needed for near vision (reading at 40 cm) was 1.87 D after 1 month, 1.66 D after 3 months and 1.5 D after 6 months. This requirement was reduced substantially for the TV intermediate distance (2 m) to 0.06 D, 0.09 D and 0.19 D, and for the computer intermediate distance (70 cm) to 0.7 D, 0.5 D and 0.5 D after 1, 3 and 6 months, respectively. This is an indirect measure of the subjective accommodative amplitude.

The objective accommodative amplitude showed the following postoperative values: 2.25 ± 1.00, 2.17 ± 0.77 and 2.25 ± 0.83 D, after 1, 3 and 6 months, respectively. Table 2 shows the mean and standard deviation for the evolution over time of the objective accommodative amplitude measured using the OQASTM (Visiometrics-System). No significant changes were observed in the amplitude of accommodation over time (p = 0.84), and it remained fairly constant from the first month.

None of the patients in this group complained of glare, halos or visualization of abnormal optical defects.

**DISCUSSION**

After assessing the preliminary results of the Synchrony® accommodating IOL, this lens appears to provide only a minimal amount of accommodation. Most of our patients required some glasses for distance vision, as the spherical equivalent indicated a slight myopic shift (Table 1) that had to be offset for the proper functioning of this intraocular lens in intermediate and near vision. This myopic shift shows a tendency, although not statistically significant, to decrease over time. The VA obtained in all cases were similar to those that can be obtained with patients implanted with monofocal IOLs in distance vision, as shown in many studies in the literature24,25.
Strenk et al., in their studies\(^2\), observed that the ciliary muscle maintains some function in presbyopic eyes, even in patients aged 70-80 years old. In our case, as can be seen, the patients did have a slight accommodative capacity, as in all cases the addition required for any of the distances evaluated was always lower than the addition that a patient without any accommodative capacity would require. However, the ciliary capacity is not maximal, as no patients were found who did not require any addition in near vision to obtain BCVA (Figures 4A and 4B). This may be because, due to the time that ciliary muscle has been unused, it requires a little training to function again. As can be observed in our results, over time the mean addition required was slightly lower (Figure 6) and a slight significant improvement was obtained in the UCVA at intermediate distances (70 cm and 2 m). These results thus suggest that, with adequate training, these patients may be able to achieve greater amplitudes of accommodation.

However, the patients in our group were elderly (mean age: 74 ± 6 years), so in theory ciliary muscle training would be completely ineffective. This could explain the better results obtained for this lens by other authors\(^22,23\), whose study groups were composed of younger patients. To analyse this fact (with our data), patients were divided into two groups aged 60-69 years and over 70 years, and all the data measured were compared. No statistically significant differences were observed, so the initial assumption of ciliary muscle training does not appear to be a bad suggestion.

With respect to the UCVA (Figures 5A and 5B), a VA below 0.4 logMAR (0.4 decimal) was not obtained for any distance, even in the worst case. In fact, at 40 cm, the minimum mean UCVA achieved was 0.27 logMAR after 6 months (the best VA was 0.22 logMAR after 6 months). Moreover, VAs higher than 0.3 logMAR (0.5 decimal) were also achieved at intermediate distances. The fact that the best UCVA was obtained for the 70 cm distance is due to patients’ residual optic compensation, as can be seen in table 1. This tells us that its distant point is close to this point in most cases. This means that, at intermediate distances, better results are obtained with this pseudo-accommodating lens than with a multifocal lens, as has been demonstrated by some authors\(^24\). With this type of lens, our patients have a VA that allows them to perform various near and intermediate tasks without needing compensation, although after adding the refraction that they required, the improvement in VA was significant. On the contrary, studies can also be found in the literature that support better quality of vision with multifocal lenses\(^25\).

Comparing the VA results in binocular (Figures 4B and 5B) with respect to monocular vision (Figures 4A and 5A), both for UCVA and BCVA, we can see that the results in binocular vision are superior to monocular vision (\(p < 0.05\)). The worst case value in binocular vision was 0.19 logMAR (0.6 decimal) in distance vision after 6 months without compensation, while for intermediate and near distances, the lowest mean value obtained was 0.16 logMAR without compensation. Therefore, in binocular vision, the patients obtained acceptable VA, which improved when compensated optically.

The estimation made by the OQAS\(^\text{TM}\) of the objective monocular amplitude of accommodation exceeded that obtained subjectively in our patient group (Table 2). Although the estimation of the need for addition for near vision (Figure 6) does not directly measure the amplitude of accommodation, these two values should correlate. However, according to the OQAS monocular amplitude of accommodation, the patient had sufficient accommodative amplitude so as not to require addition at a distance of 40 cm. This could suggest that the patient has sufficient accommodative capacity to accommodate, and that he or she simply needs training to achieve full performance.

In conclusion, we can say that the Synchrony\(^\text{TM}\) pseudo-accommodating lens allows better VA to be achieved at intermediate and near distances than can be achieved with multifocal lens. The use of this intraocular lens may be an option for compensating presbyopia, providing that the patient meets the minimum anterior chamber requirements so that the lens has sufficient space to move and to thus maximise its performance. New models that improve the future design of this lens could improve the results.

**REFERENCES**


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