Visual and subjective outcomes after diffractive trifocal lens implantation in clear lens exchange

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OBJECTIVE: To evaluate visual and subjective outcomes after diffractive intraocular lens (IOL) implantation in clear lens exchange.

SETTING: Institut Català de Retina, Barcelona, Spain.

METHODS: Prospective, non-interventional study of patients undergoing clear lens refractive surgery with implantation of a trifocal IOL. Subjective refraction and visual acuity were analyzed for uncorrected distant visual acuity (UDVA) and corrected distant visual acuity (CDVA) and for uncorrected near visual acuity (UNVA) and corrected near visual acuity (CNVA), 1, 3 and 6 months after surgery. Aberrometry was performed to determine the higher-order root mean-square (RMS). Bilateral contrast sensitivity function was obtained under mesopic conditions. The quality of visual function was evaluated using the VF-14 method.

RESULTS: Mean monocular CDVA was 0.06 ± 0.07 logMAR and mean monocular UNVA was 0.02 ± 0.05 logMAR. Spherical equivalent (SE) 6 months after surgery was 0.03 ± 0.35 D. The safety index for distant vision was 1.0 and the efficacy index was 0.91. Mean higher-order RMS was 0.27 μm. Contrast sensitivity was lower in the postsurgery period, with values within normal ranges for adults. VF-14 value was 92.96.

CONCLUSION: Diffractive trifocal IOL implantation after clear lens exchange is a safe and effective method that provides excellent outcomes and high quality visual function in distant and near vision.

J Emmetropia 2014; 5: 83-87

Multifocal intraocular lens (IOL) implantations are currently the most widely used method for correcting presbyopia and achieving independence from spectacles after cataract surgery\(^1\). Multifocal IOLs are defined optically as having multiple focal points. In the past, they were strictly limited to two focal points, one for distant vision and another for near vision. This, however, has changed recently with the introduction of a new trifocal lens. The optics of the FineVision lens (PhysIOL\(^a\); PhysIOL S.A., Liège, Belgium) combine two diffractive structures to create three focal points for distant, intermediate and near vision.

Some publications showed good visual outcomes after implantation of other diffractive trifocal IOLs, but a high rate of dysphotopsia was reported\(^2\). Another study by Sheppard et al.\(^3\) showed excellent visual outcomes and high satisfaction after implantation of the FineVision trifocal lens in cataract surgery.

The aim of this study is to evaluate the visual and subjective outcomes after FineVision trifocal IOL implantation. To date, no study has evaluated these outcomes in patients undergoing clear lens exchange.

PATIENTS AND METHODS

An interventional prospective study was carried out in ametropic presbyopes with clear lenses undergoing clear lens exchange with the FineVision trifocal IOL. Interventions were conducted in the Refractive Surgery
Unit of the Institut Català de Retina, Barcelona, Spain, between February 2012 and February 2013. Fifty-four (54) eyes of 27 patients, 22 women and 5 men, ages ranging from 47 to 69 years, were included.

Patients with any associated ocular disease (including cataracts), astigmatism of 1.50 D or more, previous eye surgery or inflammation were excluded.

The study was approved by the local research ethics committee.

**Intraocular lens**

FineVision is an aspheric trifocal IOL, composed of 25% hydrophilic acrylic material with blue and ultraviolet blocker. It is a single piece biconvex structure, with a total diameter of 10.75 mm and optic body diameter of 6.15 mm. It is available in powers of +10.00 D to +30.00 D in 0.50 D steps. The optic zone combines two diffractive structures of +3.50 D and +1.75 D adjusted for near vision and intermediate vision respectively.

**Surgical technique**

All interventions were carried out by the same experienced surgeon (FDM) using a phako-aspiration technique. Topical anesthesia (lidocaine 2.0%) and sedation with midazolam (range: 1-3 mg), fentanyl (range: 50-100 μg) and propofol (range: 10 -50 μg) were administered to all patients. A 2.2 mm sutureless incision was made in the temporal side in all cases. The IOL was implanted in the capsular bag with a Viscoject™ Bio 2.2 injector (Medicel AG, Wolfhalden, Switzerland). In myopic patients, capsular tension ring was implanted. After surgery, moxifloxacin hydrochloride (eye drops in solution, 1 mg/ml) and propofol (range: 5 mg/ml) were applied every 8 hours for one week and a tapering schedule of dexamethasone sodium phosphate (eye drops in solution, 1 mg/ml) was used for three weeks. Lens exchange was performed in the second eye one week after the initial intervention.

**Postoperative follow-up**

All patients were evaluated one day and one, three and six months post-surgery. Subjective refraction and visual acuity (logMAR) was measured for uncorrected and corrected both near and distant vision. Aberrometry (Wavelight* Analyzer; Alcon Cusí, S.A., El Masnou, Spain) was performed at 3 months to determine the higher-order root mean-square (RMS), applying Zernike terms for third-order or greater aberrations in 5 mm pupils.

At six months, the CSV-1000 test was used to measure distance binocular contrast sensitivity under mesopic conditions at spatial frequencies of 3, 6, 12 and 18 cycles per grade.

Higher-order RMS and contrast sensitivity values should not present significant variability in the post-surgical period beyond one month after surgery45, so this test was carried out once only between 3 and 6 months after surgery.

Patient satisfaction was evaluated with the modified VF-14 overall satisfaction test, 6 months after surgery.

The VF-14 questionnaire is a method for evaluating visual function quality from the patients’ point of view. It was originally developed by Steinbert et al.4 for evaluating cataract patients in their daily lives. VF-14 has been shown to correlate with visual acuity and contrast sensitivity7. It consists of 14 questions on activities of daily life that might be affected by vision (Table 1). The five responses range from “not possible” to “no difficulty at all”. These responses are scored from zero (not possible) to 4 (no difficulty at all) and the total score from the 14 questions is divided by the number of responses made. The quotient is multiplied by 25 to calculate the final score. The final result is 100 if all responses to all questions is “no difficulty at all” and 0 is the response to all questions is “not possible”. We modified the VF-14 questionnaire slightly in order to update it (see Table 1).

**RESULTS**

Mean age of the patients was 55.7 ± 5.2 years (range: 47-69 years). Mean preoperative spherical equivalent refraction (SE) was 0.36 ± 4.1 (range: −10.12 to +7.0). Mean axial length was 23.43 ± 1.53 mm (range: 21.81 to 27.39 mm). All of them underwent clear lens aspiration surgery without complications. The FineVision trifocal IOL was implanted in the capsular bag and was well-centered in all eyes. The power of the IOL varied from +10.50 to +28.00 D. There were no intraoperative complications.

Mean monocular subjective refraction was sphere 0.04 ± 0.40 D (range: −0.88 to +1.00 D) and cylinder −0.41 ± 0.36 D (range: 0 to −1.50 D) one month after surgery; sphere 0.15 ± 0.37 (range: −0.75 to +1.00 D) and cylinder −0.39 ± 0.36 D (range: 0 to −1.25) three months after surgery; and sphere 0.21 ± 0.34 D (range: −0.25 to +1.25) and cylinder −0.35 ± 0.35 D (range: 0 to −1.00 D) six months after surgery.

Spherical equivalent was −0.16 ± 0.40 D (range: −0.88 to +1.00 D) one month after surgery; −0.04 ± 0.37 D (range: −0.88 to +1.00 D) three months after surgery; and 0.03 ± 0.35 D (range: −0.50 to +1.25 D) six months after surgery. After six months, the safety index for distant vision was 1.0 and the efficacy index was 0.91. Table 2 shows mean monocular and binocular distant and near visual acuities, one, three and six months after surgery. Overall patient satisfaction determined using the VF-14 test was 92.96.
Table 1. Modified VF-14 questionnaire

With your present vision, how much difficulty do you have with the following activities?
1. Reading small print (such as, a telephone book, medicine bottle labels)
2. Reading a newspaper or a book
3. Reading a large-print book or large-print newspaper
4. Recognizing people when they are close to you
5. Seeing steps, stairs or curbs
6. Reading street signs, house numbers or colors of traffic lights
7. Doing fine handwork like sewing, fixing a plug or banging in a nail
8. Reading numbers on a mobile telephone or using devices such as an iPad
9. Playing card games, dominos or bingo
10. Taking part in activities like bowls, picking mushrooms, looking after plants or window shopping
11. Cooking
12. Watching television
13. Driving during the day
14. Driving at night

Figure 1 shows mean binocular contrast sensitivity function in mesopic conditions, comparing the preoperative status with status six months after surgery. Mean higher-order RMS was $0.27 \pm 0.07 \mu m$ and mean spherical aberration was $0.04 \pm 0.02 \mu m$ at three months in 5 mm pupils.

**DISCUSSION**

Nowadays, excellent visual outcomes and independence from spectacles for near and distant vision can be achieved by the introduction of new multifocal lenses together with clear lens extraction.

Table 2. Mean monocular and binocular visual acuities (logMAR), 1, 3 and 6 months after surgery

<table>
<thead>
<tr>
<th>Parameter</th>
<th>1 month</th>
<th>3 months</th>
<th>6 months</th>
</tr>
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<tbody>
<tr>
<td><strong>Monocular</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UDVA LogMAR</td>
<td>$0.08 \pm 0.10$</td>
<td>$0.06 \pm 0.10$</td>
<td>$0.06 \pm 0.07$</td>
</tr>
<tr>
<td>CDVA LogMAR</td>
<td>$0.02 \pm 0.04$</td>
<td>$0.01 \pm 0.03$</td>
<td>$0.01 \pm 0.02$</td>
</tr>
<tr>
<td>UNVA LogMAR</td>
<td>$0.07 \pm 0.09$</td>
<td>$0.05 \pm 0.07$</td>
<td>$0.05 \pm 0.06$</td>
</tr>
<tr>
<td>CNVA LogMAR</td>
<td>$0.03 \pm 0.07$</td>
<td>$0.02 \pm 0.05$</td>
<td>$0.02 \pm 0.05$</td>
</tr>
<tr>
<td><strong>Binocular</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CDVA LogMAR</td>
<td>$0.00 \pm 0.01$</td>
<td>$0.00 \pm 0.01$</td>
<td>$0.00 \pm 0.01$</td>
</tr>
<tr>
<td>CNVA LogMAR</td>
<td>$0.01 \pm 0.04$</td>
<td>$0.01 \pm 0.04$</td>
<td>$0.01 \pm 0.04$</td>
</tr>
</tbody>
</table>

UDVA: uncorrected distant visual acuity; CDVA: corrected distant visual acuity; UNVA: uncorrected near visual acuity; CNVA: corrected near visual acuity
The theoretical principle of diffractive trifocal IOL is based on the combination of two specific diffractive structures, permitting an asymmetric light distribution between three focal points. These combined structures of +3.50 D and +1.75 D are adjusted for near and intermediate vision, respectively. The energy loss of 20% with standard diffractive bifocal lenses is reduced with this lens to approximately 15%

There is to our knowledge, one study describing the outcome of the binocular implantation of the FineVision IOL. In our study, uncorrected distance visual acuity (UDVA = 0.06 ± 0.07) and corrected distance visual acuity (CDVA = 0.01 ± 0.02) are better than the results reported by Sheppard et al.3 (0.19 ± 0.09 and 0.08 ± 0.08 respectively) and these values remained stable over the six months of follow-up. However, in Sheppard’s study, patients had cataracts and the mean age was higher (69.8 ± 10 years compared to 55.7 ± 5.2 years), which might explain the difference.

This is the first study evaluating outcomes after FineVision trifocal IOL implantation in clear lens exchange. There were few studies evaluating this technique combined with multifocal lens implantation. The predictability achieved with this lens in our study, after a six-month period, is very high (SE: 0.05 ± 0.35 D): 95% of patients had an SE ≤ 0.50 D. The SE was lower than that found by Altaie et al.9 with the ReSTOR® IOL in patients undergoing clear lens exchange (SE: 0.15 ± 0.15 D). In the present study, the predictability was higher than that found by Fernandez-Vega et al.10 with the ReSTOR Natural in patients undergoing clear lens exchange (90.9% in myopic and 88.6% of hyperopic within ±0.50 D of the target refractive change). In another study, Alfonso et al.11 revealed a mean postoperative SE of +0.14 ± 0.22 D after presbyopic lens exchange with bilateral Acrysof® ReSTOR® Natural (SN60D3) in emmetropic eyes, however, 100% of the eyes were within ±0.50 D. Because of extreme axial lengths in myopic and hyperopic eyes, it is difficult to get an accurate measurement, which affects adequate IOL power selection. As a result, residual refractive errors are expected in this cases11.

In our study, the VF-14 method gave a value of 92.96, demonstrating high overall satisfaction. This was similar to a study comparing different types of multifocal lenses: ReZoom® (Abbott Medical Optics Inc., Santa Ana, CA, USA), AcrySof® ReSTOR® (Alcon Cusi, S.A., El Masnou, Spain) and TECNIS® Multifocal Implantable Lens (Abbott Medical Optics Inc., Santa Ana, CA, USA) which produced VF-14 scores of 92.4, 91.7 and 93.7 respectively12. The visual outcomes of our study were much better than those of the multifocal lenses described in other studies, but patient satisfaction was not greater. This may be because visual acuity was not the only determinant factor in the final VF-14 score, and independence from spectacle both for near and distant vision, freeing subjects from limitations in their activities of daily life, was achieved with all the multifocal lenses.

Multifocal IOLs split light into two or more focal points that are superimposed with the out of focus image, affecting visual quality. This includes contrast sensitivity and dyphotopic phenomena such as halos may appear13. In our study, despite a reduction of contrast sensitivity, the spatial frequencies values of 3, 6, and 18 cycles per grade obtained with the CSV-1000 (Pomerance and Evans14) are within normal ranges for adults. The mean spatial frequency of 12 cycles per grade was lower than the normal range for adults, both in the preoperative evaluation and six months after surgery. This values, in mesopic conditions, are similar to a study of Ferrer-Blasco et al. with the Acrysof® ReSTOR® IOL in patients undergoing clear lens exchange15.

Due to its apodized diffractive surface and aspheric profile, the spherical aberration induced by FineVision is minimal, and this may be reflected in the low mean higher-order RMS at 3 months in 5 mm pupils. This value is lower than that shown with the AcrySof® ReSTOR® IOL (0.27 μm vs. 0.35 μm) in a study comparing that IOL with another three monofocal IOLs16. However, it is similar to that found by Montés-Micó et al. with the ReSTOR® (0.27 μm vs 0.24 μm)17. The mean level of postoperative spherical aberration (0.04 μm) was slightly lower to that found by Rocha et al.16 (0.09 μm) and to that found by Montés-Mico et al.17 (0.08 μm) with the ReSTOR® IOL.

In conclusion, clear lens exchange with FineVision IOL implantation is a very predictable, effective and safe procedure, giving high overall patient satisfaction, that provides independence from glasses with excellent distant and near visual acuity outcomes. One year after surgery, the intermediate vision of these patients can be evaluated with a defocus curve.

REFERENCES


