The ReZoom multifocal intraocular lens: 2-year follow-up

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Purpose. To evaluate distance, intermediate, and near visual acuity and patient satisfaction over a period of 2 years after implantation of the ReZoom multifocal intraocular lens.

METHODS. Fifty-five eyes of 35 cataract patients were included in this retrospective study. Only patients with a preoperative photopic pupillary diameter superior to 3 mm were included. Monocular visual acuities and visual symptoms were compared at different time points.

RESULTS. Preoperative mean distance uncorrected visual acuity (UCVA) was 0.5 ± 0.3 LogMAR, uncorrected intermediate visual acuity (UCiVA) at 50 cm was 0.6 ± 0.3 LogMAR, and near uncorrected visual acuity (UNVA) was $J7.8\pm0.6$. Mean follow-up was 28.1 ± 7.2 months. At 6 months, UCVA improved to 0.05 ± 0.09 logMAR (p<0.001), UCiVA to 0.08 ± 0.1 LogMAR (p<0.001), and UNVA to $J2.4\pm0.4$ (p<0.001). At 24 months, UCVA was 0.04 ± 0.08 LogMAR, UCiVA was 0.07 ± 0.1 LogMAR, and UNVA was $J2.3\pm0.7$. No significant differences were observed between the values at 6 months versus 24 months. At the 3-month visit, moderate glare and halo were reported by 10% and 13% of patients, respectively. The occurrence of visual symptoms decreased with time, with only 7% and 5% of patients reporting moderate glare and halo at the last visit, respectively.

Conclusions. The ReZoom lens provides quality vision at all distances. Between 6 and 24 months of follow-up, a further improvement of optical disturbances rather than uncorrected visual acuity may be expected. (Eur J Ophthalmol 2009; 19: 380-3)

KEY WORDS. ReZoom MIOL, Multifocal intraocular lens, Long-term follow-up, Near visual acuity

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INTRODUCTION

Today's sophisticated optical designs of intraocular multifocal lenses (MIOLs) have resulted in improved postoperative near vision and reduction of spectacle dependence as compared to early generations (1). The ReZoom (Advanced Medical Optics, model NXG1) zonal progressive refractive lens belongs to this second generation MIOL and features five alternating optical zones with aspherical transitions. Zones 1 (central zone), 3, and 5 are weighted for distance, while zones 2 and 4 are weighted for near focus. The aspherical transitions between the zones provide balanced intermediate vision. ReZoom is made of hydrophobic acrylic material and has been designed to

decrease glare and halos. In this study we evaluated distance, intermediate, and near visual acuity, occurrence of photic phenomena, and spectacle independence after implantation of the ReZoom MIOL during a 2-year follow-up.

METHODS

We retrospectively reviewed the charts of all patients (n=35) who underwent ReZoom MIOL implantation between May 2005 and May 2007 at the Eye Department of the Fatebenefratelli Hospital of Benevento, Italy. Patients were randomly selected in one unmasked site. Only patients with a preoperative photopic pupillary di-

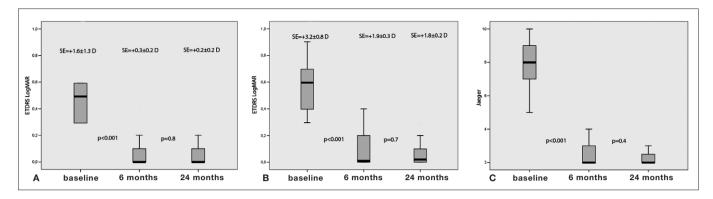


Fig. 1 - (A) Far, (B) intermediate, and (C) near monocular uncorrected visual acuity at baseline and at 6 and 24 months after ReZoom implantation. SE = spherical equivalent.

ameter ≥3 mm and an antero-posterior axis shorter than 23 mm were included. Patients with an irregular corneal topography pattern, previous corneal surgery, retinal pathology, astigmatism >3 D, or a history of ocular disease were excluded from the study. Intraoperative exclusion criteria were iris pupillary trauma, vitreous loss, and inability to place the IOL in the capsular bag. All patients signed a written consent form that, along with the study design, was approved by the institutional review board. Preoperative assessment consisted of a complete ophthalmologic examination, biometry (IOLMaster, Zeiss), and refraction. Distance uncorrected and best-corrected visual acuity (UCVA, BCVA, respectively), intermediate uncorrected and corrected visual acuity at 50 cm (UCiVA, BCi-VA. respectively), and near uncorrected and best distance corrected near acuity at 31 cm (NVA, DCNVA, respectively) were measured for each operated eye preoperatively and postoperatively. Distance and intermediate VA were tested using the Early Treatment Diabetic Retinopathy Study (ETDRS) LogMAR scale visual charts. Near VA was measured with the Jaeger near chart. Distance VA was tested in photopic conditions (85 cd cd/m²), intermediate VA was tested in mesopic conditions (6 cd/m²), and near VA was measured in mesopic conditions (6 cd/m²) using 100% contrast optotypes. Additionally, a 7-item visual functioning questionnaire (VF-7) (2) was used to assess the difficulties in vision-dependent activities of everyday life and visual satisfaction. Postoperative spectacle independence was also evaluated. The MIOL power was calculated using the SRK/T formula; the target was emmetropia in all cases. Intraocular lens implantation occurred within 35 days of the preoperative visit. All operations were performed by an experienced surgeon (P.U.). A 2.7 mm clear corneal incision was placed at the steep-

est meridian. A standard phacoemulsification technique was used. The lenses were injected into the capsular bag using an Emerald injector. Postoperative follow-up examinations were performed at 1 day, 1 week, and 1, 3, and 6 months interval. Statistical analysis was performed using the Statistical Package for Social Sciences (version 13.0, SPSS Inc., Chicago, IL, USA). For categorical variables, the Pearson chi-square test was applied when appropriate. To compare visual acuity over time, Wilcoxon rank-sum test was used. p<0.05 was defined as statistically significant.

RESULTS

Fifty-five eyes of 35 cataract patients were included in the study. The mean patient age was 71 ± 7 years. Mean pupil size was 3.1 ± 0.06 mm in photopic conditions and 3.6 ± 0.4 mm in mesopic conditions. Bilateral implantation was performed in 20 cases and monolateral implantation in 15 cases. There were no intraoperative or postoperative complications. Mean follow-up was 28.1 ± 7.2 months. A follow-up of 24 months was obtained in 47 cases.

Preoperative mean spherical equivalent (SE) at distance and intermediate distances were $+1.6\pm1.3$ D and $+3.2\pm0.8$ D, respectively, with a mean astigmatism of 0.4 ± 0.3 D. Changes over time in monocular far, intermediate, and near VA are shown in Figure 1. At the 6-month follow-up visit, mean SE at distance was $+0.3\pm0.2$ with a mean astigmatism of 0.3 ± 0.2 D, and UCVA had improved significantly from 0.5 ± 0.3 (baseline) to 0.05 ± 0.09 LogMAR (p<0.001) while BCVA was 0.05 ± 0.2 LogMAR. Similarly, significant improvement was observed with UCiVA (0.6 ± 0.3) vs 0.08 ± 0.1 LogMAR [p<0.001]) and NVA

 $(J7.8\pm0.6 \text{ vs } J2.8\pm0.4 \text{ [p<0.001]})$. BCiVA was 0.08 ± 0.07 and DCNVA was J2.1±0.2. Although nonsignificant, there was a trend for further VA improvement between 6-month and 24-month follow-up. The questionnaire revealed that 100% of patients with bilateral implantation achieved spectacle freedom for distance and intermediate vision soon after 6 months from implantation while near vision spectacle freedom was achieved in 75% of the cases (n=41). This tendency remains stable during the follow-up. All patients with monolateral implantation enjoyed spectacle freedom for intermediate vision. In one case only laser capsulotomy was performed after 18 months because of posterior capsule opacification. After 3 months of followup, moderate glare was present in 10% of cases while moderate halos were reported by 13% of patients. Visual symptoms decreased with time and at 24 months, moderate glare and halos were reported by 7% and 5% of patients, respectively. Severe glare was never reported.

DISCUSSION

To our knowledge, this study presents the longest follow-up (2 years) after implantation with MIOLs. Our data show that among patients with ReZoom bilateral implantation, good quality uncorrected distance, intermediate, and near visual acuities were obtained at 6 months. This was reflected by the questionnaire data which showed that 100% of patients were free from spectacles for distance and intermediate vision while 75% achieved spectacle freedom for near vision. Among patients with monolateral implantation the main visual improvement was intermediate vision.

These results are in agreement with the far-dominant optic design of the ReZoom (3) and clinical reports showing excellent distance vision obtained with this MIOL in cataract patients (4, 5). Also, the near add of 3.5 D at the MIOL plane and approximately 2.6 D at the spectacle plane seems to provide sufficient power for near vision and spectacle independence for intermediate vision as reported here and by others (4, 5). However, due to its multizone design, the Re-Zoom does not provide near function with a pupil diameter ≤2.0 mm while the percentage of light energy for near grows as pupil diameter increases (6). In our study only patients with a pupillary diameter ≥3 mm were included. The good near performance of the refractive ReZoom multifocal IOL was favorized by the mesopic condition under which we evaluated both monocular NVA and DCNVA allowing a wider exposure of the second near-focused annular zone.

Postoperative subjective photic symptoms are inherent to MIOLs. In a previous study by Chiam et al (4), moderate halos and glare were reported by 30% and 28% of Re-Zoom patients at 6 months, respectively. Halo issues were also cited by 66.7% of ReZoom patients at 6 months in a study by Chang (5). Similarly, in a comparative study of monofocal, diffractive, and refractive MIOLs. the presence of halo was reported at 12 months in 60% of refractive MIOL patients (1). In contrast, we observed here a low incidence of moderate halos and glare at 3 months (10% and 13%, respectively) which was reduced during follow-up (5% and 7% after 2 years). A likely explanation for the difference between results is the different patient selection criteria based on pupillary diameter for the implantation of ReZoom. In this context it is worth mentioning that, in the studies by others, patients were randomly selected to receive ReZoom and pupillary diameters less than 3 mm were not excluded.

Also noteworthy is the further improvement in visual acuity, although not significant, observed between 6 months vs 2 years follow-up. Taken together, our data support the idea that a prolonged neuroadaptation period is needed for the brain to ensure optimal visual outcomes after ReZoom implantation.

Because of the retrospective design of this study and the evaluation of a single type of MIOL, there is still a need for large prospective multicentric investigations comparing second generation MIOLs to strengthen the authors' findings. However, considering the poor data reported at national and international conferences about the use of ReZoom IOL in non-selected patients, we believe that emphasizing again the importance of preoperative patient selection as well as better understanding of adaptation issues are crucial steps to achieve optimal performances with MIOLs.

In conclusion, implantation of ReZoom in eyes with a pupillary diameter more than 3 mm offers good performance in terms of postoperative far, intermediate, and near vision and spectacle independence on a long term. Between 6 months and 24 months further significant improvements of optical disturbances rather than uncorrected visual acuity are expected.

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