

Clinical Outcomes After Mix-and-Match Implantation of Extended Depth of Focus and Diffractive Multifocal Intraocular Lenses

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Declarations

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ABSTRACT

Purpose: To evaluate clinical outcomes after bilateral mix-and-match cataract surgery using extended depth of focus (EDOF) and diffractive multifocal (DMF) intraocular lenses (IOLs).

Methods: Thirty-seven patients received Tecnis Symfony EDOF IOL (ZXR00) implantation in the dominant eye, and Tecnis +3.25 DMF IOL (ZLB00) in the non-dominant eye. Patients were followed for 3 months, and uncorrected and corrected distance visual acuity (UDVA, CDVA), uncorrected intermediate and near visual acuity (UIVA, UNVA), contrast sensitivity, defocus curves, stereopsis, and patient satisfaction were assessed.

Results: At 3 months, mean logMAR UDVA was 0.07 ± 0.09 in EDOF IOL eyes, 0.12 ± 0.11 in DMF IOL eyes, and 0.02 ± 0.05 in both eyes. UIVA was 0.11 ± 0.11 in EDOF IOL eyes, 0.16 ± 0.12 in DMF IOL eyes, and 0.04 ± 0.07 in both eyes. UNVA was 0.25 ± 0.15 in EDOF IOL eyes, 0.22 ± 0.16 in DMF IOL eyes, and 0.13 ± 0.13 in both eyes. Thirty patients(81.1%) were more than satisfied with near vision, and 8 patients(21.6%) complained of severe glare and halo. Spectacle independence for near vision was achieved in 34 patients(91.9%), and 31 patients(83.8%) had better than a 50 second arc of stereopsis.

Conclusion: Mix-and-match cataract surgery with EDOF and DMF IOL implantation provided good visual outcomes through all distances. Also excellent patient satisfaction was achieved with high level of spectacle independence and minimal photic phenomena.

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Keywords: mix-and-match, extended-depth-of-focus intraocular lens, diffractive multifocal intraocular lens, stereopsis

INTRODUCTION

Until 20 years ago, cataract surgery with implantation of monofocal intraocular lenses (IOLs) could restore only uncorrected distance visual acuity. However, due to accommodation loss, most patients must wear reading spectacles when viewing near objects (1). Javitt et al. found that only 9.8% of patients with bilateral implantation of monofocal IOLs did not require reading spectacles for near tasks, and 80.4% of patients needed reading spectacles half of the time or more (2). More recently, bilateral implantation of multifocal IOLs was suggested for treatment of presbyopia in cataract patients.

Various multifocal IOLs have been developed for correcting presbyopia during cataract surgery. These multifocal IOLs achieve good clinical outcomes when used with appropriate patient selection (3,4). Of the currently available multifocal IOLs, two types are most commonly used: diffractive and refractive lenses.

The multifocal Tecnis ZLB00 IOL (Johnson & Johnson Vision, Santa Ana, CA, USA), which has a diffractive posterior surface, creates two focal points and has a near addition of 3.25 diopters (D). This additional power is relative to the IOL plane and results in the approximate addition of 2.37 D at the spectacle plane. As a result, light entering the eye is evenly distributed between near vision (42%) and far vision (42%), independent of pupil size. In addition, the diffractive IOL has a modified, prolate anterior surface designed to reduce spherical aberrations with the goal of improving focusing ability and providing sharper vision, particularly in patients with large pupils.

The new concept of extended depth of focus (EDOF) IOLs has recently been developed, aiming to minimize photic phenomena commonly related to refractive and diffractive multifocal IOLs while maintaining a functional range of vision. The basic principle behind these lenses is to create a single elongated focal point to enhance the depth of focus and provide a full range of vision.

After the introduction of multifocal IOLs, a few multifocal IOLs were designed with the goal to improve near vision. Bilateral implantation of different multifocal IOLs with various optic designs and near additions, the so-called mix-and-match method, was developed to take neural adaptation into account and therefore achieve improved clinical outcomes (5,6).

The objective of the present study was to evaluate postoperative distance, intermediate, and near visual acuities, refraction, photic phenomena, and patient satisfaction in patients that underwent bilateral cataract surgery with implantation of the Tecnis Symfony EDOF IOL (ZXR00) in the dominant eye and the +3.25 D Tecnis multifocal IOL (ZLB00) in the non-dominant eye.

MATERIALS AND METHODS

Study Design

This study was a single-center, prospective case series, and comprised Korean patients that underwent cataract surgery at the Department of Ophthalmology, University of Ulsan College of Medicine, Asan Medical Center, Seoul, South Korea. All patients provided written informed consent prior to enrollment. The study followed the principles of the Declaration of Helsinki and was approved by the Asan Medical Center Review Board (2017-0713) and registered as a clinical trial. (KCT0004111)

Cataract patients aged 21 or older, who had a potential distance visual acuity of 20/25 or better in each eye and a corneal astigmatism ≤ 1.50 D were included. Patients desired postoperative spectacle independence, and were scheduled for binocular multifocal IOL implantation. Exclusion criteria included patient age older than 80 years, axial length (AL) more than 26.0 mm, intraoperative complications, and any ocular diseases other than cataract.

Treatment of the patients was performed based on the mix-and-match method as follows: patients received a Tecnis Symfony EDOF IOL (ZXR00) in the dominant eye and a multifocal +3.25 D (ZLB00) Tecnis IOL in the non-dominant eye. The dominant eye was determined using the pinhole test and was first implanted with the Tecnis Symfony EDOF IOL (ZXR00) (7). One week after surgery in the dominant eye, the +3.25 D (ZLB00) Tecnis IOL was implanted in the non-dominant eye. IOL power was calculated based on the corneal curvature and AL of the eye using an IOL Master optical biometer (Carl Zeiss Meditec AG, Jena, Germany). Preoperatively, the patients' age, sex, target refraction, IOL power, uncorrected (UDVA) and corrected distance visual acuity (CDVA), and subjective refraction were recorded.

The target refraction for the first eye was emmetropia. The target for the fellow eye was dependent on the patient's visual acuity and personal demands for precise near or distance vision, while also considering the postoperative refractive error (micro-monovision of ± 0.3 D). After considering corneal curvature, AL, and the anterior chamber depth of each eye, the IOL power was selected from the SRK II, SRK/T, Haigis, or Hoffer Q formula.

Study Lenses

The Tecnis Symphony EDOF IOL (ZXR00) and the +3.25 D (ZLB00) Tecnis diffractive multifocal (DMF) IOL were used for this study. Both models are posterior, one-piece, soft-foldable acrylic, UV-absorbing, diffractive IOLs from Johnson & Johnson Vision. Both IOLs have a biconvex optic that includes a wavefront-designed aspheric optic to compensate for corneal spherical aberration, and both lenses have a square and frosted posterior edge design. The IOLs differ in their posterior optic design because the ZXR00 IOL includes an achromatic diffractive surface to correct chromatic aberration and has a unique echelette feature to extend the range of vision. This creates an achromatic diffractive pattern that elongates a single focal point and compensates for corneal chromatic aberrations. Instead, the ZLB00 IOL is a DMF IOL with a low +3.25 D add power, which does not include the echelette feature, but splits the light into two focal points for distance and near vision.

Surgical Technique

All operations were performed by the same surgeon (H.T.) from the patient's superior side. After the application of topical anesthesia (proparacaine hydrochloride 0.5% [Alcaine]), a continuous curvilinear capsulorhexis (CCC) marker with a 6.0 mm diameter, was used as a reference to the corneal plane. The diameter was approximately 5.0 mm on the anterior capsule plane. A 2.2 mm clear corneal incision was made at the steep axis to reduce corneal astigmatism. A CCC and hydrodissection were then performed. Microcoaxial phacoemulsification and polishing were performed, and the multifocal IOL was implanted in the capsular bag. Stromal hydration of the incision site was performed using a balanced salt solution, and the surgery was completed without sutures. Postoperative moxifloxacin and fluorometholone 0.1% eyedrops were administered four times daily for 4 weeks.

Outcome Measures

All subjects underwent comprehensive ophthalmological examinations preoperatively, including logMAR visual acuity measurements of monocular and binocular UDVA, UIVA, UNVA, and CDVA. Preoperative assessments also included autorefractometry and keratometry (Canon R-50; Canon USA Inc., Huntington, NY, USA), slit-lamp examinations (Haag-Streit, Köniz, Switzerland), biometry (IOL Master 500; Carl Zeiss Meditec, Jena, Germany), and corneal topography (Orbscan, Bausch & Lomb, Rochester, NY, USA).

Ophthalmic examinations conducted at 1 and 3 months after surgery included logMAR measurements of monocular and binocular UDVA, UIVA, UNVA, and CDVA. Autorefractometry and keratometry were also performed. Intermediate visual acuity was measured at 60 cm. Near visual acuity was measured at 33, 40, and 50 cm, with near visual acuity expressed as the average visual acuity at these distances. In many previous studies, near VA was measured only at 40 (8,9). But we focused on that there were delicately different needs for near target distance in various situations such as reading books or watching mobile phones, therefore, we defined near VA more broadly as the average VA at 33, 40, and 50 cm in this study. In addition, monocular and binocular defocus curves were obtained at 3 months postoperatively by measuring monocular or binocular visual acuity at 4 meters starting from distance correction, and then defocusing with added lenses in half-diopter steps from -4.00 to 0.50 D.

Contrast sensitivity was measured monocularly under uncorrected condition at 3 months postoperatively using the Functional Acuity Contrast Test function of the Ophtec 6500 view-in test system (Stereo Optical Co, Inc., Chicago, IL, USA) with stimulus spatial frequencies between 1.5 and 18 cycles per degree under photopic (target luminance = 85 candelas per square meter [cd/m^2]) and mesopic (target luminance = 3 cd/m^2) conditions. Finally, stereopsis was evaluated using the Fly-S stereopsis test (Optimed, Sydney, Australia).

Finally, patients were asked to complete a questionnaire regarding their overall satisfaction, occurrence of visual symptoms, and dependence on spectacles for near and far vision. Overall satisfaction was assessed using a five-point Likert scale: 1 = very dissatisfied, 2 = dissatisfied, 3 = neither satisfied nor dissatisfied, 4 = satisfied, and 5 = very satisfied. Visual symptoms (glare, halo, and visual disturbances at night or in the dark) were scored on a five-point scale from 1 (absent symptoms) to 5 (severe symptoms). Patients were also asked if they would recommend bilateral mix-and-match implantation of multifocal IOLs to their friends or relatives, with allowed responses being “yes” or “no.”

Statistical Analyses

Results are expressed as means \pm standard deviation with range. Differences between preoperative and postoperative data were assessed using the Wilcoxon signed-rank test. The defocus curves for both eyes, the dominant eye, and the non-dominant eye were analyzed by the Kruskal–Wallis test with the Bonferroni correction. All statistical analyses were performed using SPSS® version 21 software (IBM, SPSS Inc., Chicago, IL, USA). Differences were considered statistically significant for *P*-values less than 0.05.

RESULTS

In total, this study enrolled 74 eyes from 37 consecutive patients, and all patients completed the 3 month postoperative visit. Preoperative subject and ocular characteristics are summarized in Table 1. Intraoperatively, a minor radial tear developed in one eye (1.4%) implanted with the diffractive multifocal IOL. A posterior capsule tear occurred in two eyes (2.7%) implanted with the EDOF IOL, and anterior vitrectomy was performed in these eyes due to vitreous loss. However, the posterior capsule tear was limited to the focal area, which was mostly intact. Therefore, in both cases, in-the-bag IOL implantation was possible. No other complications occurred during the study. Table 2 summarizes preoperative and postoperative monocular visual acuity. At 3 months postoperatively, monocular logMAR UDVA, logMAR UIVA, and logMAR UNVA of the dominant eye were 0.07 ± 0.09 (range: 0–0.40), 0.11 ± 0.11 (range: 0–0.30), and 0.25 ± 0.15 (range: 0–0.40), respectively. Monocular logMAR UDVA, logMAR UIVA, and logMAR UNVA of the non-dominant eye were 0.12 ± 0.11 (range: 0–0.30), 0.16 ± 0.12 (range: 0–0.40), and 0.22 ± 0.16 (range: 0–0.40), respectively. Postoperative monocular logMAR UDVA, logMAR UIVA, logMAR UNVA, and logMAR CDVA were all significantly better than preoperative values. Significant differences were also found between preoperative and postoperative binocular visual acuity for logMAR UDVA, logMAR UIVA, and logMAR UNVA (Table 3). At 3 months postoperatively, binocular logMAR UDVA, logMAR UIVA, and logMAR UNVA were 0.02 ± 0.05 (range: 0–0.20), 0.04 ± 0.07 (range: 0–0.30), and 0.13 ± 0.13 (range: 0–0.40), respectively. Binocular and monocular defocus curves are shown in Figure 1. Eyes implanted with ZLB00 exhibited the expected bimodal peaks at 0 and -2.5 D. Eyes implanted with ZXR00 exhibited a visual acuity of

0.20 logMAR or better between 0 and -2 D, although there was a sharp decrease in visual acuity over -2 D. The binocular defocus curve was better than each monocular defocus curve at all distances. Also, the binocular defocus curve exhibited a wider range of good visual acuity at all distances, as visual acuity was better than 0.20 logMAR from 0 to -3 D.

As shown in Figure 2, contrast sensitivity was evaluated under both photopic and mesopic conditions in eyes implanted with EDOF and DMF IOLs, with no significant differences at any spatial frequency. All subjects completed satisfaction questionnaires at 3 months postoperatively. Thirty subjects (81.1%) reported that they were satisfied or very satisfied with their near vision, with an average satisfaction score of 4.0 ± 1.0 (range: 2–5). Only three subjects (8.1%) reported occasionally needing glasses for near vision after surgery. The rate of visual disturbances was low, with eight (21.6%) subjects reporting glare and halo symptom scores worse than 3 (average score: 2.6 ± 1.0) (range: 1–5), and 31 (83.8%) patients exhibiting better than a 50 second arc of stereopsis. Thirty-four subjects out of 37 (91.9%) answered that they would recommend mix-and-match implantation to their relatives. (Table 4). No patients experienced significant posterior capsular opacity or IOL dislocation 3 months after surgery.

DISCUSSION

At present, several IOLs and methods are available for cataract extraction and presbyopia correction. These include the use of monovision accommodating IOLs, multifocal IOLs, and the mix-and-match approach. All of these IOLs and techniques correct presbyopia, but have limitations and disadvantages (10-12). One study using multifocal IOLs identified that patients were satisfied with unilateral implantation in the dominant eye, but that bilateral implantation yielded better visual outcomes and improvements in stereopsis (13).

Gunenc and Celik speculated that using one type of multifocal IOL would not provide a full range of vision, and therefore suggested bilateral implantation of two different types of multifocal IOLs during cataract surgery, including refractive multifocal IOLs and diffractive multifocal IOLs (6).

The Tecnis Symphony EDOF IOL (ZXR00) has been demonstrated to provide functional distance, intermediate, and near visual acuity, with excellent results for distance and intermediate vision, and

some limitations for near vision (14). However, compared with other multifocal IOLs, ZXR00 results in fewer postoperative photic phenomena (15). In this study, with the strength in photic phenomena, the limitation of decreased near visual acuity in EDOF IOLs was overcome by mix-and-match implantation of a DMF IOL in the non-dominant eye. Tecnis +3.25 DMF IOLs (ZLB00) were selected, which demonstrated the best near visual acuities among various types of DMF IOLs in a recent study (16).

In the present study, the bilateral multifocal IOL mix-and-match approach achieved good binocular UDVA, UIVA, and UNVA outcomes over the follow-up period of 3 months. Binocular uncorrected visual acuity showed a wide range of good postoperative vision across all distances. This is considered an adequate outcome, as this approach allowed patients to read the newspaper or use smartphones without glasses. Binocular uncorrected visual acuity was slightly better than monocular outcomes at all distances in both groups. These findings may be related to the bilateral summation.

Although postoperative satisfaction tends to decrease slightly as time progresses, about 80% of subjects reported that they were more than moderately satisfied 3 months postoperatively. The main cause of dissatisfaction was photic phenomena, as reported through the questionnaire. Photic phenomena are one of the main causes of multifocal IOL explantations (17). In the present study, the proportion of patients that reported severe photic phenomena was very low at about 20%. However, no case required IOL explanations, and the rate of severe photic phenomena was lower than that reported in previous studies (14,18,19). Further, over 90% of the subjects answered that they would recommend this type of surgery to relatives or friends. Moreover, over 80% of patients were able to obtain sufficient near stereopsis better than a 50 second arc after surgery without spectacles. This is an additional advantage of mix-and-match cataract surgery.

There are some limitations to this study that should be acknowledged. The small number of cases and relatively short-term follow-up duration warrant further larger and longitudinal studies. In addition, the incidence of photic phenomena was evaluated only subjectively. Finally, in the first three patients, the dominance examination was not performed before surgery. Therefore, the possibility of EDOF IOL implantation in the non-dominant eye in these patients cannot be ruled out. However, eye dominance is

not unchangeable, and the effect on this study would therefore not be significant.

In conclusion, mix-and-match cataract surgery with EDOF and DMF IOL implantation provided good uncorrected near, intermediate, and far visual acuity 3 months postoperatively with minimal photic phenomena and high patient satisfaction. This surgery is expected to improve patient satisfaction by lowering dependence on glasses without causing serious photic phenomena.

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FIGURE LEGENDS

Figure 1. Binocular and monocular defocus curves for patients after bilateral mix-and-match implantation of extended depth of focus (EDOF) and diffractive multifocal (DMF) intraocular lenses (IOLs). * $P < 0.05$.

Figure 2. Contrast sensitivity test under photopic and mesopic conditions in patients with mix-and-match implantation of EDOF and DMF IOLs. CPD, cycles per degree.

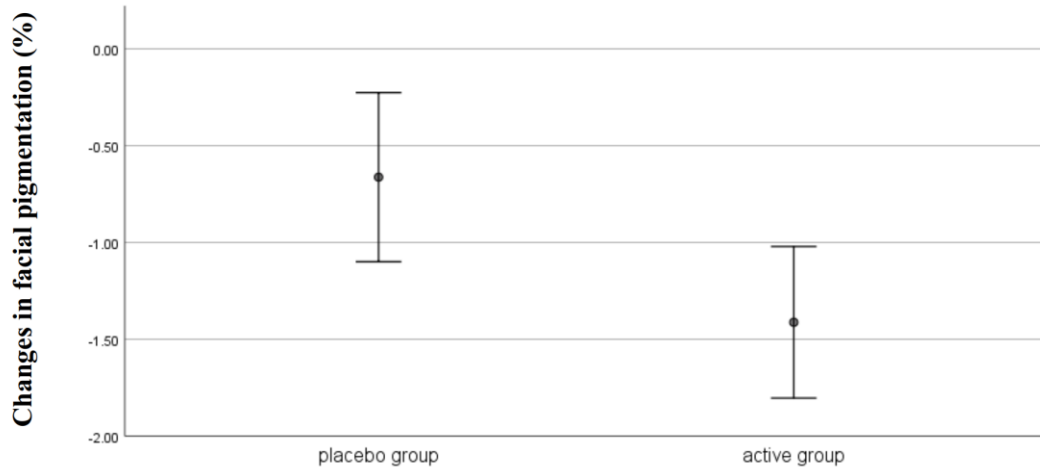


Figure 1

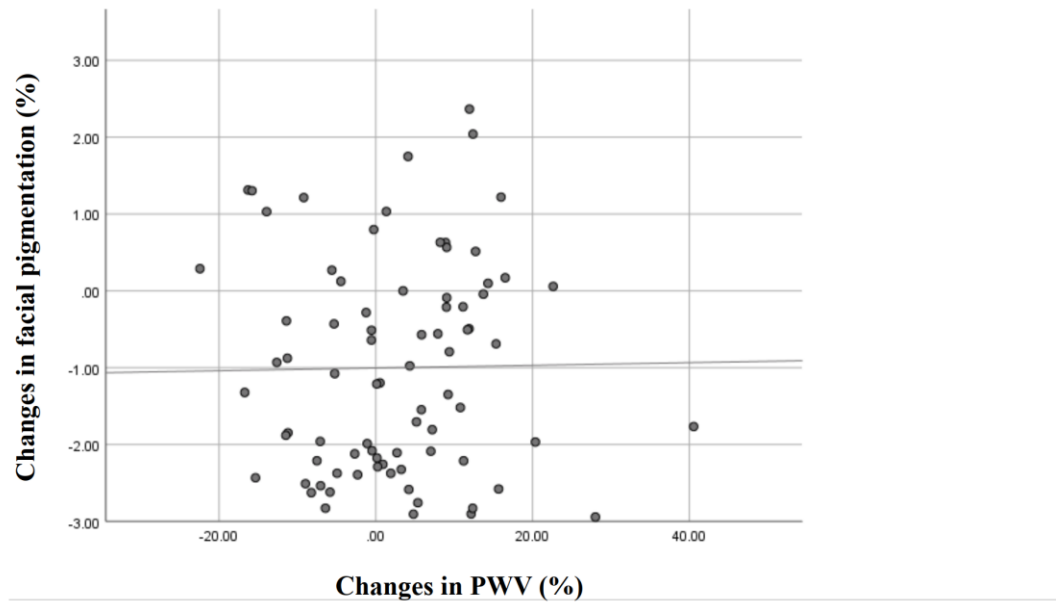


Figure 2

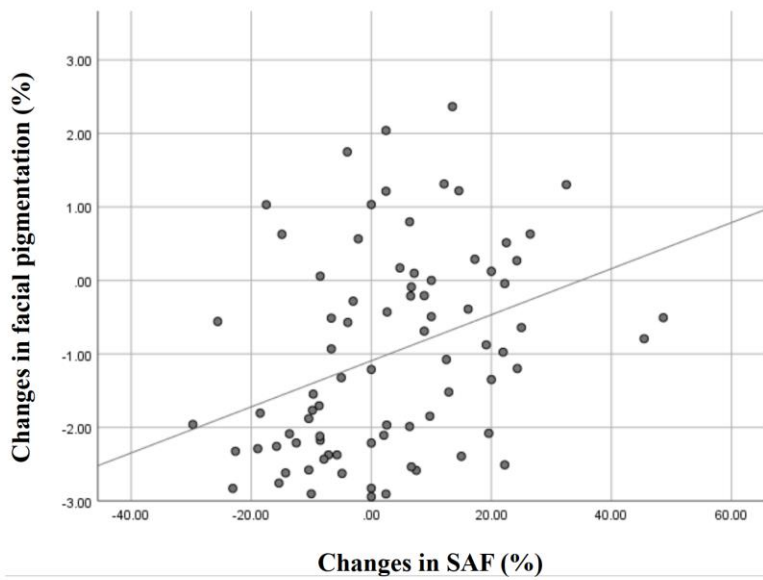


Figure 3