

Visual Performance of Wavefront-Shaping Extended-Depth-of-Focus Intraocular Lenses in Japanese Eyes after Previous Laser in Situ Keratomileusis

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ABSTRACT

Objective: To retrospectively evaluate visual performance in eyes implanted with a wavefront-shaping Extended Depth-of-Focus (EDoF) Intraocular Lens (IOL) after Laser in Situ Keratomileusis (LASIK).

Methods: Clinical records of 13 eyes from 12 patients with a history of myopic LASIK who underwent implantation of a wavefront-shaping EDoF IOL (Clareon AutonoMe (CNA0T0), Alcon) were reviewed. LASIK procedures had been performed 10-20 years earlier at other institutions. All eyes had preoperative corneal astigmatism ≤ 1.5 D because toric models were unavailable. Nineteen eyes from 17 patients without a history of LASIK were also reviewed as controls. Between 1-3 months postoperatively, evaluations included uncorrected and distance-corrected visual acuity (UCVA (Uncorrected Visual Acuity) and DCVA (Distance-Corrected Visual Acuity), respectively) at 5 m, 60 cm and 40 cm; photopic contrast sensitivity; photic phenomena (glare, halos and starbursts); and spectacle dependence.

Results: Mean logMAR UCVA was -0.04 ± 0.09 at 5 m, 0.02 ± 0.11 at 60 cm and 0.13 ± 0.12 at 40 cm. Mean logMAR DCVA was -0.15 ± 0.07 at 5 m, 0.02 ± 0.11 at 60 cm and 0.20 ± 0.16 at 40 cm. Contrast sensitivity was within the normal range. No significant differences were observed in visual acuity and contrast sensitivity compared with non-LASIK eyes ($p > 0.05$). Starburst phenomena were significantly more frequent in post-LASIK eyes ($p = 0.038$).

Conclusion: The wavefront-shaping EDoF IOL provided excellent distance and intermediate visual outcomes in post-LASIK eyes, comparable to those in non-LASIK eyes. However, the increased incidence of starbursts warrants careful preoperative counseling.

Keywords: Wavefront-shaping extended depth-of-focus IOL; LASIK; Visual function; Contrast sensitivity; Japanese eye

INTRODUCTION

Since approximately 25 years have passed since excimer laser corneal refractive surgery was approved in Japan in January 2000. Since then, Laser in Situ Keratomileusis (LASIK) has become the most widely performed procedure. Because this patient population ages, an increasing number of individuals with a history of LASIK present for cataract surgery. These patients often have high expectations for postoperative spectacle independence and frequently choose Presbyopia-Correcting Intraocular Lenses (PC IOLs), including multifocal designs.

Clinical outcomes of multifocal IOL implantation in post-LASIK

eyes have been reported since the early 2000s and more recently with newer-generation lenses, such as trifocal models [1-5]. To mitigate the limitations associated with diffractive multifocal IOLs, Extended Depth-of-Focus (EDoF) IOLs without diffractive optics have been developed. Recently, these IOLs have been categorized as PC IOLs and EDoF IOLs as partial-range-of-field IOLs [6]. Compared with earlier diffractive multifocal IOLs, EDoF IOLs have been reported to provide improved contrast sensitivity and a lower incidence of photic phenomena [7,8]. The wavefront-shaping EDoF IOL (acrysof vivity; Alcon) was developed to further optimize visual performance and favorable clinical outcomes have been reported [9,10]. More recently, the

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outcomes of cataron vivity from a Japanese perspective have also been evaluated [11].

In eyes with prior LASIK, several studies have investigated clinical outcomes with acrysof vivity [12-14]; however, outcomes with cataron vivity have not yet been reported. Therefore, we conducted this retrospective study to evaluate the clinical outcomes of cataron vivity implantation in Japanese eyes with a history of LASIK.

MATERIALS AND METHODS

Patients

This retrospective observational study included patients who had previously undergone myopic LASIK at outside institutions and subsequently received implantation of a wavefront-shaping EDOF IOL (CNA0T0, Alcon) at our hospital. Patients with no history of corneal refractive surgery who underwent implantation of the same IOL model during the same period were included as controls.

The exclusion criteria were as follows: Coexisting ocular diseases, including glaucoma, retinal disease and uveitis; corneal degeneration; irregular astigmatism; prior ocular surgery other than LASIK; target refraction other than emmetropia; and preoperative corneal astigmatism >1.5 D.

The study adhered to the tenets of the declaration of Helsinki and was approved by the Institutional Review Board of Tokyo Dental College.

Intraocular lenses and surgical technique

The CNA0T0 is a one-piece, modified hydrophobic acrylic IOL with a water content of 1.5% and an anterior surface designed to provide non-diffractive wavefront shaping to extend the depth of focus. This optical design aims to provide continuous vision from long-range to intermediate ranges while minimizing photic phenomena and contrast-sensitivity loss commonly associated with diffractive optics.

The target postoperative refraction was emmetropia in all cases. Axial length was measured using the IOLMaster (Carl Zeiss Meditec). IOL power calculations were performed using the Barrett True-K formula for post-LASIK eyes and the Barrett Universal II formula for non-LASIK eyes.

Written informed consent was obtained from all patients before surgery. All surgeries were performed using a 2.2-mm temporal

clear corneal incision with a continuous curvilinear capsulorhexis of approximately 5.0 mm, followed by phacoemulsification and aspiration and in-the-bag IOL implantation.

Postoperative examinations

Manifest Refraction Spherical Equivalent (MRSE), monocular Uncorrected and Distance-Corrected Visual Acuity (UCVA and DCVA, respectively) at distance (5 m), intermediate (60 cm) and near (40 cm) and contrast sensitivity under distance correction were evaluated between 1 and 3 months or more postoperatively. Contrast sensitivity was measured using the CSV-1000 (Vector Vision) at spatial frequencies of 3, 6, 12 and 18 Cycles Per Degree (CPD). Spectacle use and the presence of photic phenomena, including glare, halos and starbursts, were also reviewed from the medical records.

Statistical analysis

Both eyes of patients who underwent bilateral CNA0T0 implantation were included in the statistical analysis. Means and Standard Deviations (SDs) were calculated for clinical outcomes. Preoperative patient demographic data and postoperative UCVA and DCVA at distances of 5 m, 60 cm and 40 cm were compared using the Mann-Whitney U test. Categorical variables were analyzed using the chi-square test. Statistical significance was defined as $p < 0.05$.

RESULTS

A total of 13 eyes from 12 patients with a history of myopic LASIK who underwent implantation of a wavefront-shaping EDOF IOL (CNA0T0, Alcon) were included. Additionally, 19 eyes from 17 patients without a history of LASIK were also included as controls. LASIK procedures had been performed 10–20 years earlier at other institutions. Patient demographics, including age, keratometric power, corneal astigmatism, axial length and IOL power, are shown in Table 1. There were no significant differences between groups in age, corneal astigmatism, or axial length. Compared with the results of non-LASIK eyes, corneal refractive power was significantly lower in post-LASIK eyes, reflecting postoperative corneal flattening. Correspondingly, implanted IOL power was significantly higher.

The predicted postoperative refraction, postoperative MRSE, refractive cylinder, UCVA and DCVA are shown in Table 2. No significant differences were found between post-LASIK and non-LASIK eyes.

Table 1: Participant demographic data.

	LASIK group	Non-LASIK group	p-value
No. of eyes (patients)	13 (12)	19 (17)	
Age, year	62.75 ± 9.15	58.65 ± 15.45	0.69
Mean keratometric power, D	41.46 ± 1.99	43.49 ± 1.73	0.006*

Corneal astigmatism, D	0.74 ± 0.35	0.89 ± 0.49	0.939
Axial length, mm	25.08 ± 1.19	25.23 ± 1.91	0.565
Implanted IOL, power, D	20.50 ± 1.13	16.42 ± 4.28	0.006*

Note: Mean ± standard deviation.

Table 2: Postoperative refraction and uncorrected and distance-corrected visual acuity (UCVA and DCVA) at distances of 5 m, 60 cm and 40 cm.

		LASIK group	Non-LASIK group	p-value
Predicted postoperative refraction, D		-0.07 ± 0.20	-0.19 ± 0.16	0.17
Manifest refraction spherical equivalent, D		-0.42 ± 0.26	-0.21 ± 0.40	0.11
Manifest refractive cylinder, D		0.65 ± 0.55	0.50 ± 0.46	0.46
UCVA, logMAR	5 m	-0.04 ± 0.09	-0.07 ± 0.14	0.54
	60 cm	0.02 ± 0.11	0.05 ± 0.08	0.26
	40 cm	0.13 ± 0.12	0.20 ± 0.11	0.12
DCVA, logMAR	5 m	-0.15 ± 0.07	-0.16 ± 0.09	0.54
	60 cm	0.02 ± 0.11	0.05 ± 0.09	0.22
	40 cm	0.20 ± 0.16	0.32 ± 0.15	0.059

Note: Mean ± standard deviation, logMAR (logarithm of the Minimum Angle of Resolution).

Contrast sensitivity was within the normal range at all frequencies in both post-LASIK and non-LASIK eyes, with no significant differences at 3, 6, 12 or 18 cycles per degree ($p=0.875$, $p=0.827$, $p=0.732$ and $p=0.430$, respectively; Mann-Whitney U test) (Figure 1).

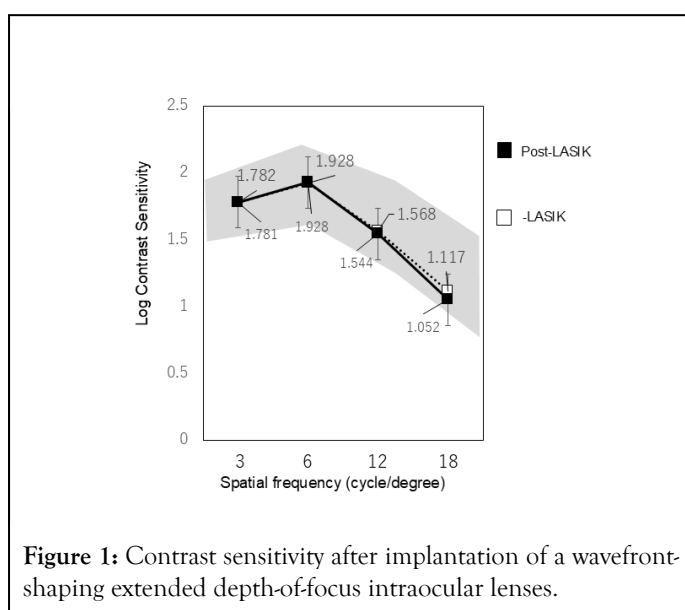


Figure 1: Contrast sensitivity after implantation of a wavefront-shaping extended depth-of-focus intraocular lenses.

Spectacle use and photic phenomena were assessed in 11 bilateral cases. The rate of spectacle use was 41.7%, primarily for near tasks. Compared with 55.6% in 11 non-LASIK cases, no statistically significant difference was observed ($p=0.635$; chi-square test). Photic phenomena, glare, halos and starbursts were reported in 45.5%, 27.3% and 36.4% of post-LASIK eyes, respectively and in 45.5%, 27.3% and 18.2% of non-LASIK eyes, respectively. All symptoms were mild and did not interfere with daily activities and were not significantly different from those in non-LASIK eyes ($p=0.377$, $p=0.827$ and $p=0.214$, respectively; chi-square test). However, starbursts were significantly more frequent in post-LASIK eyes ($p=0.039$; chi-square test). The occurrence of starbursts was not significantly associated with axial length, which would reflect the degree of corneal ablation ($p=0.347$).

DISCUSSION

This study confirmed that visual outcomes after implantation of the clareon vivity IOL were comparable between post-LASIK and non-LASIK eyes. These findings are consistent with previously reported results using acrysof vivity [12-14].

Major concerns when implanting PC IOLs in post-LASIK eyes include the accuracy of IOL power calculation, potential loss of

contrast sensitivity and photic phenomena [1-5]. Compared with diffractive multifocal IOLs, EDoF IOLs minimize concerns about reduced contrast sensitivity and photic disturbances [7, 8] and have been reported to provide favorable outcomes in eyes with prior LASIK [12-14].

Regarding IOL power, recent methods that incorporate corneal curvature changes following myopic LASIK have improved refractive accuracy. In the present study, no significant

difference in postoperative Manifest Refraction Spherical Equivalent (MRSE) was observed between post-LASIK and non-LASIK eyes. Consequently, both groups achieved comparable UCVA at distances of 6, 3 and 1 m. Our results in post-LASIK eyes with clareon vivity were compared with previously reported outcomes using acrysof vivity and are summarized in Table 3 [12-14]. Both mean MRSE and UCVA values were consistent between the AcrySof and Clareon materials.

Table 3: Comparison of uncorrected visual acuity with wavefront-shaping EDoF intraocular lenses in post-LASIK eyes.

Reference	IOL	No. of eyes (patients)	MRSE (D)	UDVA, logMAR	UIVA, logMAR	UNVA, logMAR
Carreras H, et al.	Acrysof vivity	50 (25)	Within ± 0.75	0.02 ± 0.11	-0.02 ± 0.09	0.14 ± 0.13
Srur M, et al.	Acrysof vivity	26 (13)	-0.46 ± 0.43	0.03 ± 0.05	0.02 ± 0.04	0.04 ± 0.05
Fan W, et al.	Acrysof vivity	20	-0.28 ± 0.49	0.09 ± 0.10	0.18 ± 0.06	0.31 ± 0.08
Current study	Clareon vivity	13 (12)	-0.42 ± 0.26	-0.04 ± 0.09	0.02 ± 0.11	0.13 ± 0.12

Note: Mean $\pm$ standard deviation, logMAR, logarithm of the minimum angle of resolution, MRSE (Manifest Refraction Spherical Equivalent), UDVA (Uncorrected Distance Visual Acuity); UIVA (Uncorrected Intermediate Visual Acuity), UNVA (Uncorrected Near Visual Acuity).

Reduced contrast sensitivity following implantation of diffractive multifocal IOLs has been reported in post-LASIK eyes compared with non-LASIK eyes [2]. In the present study, however, contrast sensitivity did not differ significantly between post-LASIK and non-LASIK eyes. EDoF IOLs are designed to provide an expanded range of vision while maintaining contrast sensitivity similar to that of monofocal IOLs. Our findings suggest that the wavefront-shaping EDoF design effectively extends functional vision without compromising visual quality in eyes that have undergone prior corneal refractive surgery.

Spectacle dependence for near tasks remained approximately 40–50% in both groups. EDoF IOLs primarily provide excellent distance and intermediate vision; therefore, the need for reading glasses for near tasks is expected. Previous reports have indicated spectacle dependence rates ranging from 18.7% to 52% [11,13]. The higher dependence on spectacles among Japanese patients may be due to the need to read complex Chinese characters [19]. To reduce spectacle dependence, monovision strategies combined with EDoF optics may be helpful for selected post-LASIK patients [15, 16].

Regarding photic phenomena, previous studies have reported a relatively low incidence of visual disturbances, such as glare, halos and starbursts, in eyes implanted with EDoF IOLs [7, 8, 11]. In post-LASIK eyes, computational simulations have suggested reduced halos with EDoF IOLs [17]. In our study, the halo rate was similar between post-LASIK and non-LASIK eyes; however, starbursts were significantly more frequent in post-LASIK eyes. This finding may be related to increased higher-order aberrations induced by LASIK [18]. Further investigation incorporating detailed measurements of corneal higher-order aberrations is warranted.

Clareon is a high-water-content hydrophobic acrylic material. In PC IOLs with up to 3 months of follow-up, no significant

difference in clinical outcomes has been reported between AcrySof and Clareon [11,19]. Clareon IOLs have also been reported to exhibit a lower incidence of glistening in both clinical and experimental studies and longer follow-up is necessary [20, 21].

This study has several limitations. First, the sample size was small because the analysis was limited to specific cases, such as post-LASIK eyes and nontoric IOL implantation. Second, precise evaluation of corneal higher-order aberrations was not available due to the retrospective design. Third, the follow-up period was relatively short. Further prospective studies with larger sample sizes and longer follow-up are warranted.

CONCLUSION

In conclusion, implantation of a wavefront-shaping EDoF IOL in post-LASIK eyes provides an extended range of vision with preserved contrast sensitivity and generally mild photic phenomena. This IOL design represents a viable option for patients with previous LASIK who desire an enhanced visual range following cataract surgery.

FINANCIAL DISCLOSURE

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