

# Wavefront Guided LASIK with a High-Resolution Aberrometer Induces Less Higher-Order Aberration than Early Custom LASIK

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## Research Article

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# Abstract

**Background:** The use of 'high-resolution' aberrometer wavefront-guided LASIK system offers the theoretical advantages. To date there have been a few papers that proved the clinical superiority of the 'high-resolution' wavefront-guided LASIK. The purpose of this present study was to evaluate the surgical outcomes of wavefront-guided laser in-situ keratomileusis (LASIK) via a high-resolution aberrometer to treat myopic refractive error.

**Methods:** This study involved 51 eyes of 26 consecutive patients (high-resolution group) who underwent wavefront-guided LASIK from 2012 to 2015 via high-resolution aberrometer and excimer laser surgical unit at the Baptist Eye Institute, Kyoto, Japan and who were followed for 6-months postoperative. Postoperative outcomes were compared with our historical control data (early custom group) from 2002 to 2007 (51 eyes of 26 patients) treated with the same correction amount. Measured parameters included Visual acuity (VA), spherical equivalent refractive error (SER), higher-order aberration (HOA), and contrast sensitivity (CS).

**Results:** In the high-resolution group and the early custom group, the mean SER was  $-5.86 \pm 2.57$  diopters (D) and  $-5.99 \pm 2.52$ D, respectively, and the mean patient age was  $33.8 \pm 9.2$  and  $34.3 \pm 6.9$  years, respectively. LogCS of 18 cycles-per-degree (cpd) change was more satisfactory in the high-resolution group than in the early custom group. Postoperative spherical aberration change in the high-resolution group was significantly lower than that in the control group ( $P < 0.05$ ). Decrease of induced spherical aberration produced a positive effect on the post LogCS of 18 cpd.

**Discussion:** The latest wavefront-guided LASIK induced less HOAs than early custom LASIK, and although similar VA and refractive precision findings were observed, the high-resolution group tended to acquire better visual function post surgery.

## Introduction

Since the early 2000s, laser-assisted *in situ* keratomileusis (LASIK) has been recognized as a standard technique for refractive surgery [1,2]. When performing LASIK, a microkeratome or femtosecond laser first creates a thin circular "flap" in the cornea, with the surgeon then ablating some corneal tissue using an excimer laser under the flap [3,4]. A 'custom LASIK' measures an eye's optical system and corrects higher-order aberrations (HOA) or suppresses the induction of HOA. Custom ablation includes wavefront-guided ablation [5,6], wavefront-optimized ablation [7,8]. (designed to minimize the induction of spherical aberrations), and topography-guided ablation [9].

The accuracy of wavefront-guided LASIK is ensured via a wavefront sensor that measures the aberrations of the optical wavefront. Initially, wavefront sensors for wavefront-guided ablation had only 75 measurement points within a 7-mm diameter [10,11]. However, the iDESIGN REFRACTIVE STUDIO (Johnson & Johnson, New Brunswick, NJ) makes measurements of 1257 points in that same 7-mm-diameter area [12,13]. This type of wavefront sensor is known as a 'high-resolution' aberrometer. The use

of this wavefront-guided LASIK system offers the following advantages. First is the increased number of measurement points. Second is the creation of an ablation profile using Fourier analysis [14]. The third point is the accuracy of ablation by iris recognition registration [15]. To date there have been a few papers that proved the superiority of latest wavefront-guided LASIK.

The purpose of this present study was to clarify whether or not wavefront-guided LASIK performed with a high-resolution aberrometer improves postoperative visual function more than initial custom LASIK.

## Subjects And Methods

### Subjects

This study involved the consecutive patients (high-resolution group) who underwent wavefront guided LASIK using the *iDESIGN* REFRACTIVE STUDIO [12] at the Baptist Eye Institute, Kyoto, Japan between 2012 and 2015, and who were followed up for 6-months postoperative. The control group (early custom group) underwent custom LASIK at Baptist Eye Institute between 2002 and 2007, and in whom the correction amount and patient age were matched to the patients in the high-resolution group. Approval for this study was obtained from the Institutional Review Boards of Kyoto Prefectural University of Medicine and the Baptist Eye Institute, Kyoto, Japan, and prior to enrollment, written informed consent was obtained from all patients in accordance with the tenets set forth in the Declaration of Helsinki.

### Indication

Indication criteria for LASIK were as follows, the preoperative corneal topography deemed normal, corrected distance VA (CDVA) better than decimal 0.5, and the residual corneal bed more than 250  $\mu\text{m}$  in depth. As it was required for the preoperative examination, all patients were strictly instructed to discontinue hard contact lens use for 3 weeks prior to surgery, and soft contact lens use for 2 weeks prior to surgery. Wavefront-sensor examination was performed 3 times for natural pupils and 3 times for dilated pupils. Among the wavefront data of the natural pupils, the one with the least excessive accommodation was selected and used as a data source for the corneal ablation profile. If there was excessive accommodation, the measurement was once-again performed on the day of the operation, and the measurement with the smallest difference from the subjective refraction was used for the surgery.

### Surgical Procedure

In the high-resolution group, all wavefront-guided LASIK surgeries were performed using the *iDESIGN* REFRACTIVE STUDIO and *iFS* ADVANCED FEMTOSECOND LASER (Johnson & Johnson). When the corneal thickness was  $\geq 550 \mu\text{m}$ , the flap formed was 130  $\mu\text{m}$ , and when the corneal thickness was  $< 550 \mu\text{m}$ , the flap formed was 120  $\mu\text{m}$ . In the early custom group, LASIK was performed using the EC-5000 (NIDEK Co., Ltd., Gamagori, Japan) excimer-laser system (optimized aspheric transition zone ablation) [16], the VISX STAR S4 (Abbott Medical Optics, Santa Ana, CA) excimer-laser system (wavefront-guided ablation), [17] and the TECHNOLAS 217z (Bausch & Lomb, Rochester, NY) excimer-laser system

(wavefront-guided ablation) [11] in 15, 8, and 28 eyes, respectively. A mechanical microkeratome was used in the LASIK procedure for flap creation (Table 1).

### **Pre and Postoperative care**

Three days prior to surgery, all patients received 0.5% cefmenoxime hydrochloride eye drops (BESTRON; Senju Pharmaceutical Co. Ltd., Osaka, Japan) 4 times per day and 100mg of oral cefcapene pivoxil hydrochloride hydrate (FLOMOX; Shionogi & Co., Ltd., Osaka, Japan) 3 times per day. LASIK was performed under topical anesthesia. For the first postoperative week, all patients initially received 0.1% fluorometholone eye drops (FLUMETHOLON Ophthalmic Suspension 0.1; Santen Pharmaceutical) and 0.3% gatifloxacin hydrate eye drops (GATIFLO Ophthalmic Solution; Senju Pharmaceutical) 4 times per day.

### **Ophthalmic examinations**

Prior to surgery and for 6-months postoperatively, spherical equivalent refractive error (SER) using Landolt C charts, uncorrected distance Visual Acuity (UDVA), CDVA, contrast sensitivity (CS) at 3, 6, 12, and 18 cycles per degree (cpd) using a CS testing instrument (CSV-1000; VectorVision, Greenville, OH), and HOA in a 4-mm and 6-mm area of the dilated pupil (0.5% tropicamide, phenylephrine hydrochloride) using an optical diagnostic instrument (OPD-Scan; NIDEK Co., Ltd.)<sup>18</sup> were examined in each operated eye. All examinations were performed using the same equipment.

CS and Visual Acuity (VA) were subjected to a logarithmic transformation and analyzed as a continuous variate with log CS and logMAR. The predictability was calculated from the difference between the target and the refractive error measured 6 months post LASIK. The obtained wavefront data was fitted to a six-order Zernike polynomial, total HOA, coma-like aberration (third order + fifth order), and spherical-like aberration (fourth order + sixth order), with the spherical aberration then being calculated. Changes in the CS and HOA values were calculated by subtracting the preoperative values from the postoperative.

### **Statistical Analyses**

The mixed-effect model was used to analyze study variables and changes (i.e., CS at 3 cpd, 6 cpd, 12 cpd, 18 cpd, and in 4mm and 6mm total HOA, Coma-like aberration, spherical-like aberration, spherical aberration) prior to surgery and at 6 months postoperatively with the preoperative and postoperative changes in both eyes as the objective variables, an identification (ID) number as the random effect, and each group as a fixed effect. The proportion was tested by the Fisher's direct test. The confidence level of the confidence interval was 95%, and a *P*-value of <0.05 was considered statistically significant. Linear regression analysis was used to clarify the relationship between the HOA change and the CS changes. Statistical analysis was performed with JMP PRO VERSION 14 STATISTIC SOFTWARE FOR WINDOWS (SAS Institute Inc., Cary, NC).

## **Results**

This study involved 51 eyes of 26 consecutive patients (high-resolution group). The control group (early custom group) involved 51 eyes of 39 patients. In the high-resolution group and the early custom group, the average SER was  $-5.87 \pm 2.58D$  and  $-5.99 \pm 2.52D$ , respectively, and the average patient age was  $33.8 \pm 9.2$  and  $34.3 \pm 6.9$  years, respectively. No significant difference was found between the two groups. The background of the patients in both groups is summarized in Table 1.

At 6-months postoperative, the proportion of predictability within  $\pm 0.5D$  and  $\pm 1.0D$  in the high-resolution group was 88.2% (45/51) and 98.0% (50/51), respectively, while that in the early custom group was 90.2% (46/51) and 96.1% (49/51), respectively. In the high-resolution group and the early custom group, the mean SER was  $-0.25 \pm 0.41D$  and  $-0.20 \pm 0.58D$ , respectively. The proportion of CDVA decreased by two or more lines in comparison with preoperative results, 2% for the high-resolution group (1/51) and 0% for the early custom group. It should be noted that the CDVA in that 1 eye in the high-resolution group recovered to the preoperative level during the follow-up observation period. No complications resulting in visual impairment were observed in both groups. The postoperative clinical variables of the patients in this study are shown in Table 2.

Comparison of the changes in CS between the high-resolution group and the early custom group revealed no statistically significant differences in all cycles. Post LASIK, the mean CS in the high-resolution group at all frequencies was found to have improved compared with that prior to surgery, however, it decreased in the early custom group. The maximum difference between the two groups was 18 cpd, and the average difference was 0.14 log CS (Table 3).

The HOA change with a pupil diameter of 4 mm between both groups prior to and at 6-months after surgery was compared. A lesser amount of spherical aberration change was observed in the high-resolution group compared to the early custom group. Moreover, in the high-resolution group, the changes in total HOA, coma-like aberration, and spherical-like aberration were smaller. The comparison in 6 mm pupil diameter group prior to and 6-months postoperatively revealed statistically significant decrease in the total HOA, spherical-like aberrations, and spherical aberrations changes between the high-resolution group and the early custom group. The average value of the coma-like aberration change was also lower in the high-resolution group without reaching statistical significance (Table 4). A statistically significant correlation was found between the change in the CS of 18 cpd and spherical aberration change in pupil diameter of 4 mm ( $P=0.007$ ) (Figure 1).

## Discussion

In this study, we compared two techniques within the same refractive error and precision outcomes. Our results demonstrate that wavefront-guided LASIK using a high-resolution aberrometer produced less induced HOA, and that the average change in CS was improved compared with early custom LASIK. In addition, our findings revealed a correlation between the decrease of HOA and the improvement of CS.

It has been reported that wavefront-guided LASIK proved the superiority of postoperative CS in comparison to other types of custom ablation [19,20], and standard LASIK [21,22]. A previous study

reported that the CS after wavefront-guided LASIK using the iDESIGN® Refractive Studio was sharper than that produced by small incision lenticule extraction (SMILE) [23,24]. In this present study, wavefront-guided LASIK using a high-resolution aberrometer induced smaller spherical aberration in the 4mm and 6mm pupils. Moreover, the CS change correlated significantly with the increase of spherical aberration change in 4mm pupils.

Our findings appear to clarify the superiority of performing surgery with a high-resolution aberrometer. In the early custom group, we theorize that the spherical aberration tended to increase due to the fact that wavefront-optimized ablation does not correct the spherical aberration [25,26] and the early wavefront-guided ablation does not consider induced spherical aberration [27]. Another reason for the decrease of spherical aberrations was the femtosecond laser flap [28], as it has been reported that the total HOA and spherical aberration decreased when femtosecond laser was performed in comparison with a microkeratome.

Between 2002 and 2007, three different lasers were assigned randomly to the patients in our facility. No obvious clinical differences were found in the treated eyes (data not published). However, possible obscuring of the interpretations cannot be excluded.

In conclusion, our findings revealed that LASIK using a high-resolution wavefront sensor and femtosecond laser produced less induction of HOA compared with the custom LASIK systems that were available for use 10 years ago, and that via this method, CS tend to improve. Therefore, the current LASIK procedure seems to have almost resolved the influence of induced HOA on visual function, and our findings indicate that LASIK with a high-resolution aberrometer results in a better visual function post surgery.

## Declarations

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**Contributions to Authors:** Involved in the design of the study (O.H., S.K.); conduct of the study (O.H., C.S.); collection, management, analysis, and interpretation of the data (O.H., K.K.); preparation, review (O.H., K.K.); and approval of the manuscript (O.H., C.S., K.K., S.K.).

**Statement about Conformity with Author Information:** This retrospective review of patient data was approved by the Human Studies Committee of Kyoto Prefectural University of Medicine.

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## Tables

Table1. Patient Background

	High-Resolution Group	Early Custom Group	<i>P</i> value
Number of Eyes	51 eyes of 26 patients	51 eyes of 39 patients	
Sex	Male: 11, Female: 15	Male: 16, Female: 23	1.0
Mean Age (years)	33.8±9.2 [17-51]	34.3±6.9 [20-51]	0.70
Mean SER (D)	-5.87±2.58 [-1.00-10.63]	-5.99±2.52 [-1.38-11.25]	0.59
Surgery Date	September 2012 – September 2015	January 2002 – October 2007	
Excimer Laser (eyes)	VISX <i>iDESIGN</i> <sup>®</sup> : 51	EC-5000 : 15 VISIX Star S4 : 8 T217z : 28	
Keratome	iFS	Microkeratome	
[ ] = range; SER= spherical equivalent refractive error; D = diopters			

Table 2. Postoperative Clinical Variables

	High-Resolution Group	Early Custom Group	<i>P</i> value
UDVA (LogMAR)	-0.12±0.16	-0.08±0.18	0.24
CDVA (LogMAR)	-0.18±0.08	-0.15±0.09	0.18
CDVA decrease of 2 lines or more	2% (1/51)	0% (0/51)	1.0
SER(D)	-0.25±0.41	-0.20±0.58D	0.83
Predictability			
±0.5D	88.2% (45/51)	90.2% (46/51)	1.0
±1.0D	98.0% (50/51)	96.1% (49/51)	1.0
UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity; SER = spherical equivalent refractive error			

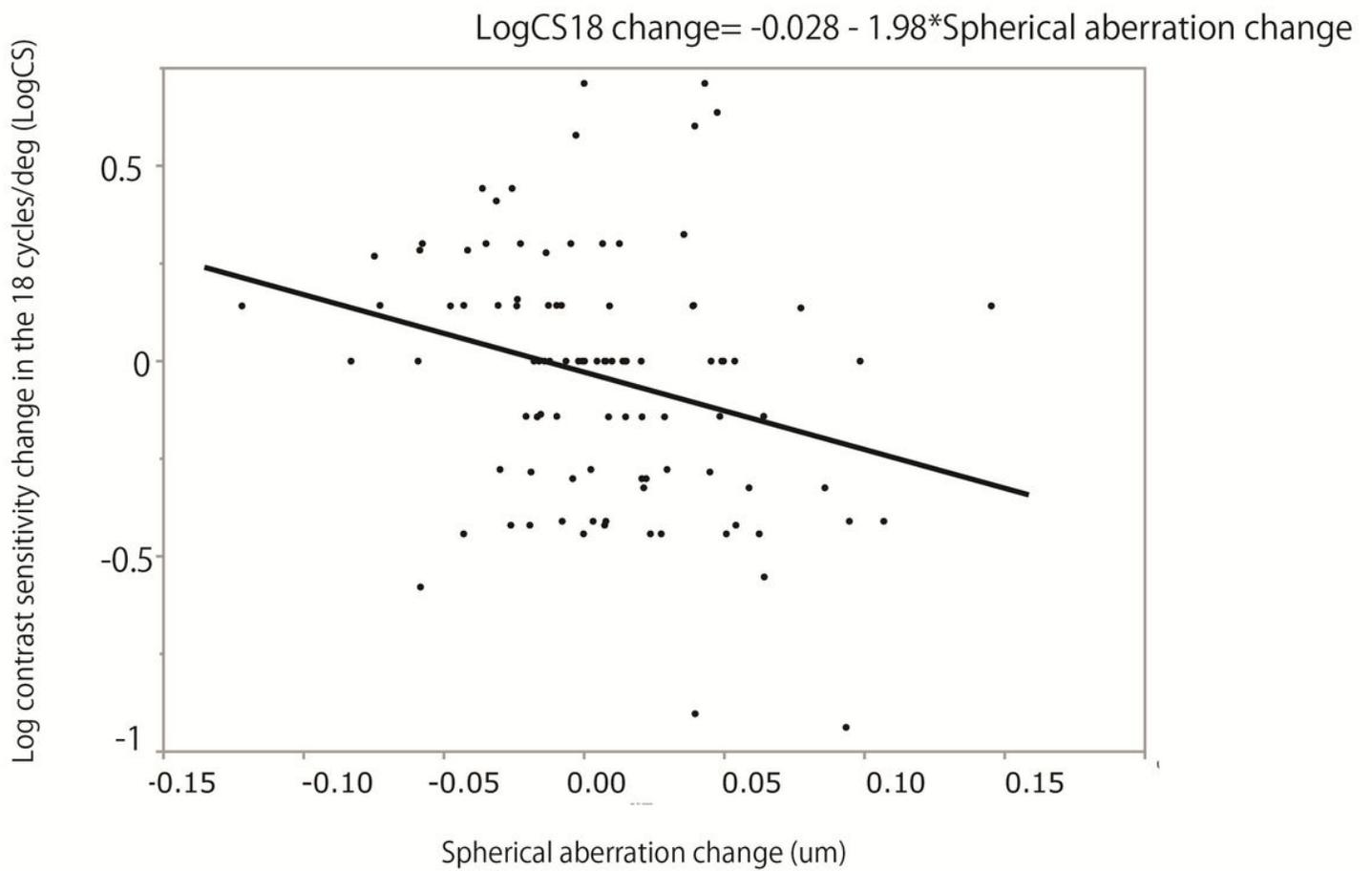
Table 3. Difference of Log Contrast Sensitivity Change Between the High-Resolution Group and the Early Custom Group

	High- Resolution Group change	Early Custom Group change	Difference	<i>P</i> value	<i>Lower</i> 95%	<i>Upper</i> 95%
3 cpd	-0.03(0.24)	-0.00(0.22)	-0.03	0.58	-0.14	0.08
6 cpd	-0.06(0.25)	0.03(0.34)	-0.09	0.14	-0.20	0.03
12 cpd	-0.02(0.32)	0.03(0.34)	-0.06	0.45	-0.21	0.10
18 cpd	-0.11(0.30)	0.02(0.33)	-0.14	0.07	-0.28	0.01
( ) = standard deviation; cpd = cycles per degree; difference = change of high-resolution group minus change of early custom group						

Table 4. Difference of Higher-Order Aberrations Change Between the High-Resolution Group and the Early Custom Group

	High- Resolution Group change	Early Custom Group change	Difference	<i>P</i> value	<i>Lower</i> 95%	<i>Upper</i> 95%
4mm (µm)						
Total HOA	0.04(0.01)	0.06(0.02)	-0.03	0.28	-0.07	0.02
Coma-like abe.	0.04(0.09)	0.05(0.10)	-0.02	0.42	-0.06	0.03
Spherical-like abe.	0.01(0.03)	0.03(0.07)	-0.02	0.05*	-0.04	-0.00
Spherical abe.	-0.01(0.01)	0.02(0.05)	-0.03	0.00*	-0.05	-0.01
6mm (µm)						
Total HOA	0.21(0.04)	0.36(0.05)	-0.16	0.02*	-0.31	-0.02
Coma-like abe.	0.15(0.04)	0.25(0.04)	-0.11	0.11	-0.24	0.02
Spherical-like abe.	0.15(0.02)	0.26(0.03)	-0.13	0.00*	-0.20	-0.05
Spherical abe.	0.15(0.02)	0.25(0.03)	-0.12	0.01*	-0.20	-0.03
( ) = standard deviation; HOA = higher-order aberration; abe. = aberration; difference = change of high-resolution group minus change of early custom group; * = $P < 0.05$						

## Figures



**Figure 1**

Graph showing the linear regression analysis between the change in the contrast sensitivity (CS) of 18 cycles-per-degree and spherical aberration change with a pupil diameter of 4 mm of all group subjects. There was a statistically significant correlation between the CS and spherical aberration (P=0.0072).