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CLINICAL STUDY

Clinical outcomes between optical path difference custom aspheric treatment and optimized prolate ablation photorefractive keratectomy in myopia exceeding 8 diopters

BJ Choi[1], YM Park[2] and JS Lee[2]

[1]Lee Eye Clinic, Pusan, Republic of Korea

[2]Department of Ophthalmology, School of Medicine, Pusan National University and Medical Research Institute, Pusan National University Hospital, Pusan, Republic of Korea

Correspondence:
JS Lee, Department of Ophthalmology, School of Medicine, Pusan National University & Medical Research Institute, Pusan National University Hospital, 1-10 Ami-dong, Seo-gu, Pusan 602-739, Republic of Korea
Tel: +82 51 240 7323;
Fax: +82 51 242 7341.
E-mail: jongsooluw@gmail.com; jongsool@pusan.ac.kr

Abstract

Purpose Comparison of visual acuity, refractive, and wavefront outcomes associated with optimized prolate ablation (OPA) and optical path difference custom aspheric treatment (OPDCAT) algorithms for correction of myopia exceeding 8 diopters (D).

Patients and Methods Patients were randomly assigned to have photorefractive keratectomy (PRK) with OPA ($n = 32$) or OPDCAT ($n = 21$) algorithms. Visual acuity, manifest refraction, ocular and corneal higher-order aberrations, corneal asphericity, modulated-transfer function, and point-spread function were compared 1, 3, and 6 months postoperatively.

Results Mean manifest-refraction spherical equivalents at 6 months were -0.24 D in both groups. All patients in both groups had an uncorrected-distance visual acuity of 20/20 or better. Predictability (± 1 D from intended refraction) at 6 months was 94% in the OPA group, and in the OPDCAT group it was 86%. The OPA group had less induced corneal and ocular spherical aberrations (SAs) than the OPDCAT group. Postoperative corneal asphericity change was lowest in the OPA group. Both the groups exhibited significantly-improved AreaRatio-Total value and insignificantly deteriorated AreaRatio-HO value throughout the postoperative period. The OPA group had significantly-higher AreaRatio-Total compared with OPDCAT group at both 1 and 6 months after the operation. Six months after surgery, the Strehl ratio had decreased in both groups, and there was no significant difference between the groups.

Conclusion The OPA algorithms yielded higher-objective visual quality and predictability, induced less corneal and ocular SAs, and preserved more preoperative-corneal asphericity than the OPDCAT algorithms.

Introduction

Refractive surgery for high myopia remains the subject of considerable investigation. These days, correction of high-myopic-refractive errors is reportedly associated with favorable outcomes in terms of safety, efficacy, and predictability.[1,2] However, in patients with myopia exceeding 8 diopters (D) it is known to produce more unpredictable-postoperative results than are associated with low and moderate myopia.[3] In addition, in some patients an increased level of higher-order aberrations (HOAs) is produced postoperatively, resulting in various forms of visual discomfort such as glare, halo, and starburst.[4–7]

The aim of many algorithms is to increase predictability, and reduce the induced HOAs. NIDEK Advanced Vision Excimer Laser System (NAVEX; NIDEK Co. Ltd., Gamagori, Japan), recently developed several algorithms that are based on the aspheric treatment zone and offer an aspheric-transition zone of more prolate shape: the optical path difference customized aspheric treatment (OPDCAT) and optimized prolate ablation (OPA). It is known that the OPDCAT algorithm, which is based on the wavefront profile, reduces induced HOAs and maintains mesopic-contrast sensitivity more than the conventional refractive surgeries by using an aspheric ablation over the central and peripheral cornea coupled with multipoint ablation.[8] However, there are studies indicating weakness of wavefront-analysis algorithms, which is presumably related to its limited resolution.[9,10] The OPA algorithm uses not only wavefront aberrometry, but also corneal topography, which is expected to overcome the limited resolution of wavefront analysis. In addition, the OPA algorithm is known to maintain the quality of vision and the physiology of the cornea by improving the natural corneal shape postoperatively.[11]

There are several studies reporting the advantages of the OPA algorithm compared with the OPDCAT algorithm.[11,12] However, no studies have compared the clinical outcomes associated with OPDCAT and OPA algorithms in patients with myopia exceeding 8 D. Therefore, in our study, we compared visual acuity, refractive, wavefront, and visual quality outcomes associated with OPDCAT and OPA algorithms for the correction of myopia exceeding 8 D.

Materials and methods

This study was designed as prospective randomized-masked clinical trial. A total of 52 eyes of 52 patients who underwent photorefractive keratectomy (PRK) for myopia or myopic astigmatism with either the OPDCAT or OPA algorithm using an excimer laser platform (NAVEX; Nidek Co. Ltd.) were invited to participate in this study. Using sealed envelopes, each of which contained one of the two algorithms, patients were randomly assigned to either the OPDCAT or the OPA treatment group (Figure 1). Both eyes of each patient received the treatment by the same algorithm, and any one eye was selected randomly for this study.

The inclusion criteria were age over 20 years, and myopia with a manifest-refraction spherical equivalent (MRSE) more than 8 D (range -8.12 to -11.0 D). Patients who had active systemic or ocular disease, or previously had ocular surgery were excluded from the study. All patients underwent a preoperative-ophthalmic examination, including uncorrected-distance visual acuity (UDVA), corrected distance visual acuity (CDVA), slit-lamp biomicroscopy including corneal-haze grading, tonometry, fundus examination, ultrasound pachymetry, pupillometry, corneal topography, and wavefront aberrometry. Corneal-haze levels were determined using a slit lamp, according to the method of Hanna et al.[13] Without moving the patients or the instrument,
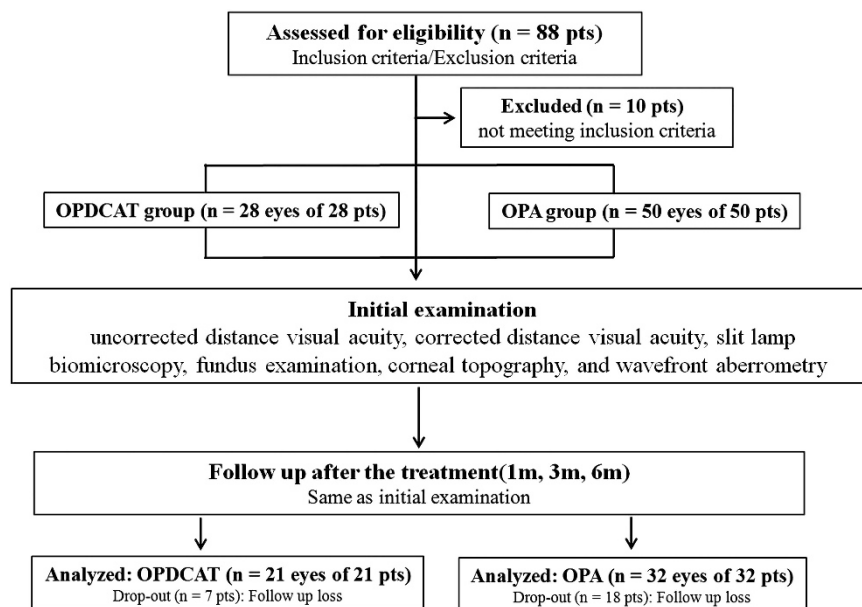

Figure 1 Flow chart of the study.

pupillometry, corneal topography, and wavefront aberrometry were measured on the same optical axis using an OPD-Scan III device (Nidek Co. Ltd.), with the pupils dilated to at least 6 mm. All wavefront measurements were performed to the 6th-Zernike order. The device's software separates corneal and internal aberrations to evaluate the effects of the optical elements in the visual system. Corneal asphericity (Q value) was measured with built-in corneal-topography software. Objective visual quality was checked via the modulation-transfer function (MTF) graph, which provides the degree of contrast transfer at different spatial frequencies. Wavefront analysis of MTF was performed using two types of AreaRatio method. AreaRatio-Total type is total wavefront aberration from the 0th to the specified order in the Zernike pyramid, and AreaRatio-HO type is higher-order wavefront aberration from the 3rd to the specified order in Zernike pyramid. AreaRatio is the ratio between the area bordered by vertical and horizontal axis and the normal eye curve, and the area bordered by vertical and horizontal axis and the Total or HO curve. The closer the ratio is to 100%, the closer the patient's curve is to a normal eye's curve. Point-spread function (PSF) was also measured by the OPD-Scan III software. The Strehl ratio is one of the parameters used to evaluate aspects of PSF. The Strehl ratio was used as a representative indication of PSF in this study.[14] All examinations were performed at 1, 3, and 6 months postoperatively.

All operations were performed by the same surgeon (BJC). The patient was prepared in a sterile fashion with topical anesthesia (proparacaine hydrochloride 0.5%—Alcaine; Alcon, Fort Worth, TX, USA). A lid speculum was used to maximally expose the globe. A Carones LASEK Pump OZ Chamber (9.0 mm or 9.5 mm in diameter; ASCIO, Copenhagen, Denmark) was placed on the eye. A 20% alcohol solution mixed with a balanced salt solution was instilled inside the cone for 40 s, followed by rinsing with additional balanced salt solution. The epithelial flap was gently lifted and removed. The iris image with the patient supine was compared with that taken by the OPD-Scan III device, to detect torsion error. If the torsion error was >2 degrees, the patient's head was repositioned to reduce the error. A 200 Hz infrared eye tracker was used to align the eye with the visual axis, and to prevent decentration. With the help of Final Fit (version 1.11; Nidek Co. Ltd.) ablation-planning software, a 4.5 to 5.0-mm optical zone was programmed in the OPDCAT group. All of the optical zones and transition zones were treated using profile 5 of the OPDCAT algorithm. In the OPA group, optical zones and transition zones were set taking into account the pupil size and ablation depth according to

OPA ablation software (version 1.00; Nidek Co. Ltd.). The optical zone in the OPA group was determined, to facilitate assessment of the ablation depth; the transition zone was 1.5 mm larger than the programmed optical zone. The mean optical zones and transition zones were 4.9 mm and 8.4 mm, respectively, in the OPDCAT group, and 5.8 mm and 7.4 mm in the OPA group. After the ablation, PTK surface smoothing was performed with masking fluid (0.3% hyaluronic acid; Santen, Osaka, Japan) for removing corneal-micro irregularities.[15] Filter paper discs soaked with 0.02% mitomycin C were applied for 29 s (range 20–40 s). These were ring shaped (devoid of paper in their centers), to preclude contact with the central portion of the cornea. Therapeutic soft-contact lenses were applied after the smoothing. In all cases, the intended refraction was emmetropia. Mean UDVA, CDVA, refractive error, wavefront aberration, and MTF values were compared between the two groups using the Mann–Whitney U test. The Wilcoxon signed-rank test was used to assess the mean changes following surgery. All analyses were performed using SPSS for Windows software (version 12.0; SPSS, Inc., Chicago, IL, USA). P-values of <0.05 were considered as statistically significant.

Results

In the study, 21 patients were assigned to the OPDCAT group, and 32 to the OPA group. The mean age of the 25 men and 27 women in the study was 25.72 ± 5.03 years (range 20–39 years). Table 1 shows the preoperative sphere, cylinder, MRSE, corneal and ocular HOAs, and the corneal asphericity of each group. There were no statistically-significant differences in baseline-characteristics between the groups, except with regard to spherical aberration (SA) of the cornea. During the followup at postoperative 1, 3, and 6 months, all eyes were assessed. No intraoperative or postoperative complications were detected.

Table 1 Baseline characteristics of the eyes in the OPDCAT and OPA groups

Category	OPDCAT (n = 21)	OPA (n = 32)	P-value
Age	24.71 ± 3.67	26.36 ± 5.72	$P > 0.05$
Sphere (D)	-7.73 ± 0.63	-7.91 ± 0.63	$P > 0.05$
Cylinder (D)	-1.54 ± 0.67	-1.52 ± 0.90	$P > 0.05$
MRSE (D)	-8.39 ± 0.34	-8.48 ± 0.31	$P > 0.05$
Ocular HOA RMS (um)	0.36 ± 0.12	0.35 ± 0.12	$P > 0.05$
Ocular spherical aberrations (um)	0.03 ± 0.11	0.08 ± 0.09	$P > 0.05$
Corneal spherical aberrations (um)	0.22 ± 0.62	0.26 ± 0.07	$P < 0.05$
Corneal asphericity	-0.21 ± 0.06	-0.17 ± 0.08	$P > 0.05$

At 1, 3, and 6 months after surgery, mean MRSE values were -0.45 ± 0.71 D, -0.34 ± 0.68 D, and -0.24 ± 0.68 D, respectively, in the OPDCAT group and -0.24 ± 0.40 D, -0.23 ± 0.56 D, and -0.24 ± 0.50 D in the OPA group. The differences between the groups were not statistically significant at any of the three time points. All patients in both groups had an UDVA of 20/20 or better. Predictability (± 1 D from intended refraction) at 6 months was 86% in the OPDCAT group, and in the OPA group it was 94%.

The HOA root mean square increased in both groups after the surgery. However, no statistically-significant differences were evident between the groups at 1, 3, or 6 months after the operation (Figure 2a). Ocular SAs were significantly lower in the OPA group throughout the postoperative period (P-values at 1, 3, and 6 months were 0.000, 0.003, and 0.013, respectively; Figure 2b). Despite the significantly-higher preoperative-corneal SAs in the OPA group compared with the OPDCAT group, corneal SA was significantly lowered in the OPA group throughout the postoperative period (P-values at 1, 3, and 6 months were 0.000, 0.000, and 0.001, respectively; Figure 2c). Ocular coma increased significantly after the operation in both groups, and continued to increase up to the 6-month follow-up, with no statistically-significant differences apparent between the groups (Figure 2d). There was also no statistically-significant difference in preoperative-corneal asphericity between the two groups; the mean-corneal asphericity remained significantly low in the OPA group (Figure 3).

Both groups exhibited significantly-improved AreaRatio-Total value and insignificantly-worsened AreaRatio-HO value, throughout the postoperative period (Figure 4). The OPA group exhibited significantly-higher AreaRatio-Total compared with OPDCAT group at 1 month and 6 months after the operation (P-values at 1, 3, and 6 months were 0.008, 0.190, and 0.039, respectively; Figure 4a). AreaRatio-HO did not differ statistically-significantly between the two groups, throughout the postoperative period (Figure 4b). Six months after the operation, the Strehl ratio decreased in both groups, without a significant difference between the groups (Figure 4c). Six months after the operation, corneal haze was present in 2/21 patients (9.5%) in the OPDCAT group, and the haze grade was 0.1 in both of these patients. In the OPA group, 3/32 patients (9.4%) showed corneal haze at 6 months postoperatively, and the haze grades in these 3 patients were 0.5, 0.5, and 1.0.

Discussion

Refractive surgery for high myopia has been a long-standing challenge. In myopic eyes, refractive surgery reduces the corneal curvature by subtracting a positive meniscus of corneal tissue, creating a flatter optical zone, sometimes increasing the corneal aberrations.[2] In other words, conventional laser ablation creates an oblately shaped cornea, inducing a sudden and marked change in the corneal-curvature gradient between the central-treated area and the peripheral-untreated area.[15] Previous studies have shown a relationship between the preoperative-refractive error and the change in corneal SA after myopic-refractive surgery.[16] The OPA algorithm uses corneal topography and wavefront aberrometry,
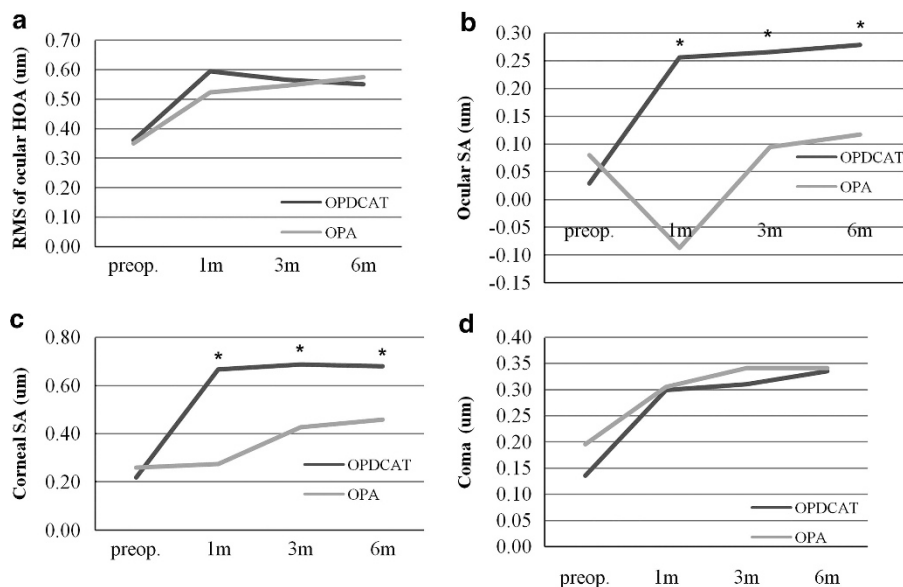

Figure 2 Wavefront aberrations over time.

which is designed to reduce preexisting ocular SAs and maintain corneal asphericity. The OPA algorithm compensates for radial energy loss on an individual basis, reducing surgically-induced HOAs.[17,18] The OPDCAT algorithm uses an aspheric ablation for optical and transition zones, and treats ocular HOAs with a multipoint-spot ablation module. OPDCAT ablation is also known to induce less HOA than the conventional refractive surgeries.[8]

Positive SA is a result of a prolate-shaped cornea, and originally compensated for the negative aberration of crystalline lenses. Myopic-excimer laser ablation induces positive SA in the natural cornea and damages negative sphericity. Maintaining a prolate-shaped cornea and minimizing induced SA are critical to improving the quality of vision.[17,18] In this study, the OPA group showed statistically-significantly fewer induced SAs and corneal asphericity changes than the OPDCAT group. We presume that this is because the OPA algorithm applies

more ablation to the midperiphery, and can maintain a physiologically-prolate cornea.[11] The OPA algorithm can maintain a more prolate cornea than the OPDCAT algorithm, and this may be closely related to the optical quality of patients' vision after surgery. In addition, mean changes in corneal asphericity at postoperative 6 months were $+1.04$ in the OPDCAT group, and $+0.58$ in the OPA group ($P = 0.006$). The increase in corneal asphericity in the OPA group was not significant. Corneas in the OPA group maintained a more prolate shape than those in the OPDCAT group, throughout the postoperative period, implying that the OPA algorithm maintains the normal-corneal shape more effectively than the OPDCAT algorithm, postoperatively. Unlike previous studies that have investigated the limitations of wavefront analysis that may increase induced-HOAs postoperatively,[9,10] in our study, the OPA algorithm was associated with significantly-less corneal and ocular SAs than the OPDCAT algorithm. This result is concordant with the report by Kang et al,[12] suggesting that the limitations of wavefront analysis can be overcome by the higher-resolution corneal topography inherent in the OPA algorithm.

Usually, patients with myopia exceeding 8 D show more unpredictable-postoperative results than patients with myopia under 8 D. In one study, only 67% of the patients with myopia exceeding 8 D showed postoperative MRSE within 1 D of intended refraction.[3] In our study, predictability at 6 months in both groups was higher than that of conventional refractive surgery. Furthermore, the OPA group exhibited higher predictability than the OPDCAT group (94% vs 86%).

In this study, MTF was used to measure the objective visual quality of patients. AreaRatio-Total was
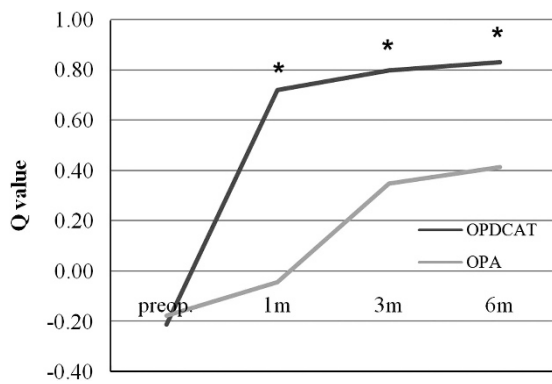

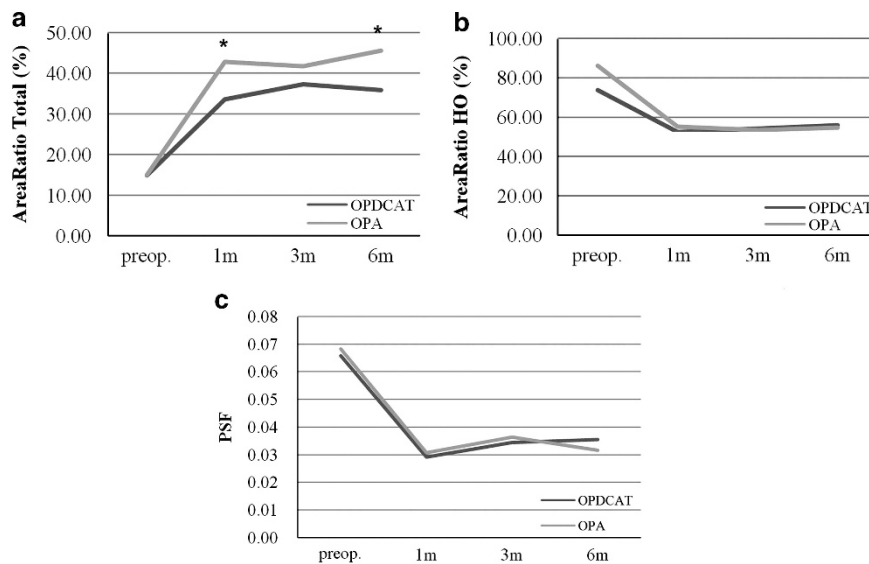**Figure 3** Corneal asphericity (Q value) over time.

Figure 4 Modulation-transfer function (AreaRatio-Total, AreaRatio-HO) and point-spread function (PSF) over time.

significantly higher in the OPA group than the OPDCAT group, and AreaRatio-HO did not differ statistically-significantly between the two groups. In other words, while objective visual quality associated with HOAs was slightly impaired in both groups after the surgery, uncorrected-visual performance in the OPA group was better than that of the OPDCAT group.

In our study, there was a lower incidence of corneal haze (9.4% in the OPDCAT group and 9.5% in the OPA group) compared with a previous study reporting corneal haze in 70% of eyes with more than 10 D of myopia, and 36% of eyes with myopia from − 6 to − 10 D, postoperatively.[19] This result can be explained by the effect of the prophylactic use of 0.02% mitomycin C, and the surface smoothing technique, which are known to be effective for the prevention of corneal-haze after PRK in highly-myopic patients.[15,20,21] According to clinical corneal-haze classification of Hanna *et al*,[13] corneal-haze grade 1.0 is mild, faint reticular haze which can be only seen by broad-tangential illumination, and vision is not affected graded 0 to 1.0. Thus, all patients in our study obtained UDVA of 20/20 or better.

For optimal outcomes after PRK in patients with myopia exceeding 8 D, ocular topography and an aberrometer both seem to be vital components. The OPA algorithm utilizes both components, which is expected to improve postoperative-objective visual quality and predictability. In our study, the OPA algorithm was associated with higher-objective visual quality and predictability, induced less corneal and ocular SAs, and preserved more preoperative-corneal asphericity than the OPDCAT algorithm.

In conclusion, the OPA algorithm seems to be more appropriate than the OPDCAT algorithm for patients with myopia exceeding 8 D who undergo PRK, with regard to postoperative-objective visual quality and predictability.

Summary

What was known before
- Patients with myopia exceeding 8 D show more unpredictable-postoperative results than patients with myopia under 8 D. Wavefront-analysis algorithms have limitations which are presumably related to its limited resolution.

What this study adds
- The OPA algorithms yielded higher-objective visual quality and predictability, induced less corneal and ocular spherical aberrations, and preserved more preoperative-corneal asphericity than the OPDCAT algorithms.

Conflict of interest

The authors declare no conflict of interest.

References

1 Alio JL, Muftuoglu O, Ortiz D, Pérez-Santonja JJ, Artola A, Ayala MJ *et al*. Ten-year follow-up of laser in situ keratomileusis for myopia of up to -10 diopters. *Am J ophthalmol* 2008; **145**(1): 46–54.

2 Vega-Estrada A, Alio JL, Arba Mosquera S, Moreno LJ. Corneal higher order aberrations after LASIK for high myopia with a fast repetition rate excimer laser, optimized ablation profile, and femtosecond laser-assisted flap. *J Refract Surg* 2012; **28**(10): 689–696.

3 Tuunanen TH, Tervo TT. Results of photorefractive keratectomy for low, moderate, and high myopia. *J Refract Surg* 1998; **14**(4): 437–446.

4 Applegate RA, Howland HC. Refractive surgery, optical aberrations, and visual performance. *J Refract Surg* 1997; **13**(3): 295–299.

5 Benito A, Redondo M, Artal P. Laser in situ keratomileusis disrupts the aberration compensation mechanism of the human eye. *Am J ophthalmol* 2009; **147**(3): 424–431.

6 Seiler T, Kaemmerer M, Mierdel P, Krinke HE. Ocular optical aberrations after photorefractive keratectomy for myopia and myopic astigmatism. *Arch ophthalmol* 2000; **118**(1): 17–21.

7 Yamane N, Miyata K, Samejima T, Hiraoka T, Kiuchi T, Okamoto F *et al*. Ocular higher-order aberrations and contrast sensitivity after conventional laser in situ keratomileusis. *Invest Ophthalmol Vis Sci* 2004; **45**(11): 3986–3990.

8 Vinciguerra P, Albe E, Camesasca FI, Trazza S, Epstein D. Wavefront- versus topography-guided customized ablations with the NIDEK EC-5000 CX II in surface ablation treatment: refractive and aberrometric outcomes. *J Refract Surg* 2007; **23**(9 Suppl): 1029–1036.

9 Hori-Komai Y, Toda I, Yamamoto T, Tsubota K. Comparison of LASIK with the OPDCAT or OATz algorithm using the NIDEK EC-5000CXII excimer laser. *J Refract Surg* 2010; **26**(6): 411–422.

10 Pop M, Payette Y. Correlation of wavefront data and corneal asphericity with contrast sensitivity after laser in situ keratomileusis for myopia. *J Refract Surg* 2004; **20**(5 Suppl): 678–684.

11 Ahn JM, Choi BJ, Kim EK, Sgrignoli B, Kim TI. Three different aspheric treatment algorithms of laser-assisted sub-epithelial keratectomy in patients with high myopia. *Jpn J ophthalmol* 2013; **57**(2): 191–198.

12 Kang EC, Choi BJ, Kim EK, Kim TI. Clinical outcomes of optimized prolate ablation and custom aspheric treatment in laser-assisted subepithelial keratectomy. *J Cataract Refract Surg* 2012; **38**(3): 445–452.

13 Hanna KD, Pouliquen YM, Waring 3rd GO, Savoldelli M, Fantes F, Thompson KP. Corneal wound healing in monkeys after repeated excimer laser photorefractive keratectomy. *Arch of ophthalmol* 1992; **110**(9): 1286–1291.

14 Ligabue EA, Giordano C. Assessing visual quality with the point spread function using the NIDEK OPD-Scan II. *J Refract Surg* 2009; **25**(1 Suppl): 104–109.

15 Vinciguerra P, Camesasca FI, Torres IM. Transition zone design and smoothing in custom laser-assisted subepithelial keratectomy. *J Cataract Refract Surg* 2005; **31**(1): 39–47.

16 Oshika T, Miyata K, Tokunaga T, Samejima T, Amano S, Tanaka S *et al*. Higher order wavefront aberrations of cornea and magnitude of refractive correction in laser in situ keratomileusis. *Ophthalmology* 2002; **109**(6): 1154–1158.

17 El-Danasoury A, Bains HS. Optimized prolate corneal
    ablation: case report of the first treated eye. *J Refract Surg*
    2005; **21**(5 Suppl): 598–602.
18 Holladay JT, Bains HS. Optimized prolate ablations with the
    NIDEK CXII excimer laser. *J Refract Surg* 2005; **21**(5 Suppl):
    595–597.
19 Vestergaard AH, Hjortdal JO, Ivarsen A, Work K, Grauslund
    J, Sjolie AK. Long-term outcomes of photorefractive

keratectomy for low to high myopia: 13 to 19 years of
follow-up. *J Refract Surg* 2013; **29**(5): 312–319.
20 Jain S, McCally RL, Connolly PJ, Azar DT. Mitomycin C
    reduces corneal light scattering after excimer keratectomy.
    Cornea 2001; **20**(1): 45–49.
21 Maldonado MJ. Intraoperative MMC after excimer
    laser surgery for myopia. *Ophthalmology* 2002; **109**(5):
    826–828.