

Comparison of Custom Ablation and Conventional Laser In Situ Keratomileusis for Myopia and Myopic Astigmatism Using the Alcon Excimer Laser

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Purpose: To compare the refractive outcomes, higher order aberrations, and contrast sensitivity after laser in situ keratomileusis (LASIK) using wavefront ablation and conventional ablation.

Setting: Private practice in Córdoba, Spain and a free-standing outpatient surgery center.

Methods: This was a prospective, nonrandomized, observational case series comparing outcomes of 239 eyes that underwent LASIK for myopia and myopic astigmatism with either wavefront or conventional ablation using the LADARVISION excimer laser. Manifest refractive sphere ranged from 0.50 D to -8.00 D with astigmatism up to -4.00 D. Eighty-nine eyes underwent conventional LASIK (conventional group), and 150 eyes underwent custom ablation (custom group). Refractive outcomes, ocular higher order root mean square (HOA-RMS), and contrast sensitivity were tested for statistically significant differences between groups. A *P*-value less than 0.05 was considered statistically significant. Six month postoperative data are reported here.

Results: Postoperatively, the mean SE was -0.03 D \pm 0.19 D for the custom group, and -0.14 D \pm 0.35 D for the conventional group (*P* = 0.003). Ninety-nine percent of the eyes in the custom group, and 92% of the eyes in the conventional group were within 0.50 D of the intended correction (*P* > 0.05). The HOA-RMS was 0.16 μ m lower in the custom group (*P* < 0.001). Contrast sensitivity was statistically significantly better at 3 cycles per degree (cpd) (*P* < 0.001) and 6 cpd (*P* = 0.009) in the custom group.

Conclusion: There was a statistically significant lower induction of HOA-RMS and better predictability and contrast sensitivity in eyes that underwent custom ablation with the LADARVISION excimer laser.

Key Words: wavefront, LASIK, myopia

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Conventional excimer laser algorithms are based entirely on the refractive error of the eye, whereas the goal of

custom ablation is the correction of the refractive error and the higher-order aberrations of the eye using an excimer laser. Although the refractive outcomes of custom ablation treatments and conventional treatment are generally similar, there may be better visual quality associated with custom ablation.^{1–4} For example, the lower induction of higher-order aberrations (HOA) compared with conventional treatments may allow better contrast sensitivity (CS).⁴ The various custom ablation platforms use different ablation algorithms, treatment zones, and treat varying types of HOA. Hence, the outcomes of individual platforms need to be investigated to determine whether custom ablation is clinically advantageous compared with conventional ablation. To our knowledge, there are 3 published comparisons of conventional and custom ablation outcomes using the Alcon platform for primary myopia and myopic astigmatism.^{5–7} Two of these studies^{5,6} were performed with a follow up of 3 months and only one measured changes in spherical aberration (SA). Binder and Rosenshein⁷ reported changes in SA, but all the patients had undergone keratectomy using a femtosecond laser.

This study compared the 6-month postoperative refractive outcomes, induction of aberrations (including SA), and CS between custom ablation and conventional treatments using the Alcon CustomCornea (Alcon Laboratories, Ft. Worth, TX) custom ablation and the Alcon LADARVision 4000 (Alcon Laboratories) conventional ablation. All patients underwent flap creation using a mechanical microkeratome.

PATIENTS AND METHODS

Patients and Examinations

Two ablation algorithms were used in this study: the Alcon CustomCornea custom ablation algorithm (custom group) and the Alcon LADARVision 4000 conventional ablation (conventional group). The preoperative age and refractive parameters are shown in Table 1 for both groups. A total of 239 eyes (107 males and 132 females) underwent laser in situ keratomileusis (LASIK). Spherical refractive error ranged from 0.50 D to -8.00 D and with cylinder up to 4.00 D. Study subjects were selected in a prospective and non-randomized fashion among patients who underwent LASIK surgery between May 2005 and December 2005. Patient selection was based on chart review of all eyes that were targeted for emmetropia that had no intraoperative and postoperative complications or retreatments. Eyes undergoing conventional or custom ablation were assigned to the appropriate group.

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TABLE 1. Preoperative Patient Data for Eyes That Underwent Laser in Situ Keratomileusis With Custom Ablation or Conventional Ablation

	Spherical Error ± SD (D) (Min–Max)	Astigmatism ± SD (D) (Min–Max)	Spherical Equivalent ± SD (D) (Min–Max)	Age ± SD (Min–Max) (years)	Infrared Pupil Size ± SD (Min–Max) (mm)
Alcon Custom Cornea (n = 150)	-3.52 ± 1.63 (0)–(-8)	-0.79 ± 0.75 (0)–(-4)	-3.94 ± 1.58 (-1.5)–(-8.2)	30.93 ± 6.41 (22)–(44)	7.07 ± 0.91 (5)–(9)
Alcon conventional ablation (n = 89)	-3.97 ± 1.77 (+0.5)–(-8)	-0.96 ± 0.89 (0)–(-4)	-4.44 ± 1.89 (-1.75)–(-8.35)	30.70 ± 6.21 (21)–(40)	6.94 ± 0.78 (5)–(9)

SD, standard deviation; (Min–Max), minimum–maximum.

Preoperative examination included uncorrected and best spectacle-corrected visual acuity (UCVA and BSCVA), infrared pupillometry (Colvard; Oasis, Inc) manifest and cycloplegic refractions, mesopic contrast sensitivity (luminance: 3 cd/m³) with the VSRC CST1800 (sinusoidal pattern) (Vision Sciences Research Corporation, San Ramon, CA), corneal topography (Carl Zeiss Humphrey, Dublin, CA), aberrometry for a 6.50-mm pupil diameter measured to the 8th Zernike order using the LADARWave aberrometer (Alcon Laboratories), ultrasound pachymetry, slit lamp biomicroscopy, and dilated funduscopy. Postoperative examinations were performed at 1 day, 4 days, 1.5 months, and 6 months. From 1.5 months onward, postoperative examination was the same as the preoperative examination with the exception of dilated funduscopy, which was conducted only if warranted. Data out to 6 months postoperatively are reported here.

Surgeries

Custom ablation and conventional surgeries were performed from May 2005 to December 2005 by one surgeon (A.V.) using the same surgical technique. Where appropriate, all patients underwent either bilateral LASIK with custom ablation or bilateral LASIK with conventional ablation. Patients were administered topical anesthesia before the placement of a sterile drape and a lid speculum on the operative eye. A corneal flap with a nasal hinge was created using the Amadeus I microkeratome (AMO, Inc., Santa Ana, CA). The laser delivery was correctly centered according to the manufacturer’s instructions.

Nomograms specific to each ablation algorithm were used to determine the laser data entry. Conventional treatments were based on subjective cycloplegic refraction and custom ablation treatments were based on the refraction and wavefront profile generated from the LADARWave aberrometer. An

optical zone of 6.50 mm and a transition zone of 1.25 mm were programmed into the laser for all treatments. After the ablation, the flap was repositioned back to its original position and irrigated using balanced salt solution and allowed to adhere for a period of 3 minutes before discharging the patient from the operating room. The postoperative eyedrop regimen included administration of topical antibiotic and steroid 3 times per day for 7 days and artificial tears as needed.

Outcomes Analysis

Visual, refractive, and safety outcomes for the 2 groups were compared for statistically significant differences. The efficacy index (EI) was calculated using the following equation:

(1) EI = UCVA postoperative ÷ BSCVA preoperative where UCVA postoperative denotes uncorrected visual acuity postoperatively and BSCVA preoperative denotes best spectacle-corrected visual acuity preoperatively. The safety index (SI) was calculated using the following equation:

(2) SI = BSCVA postoperative ÷ BSCVA preoperative where BSCVA postoperative denotes best spectacle-corrected visual acuity postoperatively and BSCVA preoperative denotes best spectacle-corrected visual acuity preoperatively.

The unpaired Student *t* test was used to determine the differences between groups. A *P* value less than 0.05 was considered statistically significant.

RESULTS

Refractive Outcomes and Visual Acuity

There were no statistically significant differences in the following preoperative parameters between groups (*P* > 0.05):

TABLE 2. Preoperative Aberrometry and Contrast Sensitivity Data for Eyes That Underwent Laser in Situ Keratomileusis With Custom Ablation or Conventional Ablation

	HOA ± SD (Min–Max) (µm)	SA ± SD (Min–Max) (µm)	CS 1.5 ± SD (Min–Max) (cpd)	CS 3 ± SD (Min–Max) (cpd)	CS 6 ± SD (Min–Max) (cpd)	CS 12 ± SD (Min–Max) (cpd)	CS 18 ± SD (Min–Max) (cpd)
Alcon CustomCornea (n = 150)	0.40 ± 0.17 (0.18)–(1.0)	0.20 ± 0.15 (0.01)–(0.51)	74.53 ± 24.32 (36)–(100)	113.92 ± 33.01 (29)–(160)	105.74 ± 39.12 (16)–(180)	43.24 ± 22.68 (8)–(120)	16.95 ± 12.51 (0)–(65)
Alcon conventional ablation (n = 89)	0.41 ± 0.15 (0.11)–(0.98)	0.18 ± 0.13 (0.03)–(0.45)	71.78 ± 24.06 (0)–(100)	107.88 ± 35.07 (57)–(160)	107.02 ± 44.42 (45)–(180)	42.58 ± 24.90 (8)–(120)	15.46 ± 12.17 (0)–(65)

HOA, higher-order aberration; SA, spherical aberration; CS, contrast sensitivity; SD, standard deviation; cpd, cycles per degree; (Min–Max), minimum–maximum.

age, sphere, astigmatism, pupil size, HOA, SA, and CS (Tables 1 and 2). The mean preoperative spherical equivalent was higher in the conventional group compared with the custom group but without statistically significant differences (Table 1).

Six months postoperatively, the mean manifest refractive spherical equivalent was $-0.03\text{ D} \pm 0.19\text{ D}$ (range, $+0.75\text{ D}$ to -0.75 D) for the custom group and $-0.14\text{ D} \pm 0.35\text{ D}$ (range, $+0.75\text{ D}$ to -1.50 D) for the conventional group. The difference in postoperative spherical equivalent between groups was statistically significant ($P = 0.003$). The mean postoperative sphere at 6 months was $-0.03\text{ D} \pm 0.17\text{ D}$ (range, $+0.75\text{ D}$ to -0.75 D) for the custom group and $-0.10\text{ D} \pm 0.28\text{ D}$ (range, $+0.75\text{ D}$ to -1.25 D) for the conventional group. The difference in postoperative sphere between groups was not statistically significant. The mean postoperative cylinder at 6 months was $-0.07\text{ D} \pm 0.24\text{ D}$ (range, 0 D to -1.25 D) for the custom group and $-0.15\text{ D} \pm 0.44\text{ D}$ (range, 0 D to -2.00 D) for the conventional group. The difference in postoperative cylinder between groups was not statistically significant. Six months postoperatively, 98.6% (148 of 150) of the eyes in the custom group and 92.1% (82 of 89) of the eyes in the conventional group were within half a diopter of the intended correction ($P > 0.05$).

At 6 months postoperatively, 94% (141 of 150) of the eyes in the custom group and 88.8% (79 of 89) of eyes in the conventional group had an UCVA of 20/25 or better ($P > 0.05$). The mean postoperative UCVA (decimal notation) over time for both groups is shown in Figure 1. The efficacy index at 6 months postoperatively was 0.98 for the custom group and 0.93 for the conventional group. There were no statistically significant differences in the mean UCVA or efficacy indices between groups at any time point ($P > 0.05$).

The BSCVA over time is shown in Figure 2. There were no statistically significant differences in the mean BSCVA

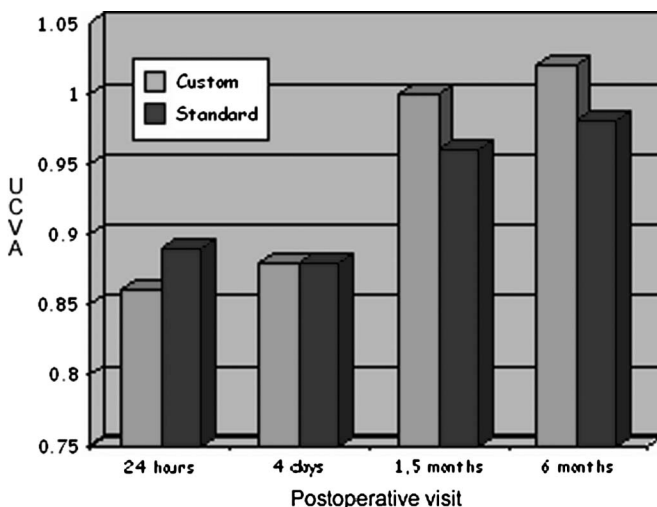


FIGURE 1. Postoperative uncorrected visual acuity (UCVA) (decimal notation) over time for eyes that underwent laser in situ keratomileusis with custom ablation (N = 150 eyes) or conventional ablation (N = 89 eyes). There was no statistically significant difference between groups at any time point ($P > 0.05$).

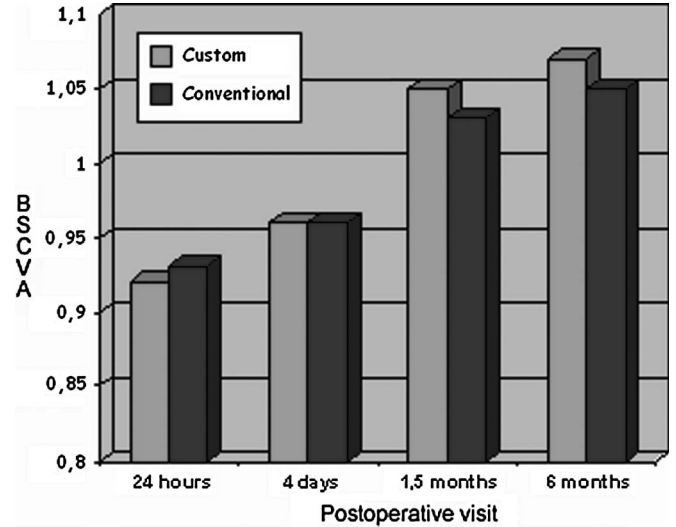


FIGURE 2. Postoperative best spectacle-corrected visual acuity (BSCVA) (decimal notation) over time for eyes that underwent laser in situ keratomileusis with custom ablation (N = 150 eyes) or conventional ablation (N = 89 eyes). There were no statistically significant differences between groups at any time point ($P > 0.05$).

between groups at any time point ($P > 0.05$). At 6 months postoperatively, 3.9% (6 of 150) of the eyes in the custom group and 3.6% (3 of 89) of the eyes in the conventional group lost one line of BSCVA. The SI at 6 months postoperatively was 1.02 for the custom group and 1 for the conventional group. There were no statistically significant differences in the number of lines lost or SIs between groups ($P > 0.05$). At 6 months postoperatively, 6.7% (10 of 150) of the eyes in the custom group and 5.4% (5 of 89) of the eyes in the conventional group gained one or more lines of BSCVA. There was no statistically significant difference in the number of lines gained between groups ($P > 0.05$).

Aberrations and Contrast Sensitivity

Six months postoperatively, the ocular HOA root mean square (RMS) was $0.56\text{ }\mu\text{m}$ for the custom group and $0.72\text{ }\mu\text{m}$ for the conventional group. The HOA RMS was statistically significantly lower in the custom group ($P = 0.000$). The RMS for SA was $0.29\text{ }\mu\text{m}$ in the custom group and $0.45\text{ }\mu\text{m}$ in the conventional group 6 months postoperatively. The magnitude of SA was statistically significantly lower in the custom group ($P < 0.001$). At 6 months postoperatively the RMS for coma was $0.40\text{ }\mu\text{m}$ for the custom group and $0.43\text{ }\mu\text{m}$ for the conventional group ($P > 0.05$). Six months postoperatively, total ocular RMS for HOA increased by 28.57% for the custom group and 43.05% for the conventional group. There was a statistically significant difference of the induction of HOA between groups ($P = 0.02$). Coma increased by 32.25% in the custom group and 41.66% in the conventional group ($P > 0.05$) 6 months postoperatively. The SA increased by 31% in the custom group and 60% in the conventional group. The induction of SA was statistically significantly higher in the conventional group ($P = 0.001$).

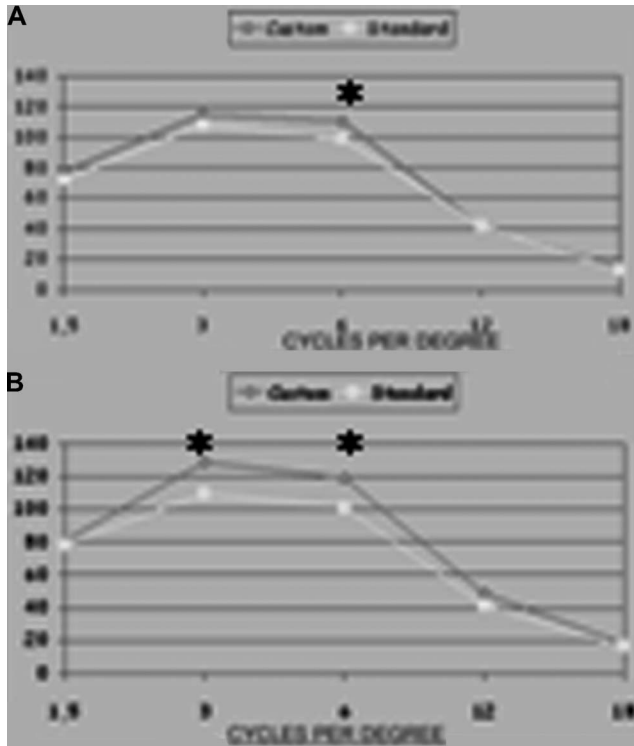


FIGURE 3. Mesopic contrast sensitivity at (A) 1.5 months postoperatively for eyes that underwent laser in situ keratomileusis with custom ablation (N = 150 eyes) or conventional ablation (N = 89 eyes). A statistically significant difference was found at 6 cycles per degree (CPD). B, Six months postoperatively for eyes that underwent laser in situ keratomileusis with custom ablation (N = 150 eyes) or conventional ablation (N = 89 eyes). Statistically significant differences were found at 3 and 6 cycles per degree (CDP). The asterisk (*) indicates a statistically significant difference ($P < 0.05$) between eyes that underwent conventional ablation and eyes that underwent custom ablation.

The mean CS at 1.5 months and 6 months postoperatively is shown in Figures 3A and 3B.

DISCUSSION

Visual Acuity and Refractive Outcomes

In this investigation of the treatment of myopia and myopic astigmatism with custom ablation or conventional ablation, there was no statistically significant difference in the visual acuity or safety between groups. However, there was a statistically significant difference in predictability favoring eyes that underwent custom ablation. LASIK using either ablation algorithm is safe and efficacious. For example, the SIs were 1 or higher in both groups, indicating an excellent safety profile for both ablation algorithms. Our results concur with reports that show no statistically significant difference in safety and efficacy between conventional and custom ablation. A comprehensive literature review found little evidence supporting better outcomes with custom ablation compared with

conventional treatments.¹ Likewise, Kim and colleagues found no difference in visual acuity between conventional and custom ablation treatments.²

A prospective, randomized study of 24 eyes with a similar range of refractive error as ours found no statistically significant differences in safety or efficacy between custom ablation and conventional ablations using the Bausch and Lomb platform.³ In a recent study, Binder and Rosenshien⁷ did not find statistically significant differences in safety or efficacy between groups using the Alcon excimer laser platforms.

However, 2 separate studies reporting outcomes using the Alcon platform on eyes with a lower refractive range than ours found statistically significantly better UCVA in the eyes undergoing custom ablation compared with conventional ablation.^{5,6} Both studies treated significantly less astigmatism than our study (up to -4.00 D); one study treated -1.50 D or less⁶ and the other -2.50 D or less⁵ of preoperative astigmatism. The treatment of astigmatism is generally less accurate as the magnitude increases and maybe a contributing factor to lack of differences in UCVA postoperatively in the current study. Furthermore, both studies report 3-month outcomes, which may not account for all the changes in UCVA over time.^{5,6} Lastly, one of the 2 studies preselected patients with BSCVA of 20/20 or better preoperatively.⁶ However, we did not preselect patients with excellent BSCVA preoperatively, opting instead to provide a representative sample of the refractive surgery candidates in our practice. Our worse preoperative BSCVA was 20/30 in 3 eyes (2 patients).

In the current comparison of custom ablation and conventional ablation, the preoperative myopic sphere, cylinder, and age were matched for both treatment groups. By reporting outcomes from one LASIK surgeon, the data more accurately reflect the performance of both ablation algorithms without confounding variables such as intersurgeon variability. Both the custom ablation and conventional ablation algorithms were effective in the reduction of refractive error to provide excellent functional vision with minimal risk. This investigation presents 6-month postoperative data, which is adequate for reporting conclusive outcomes for myopia and myopic astigmatism.

Aberrations and Contrast Sensitivity

The major advantage of custom ablation over conventional ablation is the lower induction of HOA, which may lead to better visual quality. In the current study, we evaluated visual quality data by testing mesopic contrast sensitivity and analyzing the induction of HOA postoperatively.

Coma may occur as a result of clinically insignificant decentrations or as a result of the creation of a flap.⁸⁻¹⁴ In this study, we found no significant difference in coma between groups postoperatively. In both groups, coma did increase significantly with respect to the preoperative value. Recent studies indicate that this outcome may be the result of the creation of the flap.¹¹⁻¹³ However, data from various reports have provided contradictory results and warrant further investigation to determine if this is indeed the case.¹⁰⁻¹⁴

The induction of ocular HOA and SA were significantly lower in the custom group. This difference was not the result of a greater magnitude of preoperative HOA in the conventional

group because both groups were matched preoperatively. Induced SA has been associated with night vision disturbances postoperatively.¹⁵ By compensating for pre-existing SA, the custom ablation algorithm has clearly reduced the induction of this aberration. Both HOA and SA reported in the current study were much lower than the 2-fold to 7-fold induction reported after conventional ablation with various commercially available platforms.^{16,17} The reduced induction of HOA, especially SA, may portend a reduction of night vision disturbances after custom ablation. However, it must be noted that even in the custom group, the SA increased postoperatively; this means that an algorithm has not yet been designed to avoid the induction of SA. One study does report a slight decrease in the SA in eyes treated using custom ablation with the LADARWave platform, but the authors state that this may have been the result of a higher preoperative SA in this group of patients compared with the conventional group.⁷

Mesopic CS was used as an objective measure of mesopic visual quality. The custom group performed statistically significantly better at CS testing than the conventional group (Fig. 3A–B). For example, within 1.5 months postoperatively, mesopic CS was statistically significantly better at the midspatial frequencies in the custom group (Fig. 3A). The difference in visual quality was even more pronounced at 6 months postoperatively (Fig. 3B). The increased visual quality in the custom group at 6 months postoperatively compared with 1.5 months postoperatively was likely the result of a complex interaction of corneal wound healing, reduction in edema, and residual HOAs that remains to be elucidated.^{18–20}

One drawback of the current study is the lack of patient satisfaction data through the subjective patient questionnaires that could test scotopic visual function to correlate to the CS results. However, very few validated questionnaires exist, and the ones that do can be confusing to the patients, which can affect the validity of the results. Residual refractive error and optical quality of the eye combine to affect visual quality.²¹ The current study investigated whether custom ablation offered the potential for better visual quality based on both refractive outcomes and optical quality through aberrometry measurements and CS. Eyes undergoing custom ablation did have better mesopic visual quality (Fig. 3).

Another potential drawback of this study is the lack of contralateral eye treatment data, which may be more sensitive at picking up differences between treatment groups. However, counseling a patient to have each eye treated with different ablation algorithms would be tenuous at best. Despite this drawback, the current study did find statistically significant differences between groups.

This investigation of LASIK performed by a single surgeon for the treatment of myopia and myopic astigmatism found that there were no statistically significant differences in visual acuity or safety between eyes that underwent custom ablation compared with conventional ablation using the Alcon excimer laser platform. The custom ablation algorithm induces significantly lower aberrations, including SA, and better visual quality.

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