Postoperative Corneal Asphericity in Low, Moderate, and High Myopic Eyes After Transepithelial PRK Using a New Pulse Allocation

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ABSTRACT

PURPOSE: To evaluate the postoperative asphericity in low, moderate, and high myopic eyes after combined transepithelial photorefractive keratectomy and SmartSurf^{ACE} treatment (SCHWIND eye-tech-solutions GmbH, Kleinostheim, Germany).

METHODS: In this retrospective case series, the outcomes of myopic SmartSurf^{ACE} were evaluated at 3 months postoperatively in 106 eyes and divided into low (less than -4.125 diopters [D]), moderate (-4.125 to -6.25 D), and high (more than -6.25 D) myopia groups. In all cases, standard examinations and preoperative and postoperative corneal topography (SCHWIND Sirius) were performed. The analysis comprised evaluating the change in asphericity versus planned correction, comparing expected and achieved postoperative asphericity for all eyes, and comparison of the three groups in terms of the preoperative and postoperatively expected and achieved asphericity.

RESULTS At 3 months postoperatively, the low myopia group (n = 33) improved average negative asphericity (Q = -0.04 ± 0.17 preoperative vs -0.19 ± 0.20 postoperative, $P < .05$). The moderate myopia group (n = 35) maintained or slightly improved average negative asphericity (Q = -0.07 ± 0.14 preoperative vs -0.05 ± 0.24 postoperative, $P = .35$). For the high myopia group (n = 38), the eyes became more oblate compared to the preoperative status (Q = -0.09 ± 0.15 preoperative vs 0.62 ± 0.70 postoperative, $P < .05$). In terms of asphericity, the difference between the three groups was not statistically significant preoperatively ($P > .10$), but showed significant differences postoperatively ($P < .007$). The cohort's average preoperative corrected distance visual acuity was 0.01 ± 0.04 logMAR (range: 0.0 to 0.18 logMAR) and uncorrected distance visual acuity was 0.03 ± 0.08 logMAR (range: -0.12 to 0.40 logMAR) 3 months postoperatively.

CONCLUSIONS: SmartSurf^{ACE} maintained or slightly improved preoperative corneal asphericity for low to moderate myopic corrections (up to -6.00 D). This may provide advantages in the quality of vision and the onset of presbyopic symptoms after laser refractive surgery in myopic patients.

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Precise lasers with small laser spots and high repetition rates are now widely used to manipulate the shape of the cornea to correct refractive errors including myopia, hyperopia, astigmatism, and higher order wavefront aberrations and presbyopia.[1] SmartSurf^{ACE} treatment (SCHWIND eye-tech-solutions GmbH, Kleinostheim, Germany) is a combination of transepithelial photorefractive keratectomy (PRK) implemented using the Smart Pulse Technology (SCHWIND eye-tech-solutions GmbH), which is a three-dimensional model based on a fullerene structure to improve the smoothness of the ablation beam profile to enhance the short-term outcomes without compromising stability or long-term outcomes.[2,3]

The aim of this study was to evaluate the postoperative asphericity in low, moderate, and high myopic eyes (with or without astigmatism) after the SmartSurf^{ACE} procedure performed with the aberration-free ablation profiles.

PATIENTS AND METHODS

PATIENTS

This retrospective study was based on a series of patients (106 eyes) treated by two surgeons (DTCL, SPH) with the SmartSurf^{ACE} technique to correct myopic astigmatism at the Pacific Laser Eye Centre, Vancouver, Canada. Informed consent was obtained from each patient for both the treatment and use of their de-identified clinical data for publication. The investigation in this form is not subject to the Medical Research Involving Human Subjects Act. The outcomes of

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performing SmartSurf^{ACE} in 106 consecutive eyes (62 patients) were retrospectively analyzed.

Inclusion criteria were patients older than 18 years, medically suitable for refractive surgery, myopic (with or without astigmatism) with corrected distance visual acuity (CDVA) no worse than 20/32, stable refraction (< 0.50 diopters [D] change in mean spherical equivalent) for 1 year prior to the study, discontinued use of contact lenses for at least 2 to 4 weeks (depending on contact lens type) prior to the preoperative evaluation, and photopic pupil diameter smaller than 3 mm. The pupil diameters were obtained from the topographic measurements. Patients were required to have normal keratometry and topography (visually no suspect nor form fruste keratoconus). Patients who suffered from systemic illness, had a calculated residual corneal bed thickness less than 300 µm after ablation, had preoperative central corneal thickness of less than 470 µm, or had previous ocular surgery or abnormal corneal topography were excluded from the study. Additional exclusion criteria were clinically relevant lens opacity, a pupil offset of 0.7 mm or more, and any signs of binocular vision anomalies at distance and near.

The patients were divided into three groups: low myopia (up to -4.125 D sphere + cylinder preoperatively), moderate myopia (-4.125 to -6.25 D sphere + cylinder preoperatively), and high myopia (higher than -6.25 D sphere + cylinder preoperatively). Visual acuity was evaluated in logMAR units.

Preoperative Assessment

A full ophthalmologic examination was performed by ophthalmic technicians on all patients prior to surgery, including manifest refraction, cycloplegic refraction, and corneal topography (SCHWIND Sirius; SCHWIND eye-tech-solutions GmbH) performed over a diameter of 4.5 mm. Corneal asphericity was extracted from the topography. CDVA and uncorrected distance visual acuity (UDVA) were assessed with Early Treatment of Diabetic Retinopathy Study (ETDRS) charts. The CDVA was always assessed with trial frames and not contact lenses. All tests were performed binocularly.

Surgical Procedure

All treatments were prepared using the SCHWIND Custom Ablation Manager in Aberration-Free mode (SCHWIND eye-tech-solutions GmbH). SmartSurf^{ACE} treatment was planned for each eye based on the total manifest refraction (sphere + cylinder correction in diopters). The devices used in this study bear the standards of European conformity (Conformité Européene or CE marking) but are not approved by the U.S. Food and Drug Administration.

For each treatment, the planning software calculated the size of the optimal transition zone depending on the preoperative refraction and optical treatment zone. Drops of topical anesthetic were instilled in the upper and lower fornices. A sterile drape covering eyelashes was used to isolate the surgical field. An eyelid speculum was inserted to allow maximum exposure of the globe.

Proper alignment of the eye with the laser was achieved with a 1,050-Hz infrared eye tracker with simultaneous limbus, pupil, and torsion tracking integrated into the laser system and centered on the corneal vertex. The eye tracker had a typical response time of 1.7 milliseconds with a system total latency time of 2.9 milliseconds. The ablation profile was centered on the corneal vertex determined by the topography (taking 100% of the pupil offset value[4]), which closely approximates the visual axis.[5,6] Further, the topographic keratometry readings at 3-mm diameter were used for the compensation of the loss of efficiency when ablating the cornea at non-normal incidences. Patients were requested to look at a pulsing green fixation light throughout the ablation.

Patients received topical antibiotic drops four times a day for 1 week, corticosteroid drops four times a day tapering off in 1 week, and ocular lubricants as needed.

Postoperative Evaluation

Patients were reviewed at 3 months postoperatively. A full ophthalmologic examination was performed on all patients by ophthalmic technicians, including manifest refraction, cycloplegic refraction, and corneal topography (SCHWIND Sirius). Corneal asphericity was extracted from the corneal topography. The expected postoperative asphericity was calculated from the preoperative asphericity, keratometry, and planned correction.

Statistical Analysis

The analysis comprised evaluating the change in asphericity versus planned correction, comparing expected and achieved postoperative asphericity for all eyes, and comparison of the three groups in terms of the preoperative, postoperative expected, and achieved asphericity. The paired Student's *t* test was used to evaluate the difference among groups and between preoperative and postoperative asphericity. A *P* value less than .05 was considered statistically significant.

RESULTS

The average age of the patients was 35 ± 9 years (range: 21 to 61 years). The mean preoperative spherical equivalent was -5.40 ± 2.80 D (range: -13.75 to -1.38

D) and the mean preoperative astigmatism was -0.90 ± 0.80 D (range: -4.00 to 0.00 D).

The mean optical treatment zone diameter was 6.9 ± 0.3 mm (range: 6.3 to 7.5 mm; median: 6.8 mm). The 3-month visual outcomes are shown in **Figure 1**.

Preoperatively, in terms of CDVA, statistically significant differences were seen between the low and high myopia groups ($P = .02$). Postoperatively, statistically significant differences were seen between all groups in terms of CDVA ($P < .02$) and between the low myopia and other two groups in terms of UDVA ($P < .0001$). There were no statistically significant differences between the moderate and high myopia groups in terms of postoperative UDVA ($P = .132$).

Achieved Asphericity Versus Planned Correction

The average asphericity was -0.07 ± 0.16 (range: -0.65 to 0.30) preoperatively and 0.15 ± 0.60 (range: -0.64 to 2.32) 3 months postoperatively. The expected postoperative asphericity (expected postoperative Q) and the achieved postoperative asphericity (postoperative Q) combined across all groups are compared with respect to the planned correction (sphere + cylinder correction in diopters) in **Figure 2**. The expected average asphericity was 0.13 ± 0.23 (range: -0.73 to 0.59), showing a significant difference from the preoperative status ($P < .05$) and statistically non-significant differences from the achieved postoperative asphericity ($P = .40$). Considering the trend line of the fourth order polynomial, it was expected that the eyes would become more oblate postoperatively but the asphericity would remain stable throughout the range of the planned correction. However, the postoperative asphericity varied significantly with respect to the planned correction.

For corrections ranging from -2.25 to -6.00 D, we were able to maintain negative asphericity (range of Q: -0.27 to +0.01).

The comparison of the three groups in terms of the preoperative and postoperative expected and achieved asphericity is presented in **Figure 3**. At 3 months postoperatively, the low myopia group improved average negative asphericity (Q = -0.04 ± 0.17 preoperative vs -0.19 ± 0.20 postoperative), showing statistically significant differences from the preoperative ($P < .05$) and expected postoperative ($P < .05$) asphericity.

The moderate myopia group maintained or slightly improved average negative asphericity (Q = -0.07 ± 0.14 preoperative vs -0.05 ± 0.24 postoperative), showing statistically no significant differences to the preoperative asphericity ($P = .35$) but significant differences to the expected postoperative asphericity ($P < .05$). In the high myopia group, the eyes became more oblate compared to the preoperative status (Q = -0.09 ± 0.15 preoperative vs 0.62 ± 0.70 postoperative), showing statistically significant differences to the preoperative ($P < .05$) and expected postoperative ($P < .05$) asphericity. In terms of asphericity, the differences between the three groups were not statistically significant preoperatively ($P > .10$), but showed significant differences postoperatively ($P < .007$).

Change in Asphericity Versus Refractive Correction

The progression of the achieved change in asphericity with respect to the planned correction (sphere + cylinder correction in diopters) is presented in **Figure 3**. The achieved change in asphericity was 0.22 ± 0.61 (range: -0.94 to 2.40) 3 months postoperatively ($P < .05$), with the cornea becoming more oblate on average. A weak causal relationship (coefficient of determination $r^2 = 0.66$) was seen between the achieved change in asphericity and the planned refraction (**Figure 4**). The difference between the postoperatively achieved asphericity and the expected asphericity, showing the deviation trend with respect to the planned correction, is also presented in **Figure 2**. The deviation was small for smaller corrections and increased rapidly and linearly with the increasing planned correction.

DISCUSSION

The goal of any refractive procedure is to correct the intended refractive errors and maintain the preoperative natural condition of the eye as much as possible. Corneal asphericity, spherical aberrations, and coma have been shown to increase in long-term follow-up studies after LASIK and LASEK procedures, mainly due to the healing mechanism of the cornea.[7-9] Myopic and hyperopic corrections using wavefront-guided LASIK have been shown to induce changes in the Q-value and spherical aberrations in opposite directions (ie, positive and negative, respectively). These changes depend on the magnitude of the refractive correction.[10,11] The oblate shape of the cornea following LASIK is the predominant factor in the functional vision decrease.[12] Such findings have also been reported in the simulation environment.[13]

Many commercial systems have introduced algorithms and aspheric ablation profiles to preserve the preoperative asphericity of the cornea, sometimes with unwanted effects or inefficacy of aspheric profiles. Gatinel et al.[14] showed that oblateness of the initial corneal surface, intentional increase in negative asphericity, and enlargement of the optical zone diameter result in deeper central ablations. Tuan and Chernyak[15] reported that visual acuity and contrast sensitivity after wavefront-guided LASIK are not dependent on corneal asphericity; neither preserving nor inducing asphericity

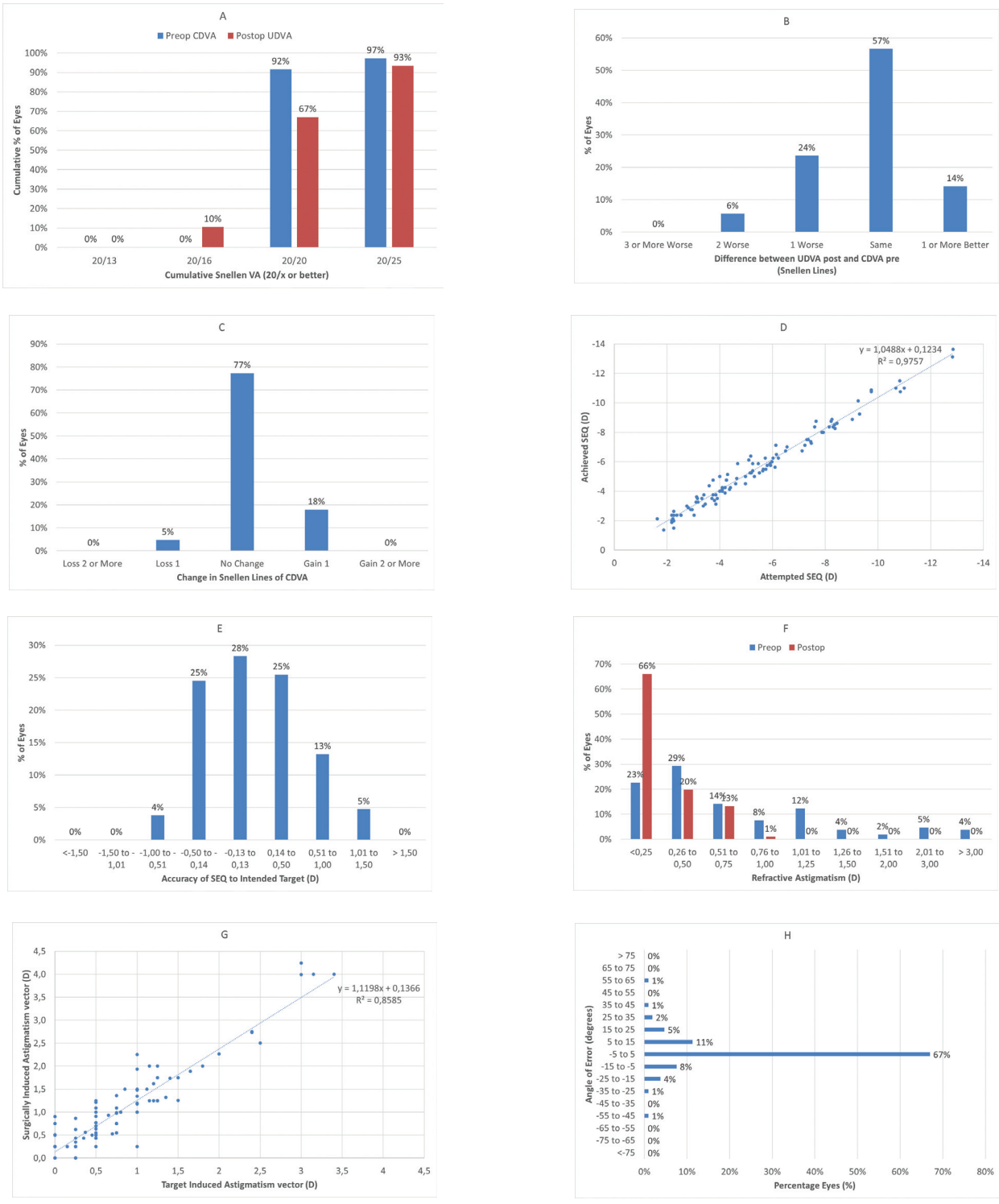

Figure 1. Standard graphs for corneal refractive surgery at 3 months. (A) Postoperative uncorrected distance visual acuity (UDVA). (B) Difference in postoperative UDVA from corrected distance visual acuity (CDVA). (C) Difference in postoperative CDVA from preoperative CDVA. (D) Scattergram for defocus correction. (E) Distribution of postoperative spherical equivalent (SEQ). (F) Distribution of refractive astigmatism correction. (G) Scattergram for astigmatic correction. (H) Distribution of the angle of error.

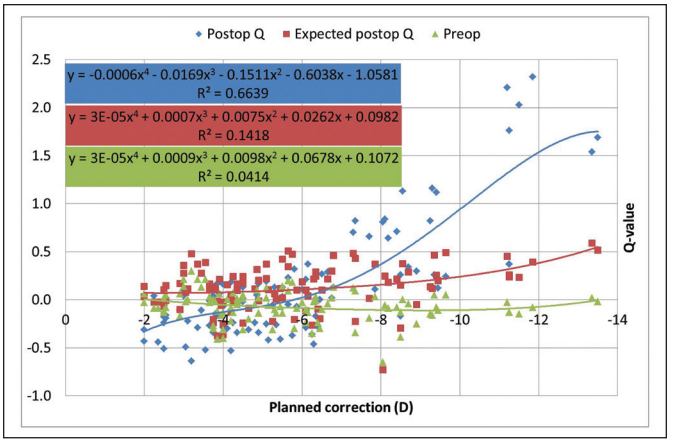

Figure 2. Planned refractive correction and Q-value outcomes. D = diopters

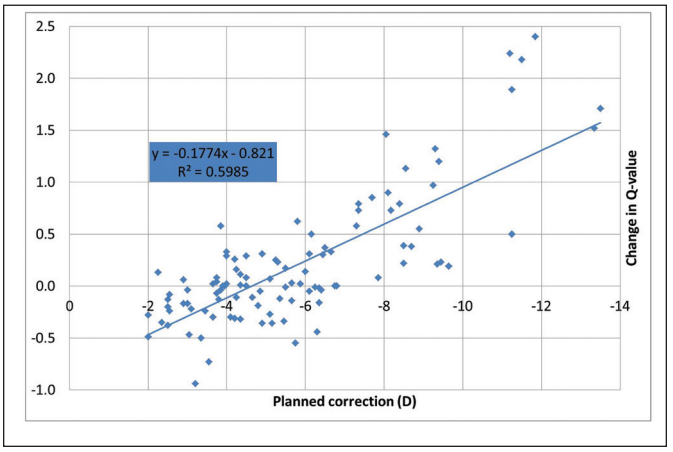

Figure 4. Progression of the change in asphericity with respect to the planned correction. D = diopters

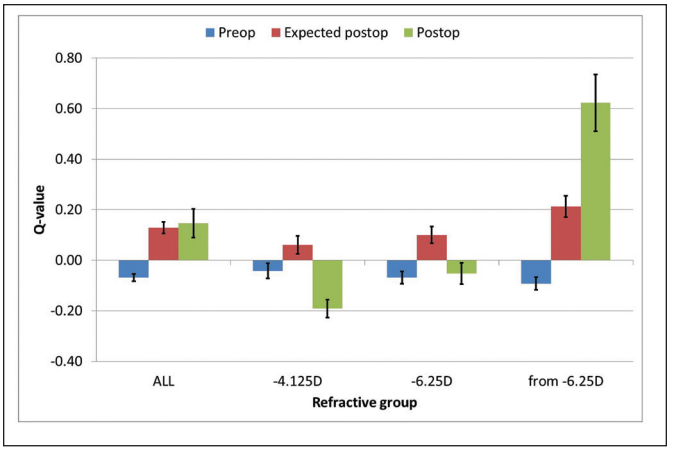

Figure 3. Preoperative and postoperative expected and achieved asphericity per subgroup. D = diopters

ensures better visual outcome. Roe et al.[16] evaluated the asphericity-adjusted Allegretto–Wave 400-Hz system (Alcon/Wavelight AG, Erlangen, Germany) for change in asphericity (Q factor) in 655 myopic consecutive LASIK cases. Preoperatively, the patient population had a mean myopia of -3.80 D (range: -0.50 to -6.75 D) and cylinder of -0.85 D (range: 0.00 to -3.75 D). They found that the Q-value changed from a mean of -0.29 D preoperatively to -0.11 D postoperatively. There was a positive shift of the Q-value proportionate to the amount of refractive error corrected.

In later studies, many groups reported findings favoring an aspherically optimized ablation profile over the conventional profiles in terms of most postoperative refractive outcomes.[17-19] In a large-scale study including 400 eyes (200 eyes in the wavefront-optimized group and 200 eyes in the custom-Q group), Tawfik et al.[20] reported a statistically significant difference in postoperative change in Q-values ($P = .02$) and postoperative visual acuity ($P = .42$) between the two groups. They reported a marginally significant change in corrected visual acuity between the two groups and less impairment in the corneal asphericity in the custom-Q group.[20]

The clinical success of aspheric ablation profiles has been published in the literature. Arbelaez et al.[21] evaluated the clinical outcomes of aspheric corneal wavefront-guided ablation profiles in LASIK treatments. In general, they reported improvements in postoperative UDVA and CDVA ($P < .001$). They concluded that apart from the risk of additional ablation of corneal tissue, systematic wavefront-customized corneal ablation can be considered a safe and beneficial method. In a study based on the preoperative and postoperative status of 146 consecutive eyes (median patient age: 36 years) undergoing LASIK based on aspheric aberration-neutral profiles, the correlations between spherical aberration and asphericity and between corneal and ocular spherical aberrations were determined using simple linear regression methods.[5] The asphericity values for which spherical aberration equals zero and the reference asphericity values for which corneal spherical aberration equals ocular spherical aberration were determined. It was reported that a Q-value of -0.19 to -0.27 can provide zero ocular spherical aberration in patients before and after LASIK for myopic astigmatism. A reference Q-value of -0.12 to +0.01 could provide corneal spherical aberration equal to ocular spherical aberration in patients before and after LASIK for myopic astigmatism.[5] In our cohort, the postoperative asphericity was maintained or the changes in asphericity to higher prolateness were achieved for corrections up to -5.00 D. The postoperative Q-value between -0.12 to -0.19 could be considered the sweet spot for aiming zero ocular spherical aberration in patients; our results show this postop-

erative asphericity range for corrections between -3.00 and -4.125 D. The extended range from -0.27 to +0.01 could be considered an extended sweet spot providing corneal spherical aberration equal to ocular spherical aberration; our results show this postoperative asphericity range for corrections between -2.25 and -6.00 D.

Centration reference during ablation is another critical aspect for successful postoperative outcomes.[22] It has been theoretically postulated and proved that aberration-free profiles should be centered on the corneal apex, whereas customized treatments should be centered according to the diagnosis reference. The main higher order aberration effects (coma and spherical aberration) come from the edge effect, which is the strong local curvature change from the optical zone to the transition zone and from the transition zone to the non-treated cornea.[23] In this study, asymmetric offset was used; this approach combines the higher order aberrations referred to the pupil center (line-of-sight) with manifest refraction values referred to the corneal vertex (visual axis).[16] Clinically, it has been shown that corneal vertex–centered treatments perform better in terms of induced ocular aberrations and asphericity in myopic eyes with moderate to large pupillary offset.[18]

Many groups have explored the optimum corneal asphericity that must be targeted in refractive procedures. Patel et al.[24] presented a model predicting that optimal optical imagery is produced when the corneal profile is represented by a flattening ellipse (shape factor = 0.65 to 0.85). They concluded that in refractive surgery involving the cornea, the postoperative corneal contour should conform to this flattening ellipse. Jiménez et al.[25] modelled the effect of pupil size, optical zone, and initial myopic level on the retinal image quality after Q-optimized myopic corneal refractive surgery. Their results showed that the Q-optimized algorithm with Q = -0.45 provided the highest modulation transfer function results, an optical measure of point spread function and contrast accuracy, for myopic corrections less than -5.00 D. For refractive errors greater than -5.00 D, Q = -0.26 provided the highest modulation transfer function results. Their results show that the Q-value that optimizes the results of the Q-optimized algorithm depends on the degree of myopia to correct and the size of the pupil. Manns et al.[26] reported that the corneal asphericity factor that produces zero primary spherical aberration ranges from -0.45 to -0.47.

Although there is no consensus on the ideal degree of negative asphericity, we do know that although higher levels of negative asphericity enhance depth of focus, they can degrade the unaided distance vision. We thus hypothesize that the negative Q-values achieved in our patients with low to moderate myopia enhance their depth of focus when attempting accommodation (with associated pupillary miosis). In our cohort, only four eyes had a postoperative asphericity below Q = -0.50 (Q = -0.51, -0.52, -0.53, and -0.64). Interestingly, all of these were relatively oblate preoperatively (Q > 0). Given that the mean postoperative Q-values in our studies were relatively low at -0.19 ± 0.20 and -0.05 ± 0.24 for the low and moderate myopic groups, respectively, the impact on unaided distance vision is likely to be negligible.

In this study, we evaluated myopic patients with low to high myopia, in terms of the achieved change in asphericity 3 months after being treated by aberration-free SmartSurf^{ACE}. Preoperatively, the eyes had significant differences in terms of the refractive error ($P < .05$), but the three groups had comparable corneal asphericity (Q-value, $P > 0.1$). The postoperative corneal asphericity showed a high dependence on the planned refractive correction. Although the negative corneal asphericity improved for the low myopia group, it was maintained or slightly improved for the moderate myopia group and deteriorated for the high myopia group (with the cornea becoming more oblate postoperatively). The ability to preserve naturally low negative Q-values with SmartSurf^{ACE} after treatment will also likely benefit the emmetropic presbyopic group of patients, many of whom will also have spherification (Q-value approaching 0) of their crystalline lens and therefore benefit from the negative asphericity of their corneas after treatment.

AUTHOR CONTRIBUTIONS

Study concept and design (DTCL, SA-M); data collection (SPH); analysis and interpretation of data (SPH, SV, JH, SA-M); writing the manuscript (SPH, SV, JH); critical revision of the manuscript (DTCL, SPH, SV, JH, SA-M); statistical expertise (SV, SA-M); administrative, technical, or material support (SPH, JH); supervision (DTCL, SPH)

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