Pseudoaccommodative Cornea Treatment Using the NIDEK EC-5000 CXIII Excimer Laser in Myopic and Hyperopic Presbyopes

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ABSTRACT

PURPOSE: To investigate the refractive outcomes and spherical aberration of multifocal LASIK to create a distant-dominant center and near-dominant periphery in hyperopic, myopic, and emmetropic presbyopia.

METHODS: One hundred ninety-five eyes with myopic presbyopia and 119 eyes with hyperopic or emmetropic presbyopia that underwent LASIK or epithelial LASIK (epi-LASIK) were assessed out to 3 months postoperatively. All eyes underwent the pseudoaccommodative cornea (PAC) treatment using aspheric ablation profiles and wavefront correction with the NIDEK CXIII excimer laser. Mean preoperative spherical equivalent refraction was $-3.80 \pm 2.10$ diopters (D) for myopic presbyopia and $+1.00 \pm 0.92$ D for hyperopic or emmetropic presbyopia.

RESULTS: Mean postoperative spherical equivalent refraction was $0.40 \pm 0.77$ D for myopic presbyopia and $0.15 \pm 0.62$ D for hyperopic or emmetropic presbyopia. Functional vision, defined as 20/30 or better distance uncorrected visual acuity (UCVA) combined with J3 or better near UCVA, was achieved in 162 (83%) eyes with myopic presbyopia and 103 (87%) eyes with hyperopic or emmetropic presbyopia. An induction of $0.312 \, \mu m$ of spherical aberration was noted at 6 mm for myopic presbyopia treatments and $0.016 \, \mu m$ for hyperopic presbyopia treatments.

CONCLUSIONS: The distance-dominant center used for PAC treatments is effective in emmetropic, myopic, and hyperopic presbyopia. The induced spherical aberration allows for depth of focus in patients with presbyopia.

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Final Fit ablation planning software (NIDEK Co Ltd). The tenets of the Declaration of Helsinki were followed in this study.

Patients who underwent LASIK had ophthalmic evaluations preoperatively and at 1 week, 1 month, 3 months, 6 months, 1 year, and 2 years postoperatively. Epithelial-LASIK (epi-LASIK) patients underwent ophthalmic evaluations at 4 days, 1 month, 3 months, 6 months, 1 year, and 2 years postoperatively. Evaluations included the measurement of uncorrected visual acuity (UCVA) at near (33 cm) and distance, best spectacle-corrected visual acuity (BSCVA) at near and distance, manifest refraction (push plus method), slit-lamp examination, intraocular pressure (IOP), corneal topography and wavefront aberrometry using the OPD-Scan, corneal thickness, and dilated funduscopy. Postoperatively, dilated funduscopy was performed only if clinically warranted, and IOP was measured from 3 months onward. Due to significant drop-out rates after 3 months, follow-up data at 3 months will be discussed; however, data for all visits are presented.

Patients were divided into two groups based on their preoperative refractive error: patients with myopic presbyopia and patients with hyperopic or emmetropic presbyopia. The myopic presbyopia group comprised 195 (62.1%) eyes of 98 patients and the hyperopic-emmetropic presbyopia group comprised 119 (37.9%) eyes of 60 patients. The hyperopic-emmetropic presbyopia group comprised 59 (18.8%) hyperopic eyes and 60 (19.1%) emmetropic eyes.

Patients With Myopic Presbyopia. Mean patient age was 46 years (range: 30 to 65 years). In the myopic presbyopia group, 26 (26.5%) patients were in their 40s, 40 (41%) patients were in their 50s, 26 (26.5%) patients were in their 60s, and 6 (6%) patients were in their 70s. Mean preoperative manifest refraction spherical equivalent (MRSE) was \(-3.80 \pm 2.10\) diopters (D) (range: \(-8.25\) to \(-0.50\) D).

Patients With Hyperopic and Emmetropic Presbyopia. Mean patient age was 56 years (range: 37 to 73 years). In the hyperopic-emmetropic presbyopia group, 1 (1%) patient was in his 40s, 11 (19%) patients were in their 50s, 25 (42%) patients were in their 60s, 20 (34%) patients were in their 70s, and 3 (4%) patients were in their 80s. Mean preoperative MRSE was \(+1.00 \pm 0.92\) D (range: 0.00 to \(+3.50\) D)

Final Fit and PAC Simulations

All treatment simulations and calculations were performed using the PAC calculator (NIDEK Co Ltd) and Final Fit software. The PAC calculations were manually entered into the laser and Final Fit shot data were transferred to the laser via universal serial bus disk.

The PAC calculation software requires entry of the patient’s refraction, age, photopic and mesopic pupil size, and answers to a preoperative questionnaire assessing the patient’s activities and visual requirements. Based on these parameters, the laser data entry parameters and optical and transition zones are generated for the presbyopic treatment. Final Fit software has been described previously. The manifest refraction was adjusted using the nomogram S095-C118-S30 in Final Fit version 1.13 to determine the laser data entry for the distance correction. The distance refractive error and preoperative irregularity were treated using the optimized path difference custom ablation treatment (OPDCAT) algorithm with aspheric profile #5 in Final Fit. The PAC algorithms have been described previously. In all cases, the distance correction was performed prior to PAC treatment in the same session. For example, a 50-year-old myopic patient with a manifest refraction of \(-4.00 -0.50 \times 179°\) with a 3-mm photopic pupil diameter and 6-mm mesopic pupil diameter with normal daily driving habits, who reads approximately 1 hour a day, occasionally uses the computer, and participates in a sports once a week would require the following treatment using PAC and Final Fit:

- 1) OPDCAT ablation of \(-3.623 -0.590 \times 179°\) using a 5.0-mm optical zone (OZ) and 8.5-mm transition zone (TZ) to treat the distance correction;
- 2) +3.00 D using a 6.5-mm OZ and 9.5-mm TZ for the near add;
- 3) −3.00 D using a 3.5-mm OZ and 4.5-mm TZ to bring the central cornea to emmetropia;
- 4) −1.00 D using a 4.0-mm OZ and 5.0-mm TZ to bring the central cornea to emmetropia; and
- 5) Irregularity component using a 5.0-mm OZ and 8.0-mm TZ to treat the pre-existing wavefront aberrations.

An aspheric ablation profile was used for all myopic treatments (steps 1, 3, and 4 above). Hyperopic and irregular components (steps 2 and 5 above) do not require the selection of a specific profile. In this example, 161.30 µm is the total depth of ablation.

Surgery

Two hundred sixty-eight eyes underwent LASIK and 46 eyes underwent epi-LASIK. LASIK or epi-LASIK was performed based on preoperative corneal thickness and residual stromal bed calculations that would leave 300 µm postoperatively. Patients with adequate residual stromal tissue or corneas thicker than 450 µm underwent LASIK. All surgeries were performed by one surgeon (E.U.).

LASIK. Eyes were prepared for surgery in a sterile manner. Two drops of topical anesthetic were instilled,
and a sterile drape was used to isolate the surgical field. A lid speculum was inserted in the operative eye, followed by two drops of topical anesthetic. Gentian violet marks were placed from the midperipheral cornea to the limbus for flap alignment. The Moria M2 keratome (Moria, Antony, France) was used to create a superior hinged corneal flap using the M2 M90 blade, LC ring (large cut ring), with the stop at 8 for corneas with an average preoperative keratometry of 41.00 to 44.50 D. In corneas with an average preoperative keratometry between 44.50 and 45.50 D, the 0 ring with an 8 stop was used, and in corneas steeper than 45.50 D, the 2 ring with a 7.50 stop was used. The flap was reflected, and a 200-Hz infrared eye tracker centered on the visual axis was enabled. Laser ablation was delivered to the corneal stroma centered on the visual axis. Patients fixated on a red fixation light throughout the ablation. The flap was repositioned, and the interface was irrigated with balanced salt solution to remove interface debris. The flap was inspected for adherence and to verify correct alignment. One drop each of topical fluoroquinolone, topical corticosteroid, and artificial tears was instilled. The patient remained supine for 1 minute to allow the flap to adhere. Postoperatively, patients were instructed to instill topical fluoroquinolone and corticosteroid drops 4 times a day for 1 week and preservative-free artificial tears as needed.

ANALYSIS

The mean, standard deviation, and range of refractive outcomes; near and far visual acuity; corneal asphericity; and corneal spherical aberration were calculated using Microsoft Access (Microsoft Corp, Redmond, Wash). Corneal spherical aberration was calculated at 4, 5, and 6 mm to determine the induced multifocality using the NIDEK OPD-Station software. Corneal asphericity was measured at 4.40, 5.20, 6.40, and 7.40 mm to determine the change in corneal shape associated with the multifocal corneal profile.

RESULTS

MYOPIC PRESBYOPIA

Postoperatively, 96 (49.2%) eyes were available for follow-up at 3 months, 36 (18.5%) eyes at 6 months,
63 (32.3%) eyes at 1 year, and 35 (17.9%) eyes at 2 years. Mean postoperative MRSE was $-0.40\pm0.77$ D (range: $-2.50$ to $+1.25$ D) at 3 months, $-0.31\pm0.67$ D (range: $-2.00$ to $+0.75$ D) at 6 months, $-0.86\pm0.91$ D (range: $-2.25$ to $+0.75$ D) at 1 year, and $-0.45\pm0.53$ D (range: $-1.88$ to $+0.75$ D) at 2 years. Figure 1 plots the predictability at all follow-up evaluations. A trend toward undercorrection was noted for corrections of MRSE $\geq6.00$ D (see Fig 1). Stability of the myopic presbyopic treatments is plotted in Figure 2. Figure 3 plots the distance and near UCVA and the number of patients who achieved “functional vision,” defined as 20/30 or better distance UCVA combined with J3 or better near UCVA. Retreatments were performed on 4 (2.1%) eyes at 3 months or later.

**Hyperopic and Emmetropic Presbyopia**

Postoperatively, 46 (38.7%) eyes were available for follow-up at 3 months, 30 (25.2%) eyes at 6 months, 43 (36.1%) eyes at 1 year, and 19 (15.9%) eyes at 2 years. Mean postoperative MRSE was $+0.15\pm0.62$ D (range: $-1.25$ to $+1.38$ D) at 3 months, $+0.03\pm0.63$ D (range: $-1.50$ to $+1.25$ D) at 6 months, $-0.50\pm0.21$ D (range: $-0.88$ to $+0.25$ D) at 1 year, and $+0.06\pm0.74$ D (range: $-1.00$ to $+1.38$ D) at 2 years. Figure 4 plots the predictability at all follow-up evaluations. Figure 5 plots the stability of the hyperopic and emmetropic presbyopic treatments. Figure 6 plots the distance and near UCVA and the number of patients who achieved “functional vision.” Retreatments were performed on 1 (0.8%) hyperopic eye and 1 (0.8%) emmetropic eye.

**Corneal Spherical Aberrations and Corneal Asphericity**

Figure 7 plots the corneal spherical aberrations at various pupil diameters 3 months postoperatively. Figure 8 plots the corneal asphericity at 3 months.
postoperatively. All corneas became increasingly steeper from center to periphery (see Fig 8). There was an induction of corneal spherical aberration of 0.312 µm at 6 mm for patients with myopic presbyopia and 0.016 µm for patients with hyperopic presbyopia (see Fig 7).

**DISCUSSION**

In this study of the treatment for presbyopia using an excimer laser, treatment with PAC software combined with OPDCAT was predictable (see Figs 1 and 4) and allowed functional vision (see Figs 3 and 6). Three months postoperatively, the MRSE was −0.40 D in myopic presbyopes and +0.15 D in hyperopic presbyopes.

The outcomes in this study are similar to or exceed those reported for previous trials regarding LASIK for presbyopia. A recent study also using the distance-dominant central treatment in a similar range of patients with hyperopic presbyopia but having a much smaller sample size (N=44 eyes) than our study (N=119 eyes) reported an MRSE of −0.42 D. In an investigation of an earlier version of the PAC technique without wavefront treatment, the majority of patients with hyperopia and myopia achieved functional vision as defined in this study.

This study confirms that PAC combined with OPDCAT is a viable alternative to other corneal treatments such as monovision or conductive keratoplasty for presbyopia.

Within 3 months postoperatively, 83.5% of patients with myopia and 87% of patients with hyperopia and emmetropia had functional vision for daily activities. Further, the overall retreatment rate was less than 2%, which is appreciably lower than 7% recently reported for 82 LASIK patients with myopia who chose monovision. Although older age has been associated with an increased trend toward retreatments, the retreatment rate in this study remained low. Compared with “light touch” conductive keratoplasty, which may still result in some loss of effect over time, the PAC procedure is relatively stable (see Figs 2 and 5).

Presbyopic intraocular lenses (IOLs) are another alternative to treating patients with presbyopia. However, explantation rates remain relatively high (7.3%), and greater inherent risks are present with intraocular surgery compared with corneal surgery. In addition, there have been reports of decreased near contrast sensitivity associated with multifocal IOLs.

This study used an aspheric ablation algorithm (OPDCAT) for all myopic ablations, whether to correct distance refractive error or to create the near add. The use of aspheric algorithms is beneficial to patient satisfaction. Hori-Komai et al compared conventional LASIK with aspheric LASIK using profile #5 with the NAVEX platform and reported a statistically significant difference favoring the aspheric group in postoperative effective optical zone and contrast sensitivity.

In this study, an average induction of 0.164 µm of spherical aberration (at 6 mm) was noted in all eyes, with the myopic eyes showing greater induction of spherical aberration (0.312 µm) (see Fig 7). Peripherally, the cornea became increasingly prolate for hyperopic treatments and less oblate in myopic treatments (see Fig 8). The increasing corneal curvature in the periphery was likely due to the delivery of multiple ablations with different treatment zones that were de-
Presbyopia Treatment With PAC Using NAVEX/Uy & Go

Figure 6. A) Distance and B) near uncorrected visual acuity (UCVA) of 119 hyperopic and emmetropic presbyopic eyes that underwent pseudoaccommodative cornea (PAC) treatment. C) Distance UCVA versus near UCVA at 3 months postoperatively. The red circle denotes functional vision of 20/30 or better distance UCVA combined with J3 or better near UCVA.

In our experience, this multifocal cornea results in an emmetropic center and myopic periphery for patients with hyperopia and myopia, the hallmarks of positive spherical aberration (Fig 9).

Past investigations of presbyopic LASIK studies have reported success for patients with myopic or hyperopic presbyopia but not both. El Danasoury et al report success only in patients with myopia, whereas Pinelli et al report success with hyperopia treatment only. Our study found that presbyopia treatments were successful regardless of preoperative refractive status. The difference in outcomes may be attributable to the use of an entirely different ablation architecture from a different laser model (Technolas 217z; Bausch & Lomb Inc, Rochester, NY) or to the use of conventional ablation algorithms rather than the incorporation of OPDCAT in the treatments. This study incorporated a number of refinements to the original PAC procedure, including the use of an aspheric profile for all myopia treatments (ie, OPDCAT) and the treatment of irregularities as detected by Final Fit.

In our experience, candidates for presbyopic excimer laser treatments require thorough preoperative evaluation of their near and distance vision requirements along with an assessment of their lifestyle. Patients must have realistic expectations that include the fact that vision may be compromised yet functional enough to reduce or eliminate dependence on spectacles postoperatively. In addition, the effects and implications of cataract progression must be thoroughly explained.

Drawbacks of this study include the lack of control data such as eyes that were treated for distance refractive error only. Furthermore, a significant number of patients were lost to follow-up 3 months after surgery. In our experience, the majority of satisfied patients tend not to return for follow-up. Thirty-five myopic presbyopic eyes and 19 hyperopic presbyopic eyes were available for follow-up at 2 years postop-
Presbyopia Treatment With PAC Using NAVEX/Uy & Go

Thirty-four (97%) myopic presbyopic eyes and 18 (95%) hyperopic presbyopic eyes had 20/30 or better distance UCVA. Thirty-three (94%) myopic presbyopic eyes and 12 (63%) hyperopic presbyopic eyes read J3 or better without spectacle correction. Some patients retained functional vision 2 years postoperatively, which suggests the stability of this procedure with an adequate sample size.

Pseudoaccommodative cornea treatments that incorporate OPDCAT to create a center-distance or peripheral-near multifocal cornea are successful for the treatment of myopia up to −8.25 D MRSE and hyperopia up to +3.50 D MSRE in patients with presbyopia. However, long-term outcomes with larger sample sizes are required to determine the stability of this procedure.

**REFERENCES**

Presbyopia Treatment With PAC Using NAVEX/Uy & Go


Figure 9. Pre- and postoperative OPD-Scan evaluation of a) sample patient with myopic presbyopia treated using pseudoaccommodative cornea (PAC) treatment and OPDCAT. The postoperative corneal topography (Instantaneous) map shows a multifocal corneal profile that results in an overall refractive error gradient of plano centrally and −3.00 D peripherally as seen on the OPD map. B) Sample patient with hyperopic presbyopia treated with PAC and OPDCAT. Postoperative corneal topography shows a multifocal corneal profile that results in an overall refractive gradient of 0 centrally and −1.00 D peripherally.