

Photorefractive keratectomy using a 213 nm wavelength solid-state laser in eyes with previous conductive keratoplasty to treat presbyopia: Early results

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PURPOSE: To evaluate the efficacy and safety of photorefractive keratectomy (PRK) using a 213 nm wavelength solid-state laser to treat regression in eyes that had previous conductive keratoplasty (CK) for presbyopia.

SETTING: Outpatient refractive surgery center, Manila, Philippines.

DESIGN: Prospective consecutive case series.

METHODS: Consecutive eyes that had previous CK for presbyopia were treated with PRK using a 213 nm wavelength solid-state laser (Pulzar Z1). Uncorrected near (UNVA) and distance (UDVA) visual acuities (monocular and binocular), corrected distance visual acuity (CDVA), refraction, keratometry, and slitlamp evidence of corneal haze and other complications were evaluated for up to 6 months after surgery.

RESULTS: The study evaluated 20 eyes (20 patients). Six months after PRK, 47% of eyes had monocular UNVA of Jaeger (J) 3 or better and 27% had a binocular UDVA of 0.10 logMAR (20/25 Snellen equivalent) or better with a concurrent UNVA of J3 or better. Seventy-three percent of eyes were within ± 1.00 diopter of the attempted refraction. No eye lost 2 or more lines of CDVA or developed significant corneal haze.

CONCLUSION: Photorefractive keratectomy after CK using a 213 nm wavelength solid-state laser produced functional visual acuity in presbyopic patients in the short term (6 months).

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Conductive keratoplasty (CK) is a nonablative collagen-shrinking procedure approved by the U.S. Food and Drug Administration (FDA) for the correction of low levels of hyperopia.^{1–3} Conductive keratoplasty is based on the delivery of radiofrequency energy through a fine conducting tip inserted into the peripheral corneal stroma. This steepens the central cornea and corrects hyperopic refractive errors. In 2004, the FDA also approved the use of CK for presbyopia. The treatment induces mild myopia (–0.50 to –1.50 diopters [D]) in 1 eye (nondominant eye) of an otherwise emmetropic patient to produce monovision. Although it does not affect the accommodation amplitude, this level of myopia is associated with only

a mild decrease in distance vision, retention of good stereopsis, and a significant increase in the intermediate zone of functional vision.

However, refractive instability and regression are common complications of collagen-shrinking procedures.^{4–8} A study of the long-term effects and stability of CK by Ehrlich and Manche⁴ showed significant linear regression beginning at 6 months, with a +0.0184 D regression rate per month. This is 3- to 6-fold greater than the natural rate of normal hyperopic progression and presbyopic changes in the elderly. Conductive keratoplasty enhancements have been tried; however, at present there are no data on the safety and effectiveness of reapplication of CK in

eyes that have regression after the primary procedure. Several methods have been used to correct refractive errors in eyes that have had previous ocular surgery; these include photorefractive keratectomy (PRK) and laser in situ keratomileusis (LASIK). In 1995, Maloney et al.⁹ studied the safety, stability, and efficacy of PRK in eyes with previous refractive and cataract surgery and reported encouraging results.

Solid-state lasers with an output wavelength of 213 nm have been gaining popularity in recent years. Various reports indicate that they can be a reliable alternative to traditional excimer laser systems with a 193 nm wavelength.¹⁰⁻¹⁴ Studies¹³⁻¹⁵ show that the clinical course and corneal histopathological findings of the 213 nm solid-state lasers are comparable to those of a 193 nm wavelength excimer laser. The 213 nm lasers are also cost effective and have a good safety profile.

The purpose of the study was to evaluate the efficacy and safety of photorefractive keratectomy (PRK) using a 213 nm wavelength solid-state laser in eyes that had regression after previous CK for presbyopia. To our knowledge, there are no published studies of the use of PRK in eyes that had previous CK to treat presbyopia.

PATIENTS AND METHODS

The prospective consecutive case series was performed at an outpatient refractive surgery center in Manila, Philippines. All enrolled patients had a previous CK procedure at the same center using a Refractive CK system (Refractive, Inc.) for the treatment of presbyopia. Standard near vision CK was performed in the nondominant eye to produce monovision. Most patients were hyperopic before CK; therefore, the nondominant eye was overcorrected to produce monovision. Eyes were excluded if they were treated primarily for hyperopia or had fewer than 6 months of postoperative follow-up.

All patients before the procedure provided informed consent for PRK. The preoperative and postoperative examinations included monocular uncorrected distance visual acuity (UDVA) (Snellen chart converted to logMAR

notation), uncorrected near visual acuity (UNVA) (Jaeger [J] near-vision chart), binocular uncorrected visual acuity, subjective manifest refraction, corrected distance visual acuity (CDVA), slitlamp evaluation, and keratometry (K).

The same surgeon (R.P.E.) performed all PRK procedures. The corneal epithelium was debrided chemically with 20% alcohol, after which it was irrigated with a balanced salt solution. Conventional PRK was performed with a Pulzar Z1 213 nm wavelength solid-state laser, (CustomVis). The ablation zone was 7.5 mm and the optical zone, 5.5 mm. Mitomycin-C 0.02% was applied for 30 seconds at the conclusion of the ablation. A bandage contact lens was placed on the cornea after surgery. Topical antibiotic agents, corticosteroid agents, nonsteroidal antiinflammatory drugs, and artificial tears were prescribed and tapered after 2 months. Follow-up visits were at 1 week, 1 month, 3 months, and 6 months.

Outcome measures were monocular and binocular UDVA and UNVA, CDVA, manifest refraction, K readings, and slitlamp evidence of corneal haze or other complications. Refraction was converted to the manifest refractive spherical equivalent (MRSE). Preoperative and postoperative monocular UNVA and concurrent binocular UDVA and UNVA were compared to ascertain efficacy. Safety was evaluated using the CDVA and presence of complications, such as corneal haze. Preoperative and postoperative refractive data and K values were used to assess accuracy and stability. Mean values are given with the standard deviation.

RESULTS

Demographics

Twenty eyes of 20 post-CK patients treated for near-vision correction were enrolled and treated with PRK. Table 1 shows the patients' demographic and baseline information. Nine of the 20 patients had at least 1 CK enhancement in the nondominant eye to induce monovision. Instead of CK enhancement, 5 patients had early PRK (at fewer than 6 months postoperatively) to induce monovision.

All 20 eyes were available for follow-up at 1 month and 3 months, and 15 eyes (75%) were available at 6 months. All eyes were treated once (no retreatments).

Visual Acuity

Figure 1 shows the monocular UNVA and Figure 2 the binocular UDVA and UNVA after PRK. Six months after PRK, 47% of eyes had monocular UNVA (nondominant eye) of J3 or better and 27% had a concurrent binocular UDVA of 0.10 logMAR (20/25 Snellen equivalent) or better and a UNVA of J3 or better.

Accuracy and Stability

Of 15 eyes evaluated at 6 months, 2 (13%) had an MRSE within ± 0.50 D of the intended correction, 11 (73%) within ± 1.00 D, and 15 (100%) within ± 2.00 D (Figures 3 and 4). The mean change from

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Table 1. Demographic and baseline information.

Parameter	Value
Patients/eyes (n)	20/20
Men/women (n)	11/9
Age (y)	
Mean ± SD	50.4 ± 2.66
Range	45 to 54
Interval from last CK (mo)	
Mean ± SD	12.9 ± 9.81
Range	2 to 38
Preop monocular UDVA	
Mean logMAR (Snellen equivalent)	0.10 (20/25)
Range	0.00 to 0.30 (20/20 to 20/40)
Preop monocular UNVA	
Mean	J8
Range	J4 to J12
Preop binocular UDVA	
Mean logMAR (Snellen equivalent)	0.00 (20/20)
Range	0.00 to 0.10 (20/20 to 20/25)
Preop MRSE (D)	
Mean ± SD	+0.98 ± 0.55
Range	Plano to +1.62
Preop astigmatism (D)	
Mean ± SD	0.31 ± 0.47
Range	0.00 to 1.50
Preop cyclorefraction (D)	
Mean ± SD	+0.86 ± 0.66
Range	-0.75 to +1.50
Intended correction (D)	
Mean ± SD	1.21 ± 0.19
Range	1.00 to 1.50
Follow-up (wk)	
Mean ± SD	22.40 ± 6.18
Range	12 to 26

CK = conductive keratoplasty; MRSE = manifest refraction spherical equivalent; UDVA = uncorrected distance visual acuity; UNVA = uncorrected near visual acuity

the preoperative refraction was 2.26 ± 0.72 D (range 1.50 to 4.00 D) 1 month postoperatively, 2.00 ± 0.79 D (range 1.00 to 3.75 D) at 3 months, and 1.73 ± 0.77 D (range 0.63 to 2.50 D) at 6 months.

Refraction was relatively stable in all eyes at each follow-up. No eye had a change of more than 1.00 D in MRSE between 1 month and 6 months (Figure 5).

Safety

Figure 6 shows the lines of CDVA lost or gained. The 4 eyes that lost 2 lines 1 month after PRK had improvement in acuity by 6 months. The 1 eye that lost more than 2 lines at 3 months had a CDVA of 20/20 by 6 months. No eye had a CDVA worse than 20/40 or

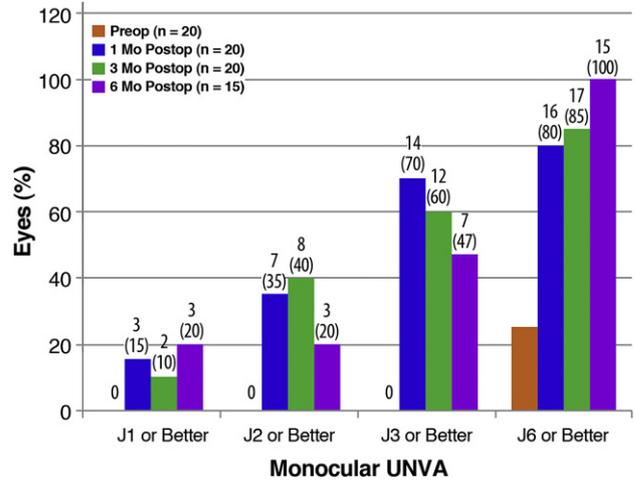


Figure 1. Monocular uncorrected visual acuity for near at 1, 3, and 6 months after PRK (PRK = photorefractive keratectomy).

an increase in cylinder of 2.00 D or more. The mean cylinder was 0.93 ± 0.64 D 1 month postoperatively, 0.79 ± 0.48 D at 3 months, and 0.84 ± 0.54 D at 6 months. The induced cylinder was more than 0.75 D greater than the baseline value in 7 eyes (35%) at 1 month and 6 months and in 5 eyes (33%) at 6 months. No eye developed astigmatism higher than 2.00 D.

The mean K value was 44.69 ± 1.94 D (range 38.25 to 47.75 D) preoperatively, 45.80 ± 2.14 D (range 39.00 to 48.50 D) 1 month postoperatively, 45.66 ± 2.05 D (range 39.00 to 48.50) at 3 months, and 45.47 ± 2.15 D (range 39.00 to 48.00 D) at 6 months. The mean difference between the preoperative K and the postoperative K was 1.11 D, 0.98 D, and 1.02 D, respectively. No eye developed corneal haze over the 6-month follow-up.

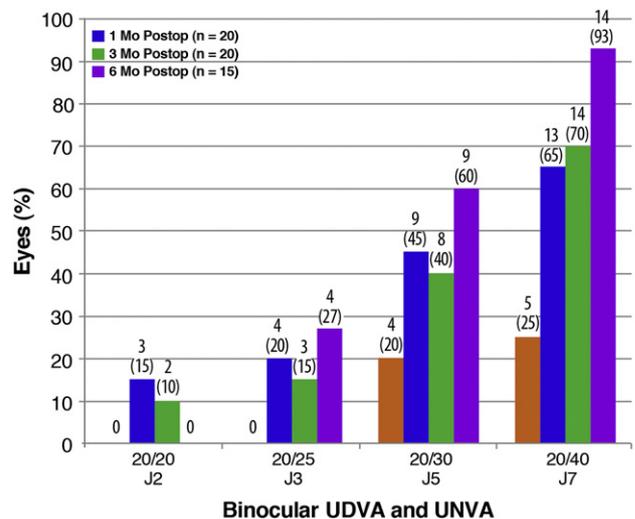


Figure 2. Binocular uncorrected visual acuity for distance and near at 1, 3, and 6 months after PRK (PRK = photorefractive keratectomy).

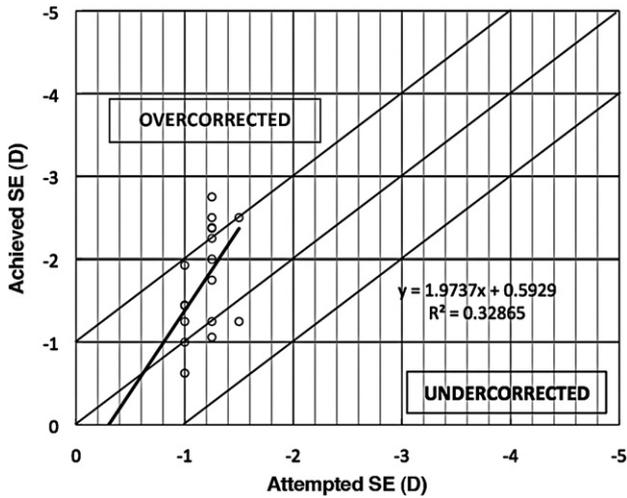


Figure 3. Accuracy of PRK after CK at 6 months (CK = conductive keratoplasty; PRK = photorefractive keratectomy; SE = spherical equivalent).

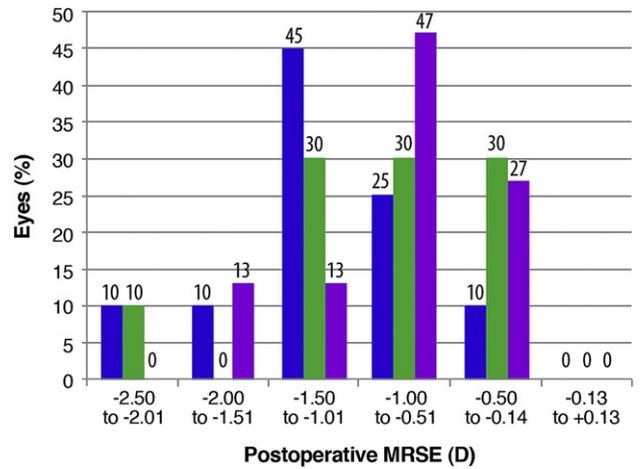


Figure 4. Spherical equivalent refractive accuracy at 1, 3, and 6 months after PRK (MRSE = manifest refraction spherical equivalent; PRK = photorefractive keratectomy).

DISCUSSION

Refractive regression and instability are common complications of collagen-shrinking procedures such as holmium:YAG laser thermal keratoplasty (LTK)^{7,8} and CK.⁴⁻⁶ Although there is less of a tendency toward regression with CK than with LTK, long-term studies of CK²⁻⁶ report a slow, continued drift toward increasing hyperopia. The wound-healing process in the corneal stroma may be responsible for the refractive regression in eyes after CK. After any insult that damages the stromal collagen, there is remodeling of collagen and a return of normal stromal clarity over a long period of time because the primary function of the

keratocytes is to monitor and repair the collagen molecules that make up the lamellae of the cornea.^{16,17} Esquenzi et al.¹⁸ studied the corneal wound-healing response after CK in rabbit eyes. Immunohistochemical analysis of the rabbit eyes showed keratocyte apoptosis, a myofibroblast appearance, and upregulation of chondroitin sulfate, matrix metalloproteinase-1, and collagen type III in the area surrounding the tip of each CK spot. Activated myofibroblasts contribute to the purse-string tightening of the midperipheral cornea that result in central corneal steepening. Unfortunately, the myofibroblasts diminish over time. Esquenzi et al. concluded that corneal collagen remodeling and the disappearance of myofibroblasts are

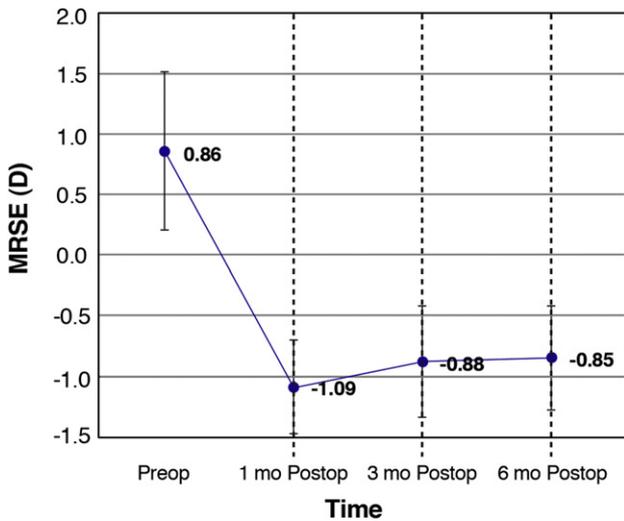


Figure 5. Stability of PRK after CK at 6 months (CK = conductive keratoplasty; MRSE = manifest refraction spherical equivalent; PRK = photorefractive keratectomy).

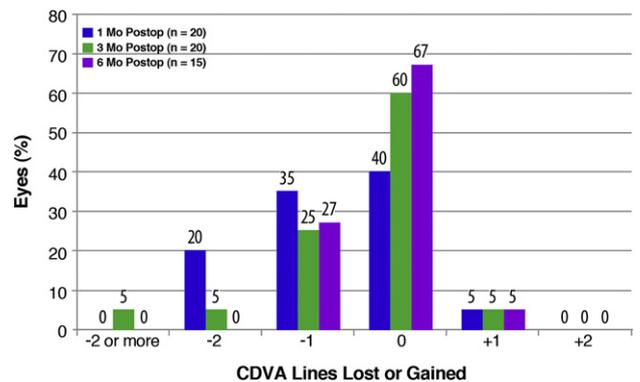


Figure 6. Percentage of eyes that gained or lost lines of CDVA after 6 months (CDVA = corrected distance visual acuity).

likely responsible for the high rate of long-term regression after CK.

To address this regression effect, CK enhancements have been attempted; however, there are currently no data on the safety and effectiveness of reapplication of CK in eyes that have had regression after the primary procedure. Although other refractive procedures for enhancement have been attempted, only anecdotal data are available. In 2 case reports,^{19,20} LASIK was performed to correct residual hyperopia and astigmatism 1 year after CK. Both reports showed the effectiveness of excimer laser ablation in treating residual hyperopia after CK.

The present study evaluated the efficacy and safety of PRK using a 213 nm solid-state laser to improve near vision in patients with regression after CK to correct presbyopia. Six months postoperatively, 47% of eyes had J3 or better monocular UNVA. No patient in our study had that level of monocular UNVA preoperatively. Although 70% of eyes had a UNVA of J3 1 month postoperatively, the percentage decreased to 47% by 6 months. However, because the patients' monocular UNVA decreased, there was some improvement in binocular UNVA and UDVA. Preoperatively, no patient had a binocular UDVA of 20/25 or better with a concurrent UNVA of J3 or better; postoperatively 27% had that combination of distance and near acuity, which represents functional acuity for a presbyopic patient. Furthermore, 60% of patients had a binocular UDVA of 20/30 or better with a concurrent UNVA of J5 or better, which allow a high degree of uncorrected function, especially at intermediate distances.

In terms of refractive accuracy, at 6 months only 13% of the patients were within ± 0.50 D of the intended refraction while 73% were within ± 1.00 D. The relatively poor predictability can be attributed to early PRK treatment in some cases and a lack of data and an available nomogram for PRK in post-CK eyes. Although some studies^{1,3} report that refraction after CK seemed to stabilize from 3 to 6 months, the early PRK treatment in a few cases in our study may have contributed to the decreased accuracy. The overcorrection in our study (mean 1.05 D at 1 month postoperatively, 0.79 D at 3 months, and 0.52 D at 6 months) can be attributed to several factors. Elderly patients with reduced corneal wound healing are prone to overcorrection.²¹ A small optical zone can also be a contributing factor. Studies^{21,22} show that a small optical zone causes a lower ablation depth but results in overcorrection, regression, glare, and halos. We opted to use a smaller optical zone (5.5 mm) to avoid a greater ablation depth and prevent corneal haze and encroachment into the CK radiofrequency spots. Last, after refractive surgery, eyes can be unpredictable, especially if the refraction has not yet stabilized.

Because there are no previous clinical or histological studies of post-CK eyes that had PRK, it is difficult to determine whether structural changes caused by a previous refractive procedure might cause overcorrection. In the present study, the overcorrection proved to be advantageous to the patients because the mean diopter change approached the intended correction in each eye by 6 months postoperatively.

The mean difference in the mean K values between preoperatively and 1 month, 3 months, and 6 months postoperatively was 1.11 D, 0.98 D, and 1.02 D, respectively. These keratometric changes mirrored the attempted correction (1.21 D) more closely than the changes in the refraction, which led to overcorrection. This reflects the relative accuracy of the laser system in terms of its ablation profile. However, when keratometric or corneal topographic measurements are significantly different from the refraction, the refractive accuracy should be reassessed. Lenticular and posterior corneal curvature variations may account for the difference between refractive and keratometric topographic values. Because most of our patients were in their late 40s, beginning cataracts and the normal hyperopic shift that comes with aging are factors that may have contributed to the inaccurate refraction.

Stability was relatively good over the short duration of the study. Based on the mean diopter change, the regression rate was 0.07 D per month during the first 3 months; this decreased to 0.01 D between 4 months and 6 months. Although regression decreased over time, no eye had a change of more than 1.00 D in spherical equivalent between 1 month and 6 months. Because no retreatments were performed, these results reflect the actual corneal refractive stability over the 6-month follow-up.

Concerning safety, there were no perioperative complications or adverse events during the follow-up. By 3 months postoperatively, 1 eye had lost more than 2 lines CDVA; however, the acuity improved to 20/20 by 6 months. Four eyes lost 2 lines of CDVA during the first month postoperatively but had improved acuity at 6 months. No eye had a CDVA worse than 20/40, and none developed corneal haze over the 6-month follow-up. The induced cylinder that occurred after PRK is a cause of concern, however. It may explain the relatively poor functional visual acuity at near and distance that occurred in some cases.

We used a 213 nm wavelength solid-state laser, which has advantages over conventional excimer lasers. At present, there are 2 main sources of ultraviolet radiation in corneal photoablation; that is, the argon fluoride excimer laser (193 nm wavelength) and the fifth harmonic of the neodymium:YAG solid-state laser (213 nm wavelength). Solid-state lasers use a slightly higher wavelength than conventional

excimer lasers, resulting in a strong corneal absorption in the far ultraviolet region (190 to 220 nm). This produces a very precise corneal ablation without damage to adjacent tissue.²³ The higher wavelength may also result in a greater penetration depth and larger actinic damage. In addition, the solid-state laser has many characteristics that may prove useful in corneal laser surgery. The small spot size (0.6 mm diameter, 2.5 times smaller than a typical excimer laser spot), uniform intensity beam distribution, high pulse-to-pulse stability, and very fast tracking system contribute to the accurate transfer of the planned treatment into the corneal stroma, creating a smooth ablation surface. Another potential benefit of the smaller spot size is less mechanical stress on the cornea during ablation,²⁴ which might cause fewer alterations to cells and result in less damage to the corneal structure.²⁵ Furthermore, because of its proximity to the absorption peak of corneal collagen, the 213 nm wavelength solid-state laser is less sensitive to corneal hydration than a 193 nm radiation laser.²⁶ Thus, corneal hydration²⁷ and environmental humidity,²⁸ factors that could affect the final outcomes with conventional excimer laser systems, are limited with solid-state lasers. Last, unlike traditional excimer laser, solid-state lasers do not use toxic gas (argon fluoride).

The limitations of this study include the relatively small number of eyes enrolled; the relatively short follow-up in regard to determining stability; topographic changes, contrast sensitivity, and wavefront aberrations were not evaluated; and the lack of assessment of patient satisfaction and vision quality. This is important because there is no good single measure to quantify the success of a monovision treatment.

In conclusion, early results of PRK performed with a 213 nm wavelength solid-state laser in eyes that had previous CK showed promise in producing functional visual acuity in presbyopic patients. However, the accuracy was not satisfactory and safety must be established. Additional studies should be performed to assess the safety, efficacy, and long-term benefits of this method.

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