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ORIGINAL RESEARCH

Transepithelial Versus Conventional PRK: A Randomized Controlled Study

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ABSTRACT

***Introduction*:** Transepithelial photorefractive keratectomy (t-PRK) is an updated maneuver based on the proven surgical procedure of conventional photorefractive keratectomy (PRK) for the correction of ametropia. Unlike conventional PRK, which is a two-step process involving the physical removal of the corneal epithelium prior to excimer laser treatment of the stroma, t-PRK uses the excimer laser to complete both activities in a single-step procedure.

***Methods*:** This was a prospective, randomized, controlled, contralateral, masked, single-surgeon study of adult subjects with myopia with a manifest residual spherical equivalent (MRSE) of ≤ 1.5 D or hyperopia with an MRSE of ≥ + 1.5 D, conducted at a single center in the Philippines. Eligible subjects were randomized to undergo conventional PRK in one eye and t-PRK in the other. The follow-up was for 6 months. The primary endpoint evaluated the absolute refractive predictability at 3 months. Secondary endpoints during the 6-month follow-up included safety, manifest refraction, visual acuity, halos and glare, slit-lamp examinations, and patient-reported outcomes.

***Results*:** A total of 35 subjects (70 eyes) were enrolled (63% female, 94% Asian, mean age 30 years). The mean (standard deviation [SD]) absolute prediction error was 0.26 D (0.23) for conventional PRK and 0.34 D (0.32) for t-PRK, meeting the threshold for demonstration of noninferiority ($p = 0.2253$). There were no statistically significant differences between conventional PRK and t-PRK for manifest sphere, manifest cylinder, MRSE, or uncorrected or corrected visual acuity at 6 months. All subjects were satisfied with both procedures and there was no preference for one treatment over the other.

***Conclusions*:** Both conventional and t-PRK are equally safe and effective, and result in favorable outcomes for subjects with ametropia. The efficiency of the t-PRK procedure versus conventional PRK should be considered when PRK is indicated.

***Trial Registration*:** ClinicalTrials.gov, NCT04698174.

Keywords: Alcohol-assisted photorefractive keratectomy; Ametropia; Hyperopia; Myopia; Refractive surgery; Transepithelial photorefractive keratectomy

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Key Summary Points

Why carry out this study?

Photorefractive keratectomy (PRK) remains an effective and important surgical option for correcting ametropia.

Transepithelial PRK (t-PRK) is a more recent innovation in PRK surgery and reduces the time required for surgery. This study was performed to investigate the outcomes of the two procedures, for which historical literature provides arguments for and against each.

This study tested the noninferiority of t-PRK compared with PRK on different eyes in the same subjects to assess objective and subjective outcomes between the procedures.

What was learned from this study?

No statistically or clinically significant differences were observed between conventional PRK and t-PRK in this study.

Because the outcomes from both procedures are equivalent, the practical benefits of t-PRK, with greater surgical efficiency and reduced time required for surgery, should be considered when planning PRK procedures.

INTRODUCTION

Photorefractive keratectomy (PRK) is a laser-based corneal surgical procedure to correct refraction in myopia and hyperopia [1, 2]. It was developed during the 1980s and approved for clinical use by the United States Food and Drug Administration (FDA) in 1996 [3]. Conventional PRK involves the removal of the corneal epithelium (under topical anesthetic, with or without topical alcohol application) using a brush or hockey knife, followed by excimer laser treatment of the corneal stroma. The long-term safety and effectiveness of PRK have been well demonstrated, and it continues to be used successfully in patients with ametropia [4]. In many instances, PRK has been superseded by laser-assisted in situ keratomileusis (LASIK) [2] owing to faster recovery of vision, lower postoperative haze, and reduced postoperative discomfort [5]; however, PRK remains the preferred procedure for many considering surgery, such as in patients with thin corneas [3]. The risk of flap-related complications with LASIK may also lead some patients, such as pilots or athletes, to prefer the use of PRK over LASIK [6].

Since its introduction, variations on the PRK procedure have been developed, including transepithelial PRK (t-PRK). In contrast to conventional PRK, in which the corneal epithelium is removed manually by the surgeon, t-PRK uses an excimer laser to enable greater precision in addition to allowing refractive ablation in a single step [7]. The benefits of t-PRK over conventional PRK include reduced time required for surgery [5], making it simpler for the surgeon and reducing potential concerns for the subject with regard to longer surgical procedures, with the potential for less postoperative discomfort and faster recovery. Data suggest that both PRK and t-PRK are effective and broadly equivalent in outcomes [8, 9]. Because of the promise of t-PRK, and the opportunity to improve treatment for patients considering PRK surgery, this study was created to gain a comprehensive understanding of both objective and subjective outcomes of t-PRK compared with conventional (alcohol-assisted) PRK.

The objective of this post-marketing clinical follow-up study was to assess clinical outcomes of t-PRK compared with conventional PRK in adult subjects with ametropia.

METHODS

This was a prospective, randomized, controlled, contralateral, single-masked, single-surgeon study conducted at a center in the Philippines (NCT04698174, clinicaltrials.gov). It was performed in accordance with the ethical principles of the Declaration of Helsinki [10] and Good Clinical Practice (GCP) [11]. The study was approved by the Asian Eye Institute (AEI) and the St. Frances Cabrini Medical Center (SMSC) SCMC-AEI Ethics Review Committee (ERC No. 2019-037). Before the start of investigations,

subjects were advised verbally and in writing concerning the nature and consequences of the planned intervention. Their agreement was documented along with consent for anonymized study-related medical data to be used in subsequent publications and communications with authorities.

Participants

Subjects aged 18–85 years with myopia with a manifest residual spherical equivalent (MRSE) of ≤ − 1.5 D or hyperopia with an MRSE of ≥ + 1.5 D were eligible. Subjects were required to have corneal topography suitable for t-PRK treatment (as assessed by an investigator). Subjects who were contact lens wearers were required to discontinue use of gas permeable lenses at least 3 weeks prior and/or soft lenses at least 1 week prior to preoperative evaluation. In addition, contact lens wearers were required to have two central keratometry readings and two manifest subjective refractions taken preoperatively at least 1 week apart; MRSE refraction was not to differ by more than 0.50 D, and keratometry values were not to differ between assessments by more than 0.50 D in either meridian. Subjects must have read, understood, and signed the informed consent statement and be willing to and able to return for scheduled follow-up appointments for up to 6 months following surgery.

Subjects were excluded if: the combination of their baseline corneal thickness and the planned operative parameters for the refractive procedure would result in less than 300 µm of remaining corneal thickness below the epithelium; they had a refractive sphere (not spherical equivalent) of ≤ − 7.0 D or ≥ 4.0 D, refractive spherical equivalent of ≤ − 9.0 D or ≥ 5.25 D, or refractive cylinder (negative cylinder notation) of ≤ − 4.0 D or ≥ 2.5 D; they had a binocular corrected distance visual acuity (CDVA) of < 20/20 (> 0.0 logMAR) or monocular CDVA of < 20/25 (> 0.1 logMAR); they had hyperopic eyes for which the baseline manifest subjective refraction exhibited a difference of greater than ± 0.75 D in sphere power, or a difference of greater than ± 0.50 D in cylinder power, or a difference in cylinder axis of more than 15 degrees compared with baseline cycloplegic subjective refraction; they had anterior segment pathology, ocular disease or corneal abnormality that would, in the investigator's opinion, interfere with CDVA or successful treatment; had evidence of retinal vascular disease or keratoconus; they had unstable central keratometry readings with irregular mires, previous intraocular or corneal surgery, corneal edema or increased intraocular pressure (IOP) > 22 mmHg, a history of herpes simplex or herpes zoster keratitis, a history of (or suspected) glaucoma, an ocular muscle disorder, or anterior or posterior synechiae; they were at risk of angle closure; they were immunocompromised or had a chronic, acute and/or autoimmune disease that might increase the risk to the subject or confound the study outcomes; they were taking systemic medications likely to affect wound healing; they were pregnant, lactating or planned to become pregnant during the study period; or they had known sensitivity to medications used in standard t-PRK. Subjects were not permitted to participate in any other ophthalmic clinical trial during the study period.

Subjects were randomized after successful screening, with the far-dominant eye of each subject randomized to receive either conventional or t-PRK. After randomization, a further 1:1 randomization was applied within the t-PRK group for eyes to receive or not receive end-treatment laser polishing.

Study Interventions

Refractive surgery was conducted using the TENEO 317 Model 2 laser work station (Bausch and Lomb) and performed according to the standard nomograms provided by the manufacturer and the user's manual.

In all subjects, topical anesthesia was applied to reduce eye movements and a speculum was used to avoid unintended closure of the eye during surgery.

For conventional PRK, alcohol (20%) was applied to the eye for 30 s and the epithelium was manually removed using a microhoe. After complete removal of the epithelium, the PRK laser procedure was applied. For t-PRK, a default

setting of 54-µm epithelial thickness was used to remove the epithelium by laser ablation. Following the PRK procedure, eyes randomized to receive end-treatment laser polishing had an additional stromal layer removed at a fixed thickness of 5 µm to assess whether recovery times can be improved by stimulating epithelial regrowth.

Following either PRK protocol, mitomycin C 0.02% was applied for 30 s on the cornea using a sponge to lower the risk of postoperative haze. Protective contact lenses were used to ensure the subject did not touch the operated eyes during the healing process.

Study Design and Outcomes

This was a 6-month study from the day of surgery, with subjects attending six follow-up visits 1 day, 4 days, 1 week, 1 month, 3 months, and 6 months postoperatively. Baseline assessments were made during a screening visit within 60 days prior to surgery.

The primary endpoint was the statistical noninferiority of t-PRK compared with conventional PRK for absolute refractive predictability at 3 months post-surgery. The noninferiority margin was 0.2 D and a significance level of 0.05 or lower was considered statistically significant. Refraction was measured by a physician, optometrist, or trained ophthalmic technician using a phoropter or a trial frame, in 0.25 D steps, in a calibrated refraction lane with a standardized ETDRS letter chart. For manifest subjective refraction, the use of a cross cylinder was mandatory.

The secondary endpoints, assessed at visits up to 6 months, were: adverse events (AEs); IOP, measured by Goldmann applanation tonometer; manifest refraction; monocular uncorrected distance visual acuity (UDVA) and CDVA (both under photopic and mesopic light conditions), at 4 m in logMAR scale; monocular contrast sensitivity and pupil size (under photopic and mesopic light conditions), measured using a pupillometer manufactured by NeurOptics (Laguna Hills, CA, USA); keratometry and biometry, assessed using the IOL Master 500 (Zeiss, Oberkochen, Germany); corneal topography and pachymetry, assessed using the Technolas Perfect Vision Orbscan II/IIz Anterior Segment Analyzer (Orbscan II/IIz, Bausch and Lomb, Rochester, NY, USA); wavefront aberrations assessed using the Zywave II Wavefront Aberrometer (Zywave II, Bausch and Lomb, Rochester, NY, USA) and the iTrace (Tracey Technologies, Houston, TX, USA); patient-reported outcomes (PROs) of pain, perception of vision, satisfaction, and observation between the two procedures; halo and glare assessment using a halo and glare simulator and the Siepser Glarometer (Gulden Ophthalmics, Elkins Park, PA, USA); and slit-lamp examinations.

Statistical Analysis

To show noninferiority between the study eyes and the control eyes, 28 eyes were needed per study group. With an expected drop-out rate of 15%, 33 patients were needed to prove the primary outcome. The sample size calculation was based on a one-sided α of 0.05, power of 0.90, an expected standard deviation of outcome 0.255 D (based on averaged literature data on comparable t-PRK treatments [8, 12, 13]), and a noninferiority limit of 0.2 D.

Data were provided as the mean ± standard deviation (SD). To determine if the data were normally distributed, the Kolmogorov–Smirnov test was used. In cases of normally distributed data, the differences between the two study groups were compared with Student's *t* test. If data were not normally distributed, the Mann–Whitney test was used to compare the outcomes. In addition to a comparison between PRK and t-PRK groups, a subgroup evaluation within the t-PRK group was performed to identify differences in the clinical outcomes of eyes treated with and without end-treatment laser polishing.

Differences between categorial variables were evaluated with the chi-square test or Fisher's exact test (if > 20% of expected values were less than 5). Yates correction was used for 2 × 2 tables to correct for the assumption that the chi-square distribution can be approximated to a continuous distribution, which may be confounded by small study numbers. Differences

were considered statistically significant when the *p* value was less than 0.05.

The safety analysis set (SAS) comprised all eyes and patients that were exposed to treatment, whether successful or not. If an eye or a subject discontinued during the study, any available data prior to the study exit are presented. The overall analysis set (OAS) is defined as all patients exposed to the treatment and having at least one efficacy assessment after treatment.

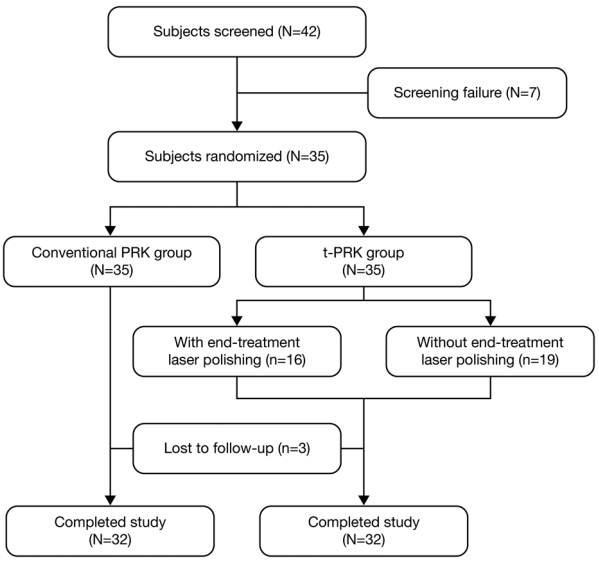


Fig. 1 Subject disposition. Transepithelial photorefractive keratectomy (t-PRK)

RESULTS

A total of 42 subjects (84 eyes) were screened and 35 subjects were enrolled. Both the SAS and OAS comprised 35 patients (70 eyes). Three patients were lost to follow-up, two after the 1-month visit and one after the 3-month visit (Fig. 1). Conventional PRK was conducted on the right eye in 18 patients and the left eye in 17 patients. t-PRK was conducted on the right eye in 17 subjects, of whom ten (62.5%) received end-treatment laser polishing and seven (36.8%) did not; of the 18 left eyes receiving t-PRK, six (37.5%) received end-treatment laser polishing and 12 (63.2%) did not. Of the 35 patients who received treatment, 22 (62.9%) were female, 33 (94.3%) were Asian, and the mean age was 29.5 years (range, 18–53 years); most patients were right-eye dominant (Table 1). There were no statistically significant differences in preoperative manifest refraction between PRK- and t-PRK-treated eyes. All patients enrolled presented with myopia (Table 2).

The primary endpoint of noninferiority between conventional PRK and t-PRK at 3 months was met (Fig. 2): the mean (SD) absolute prediction error was 0.26 D (0.23) for conventional PRK and 0.34 D (0.32) for t-PRK, $p=0.2253$. The 95% confidence interval (95% CI 0.06, – 0.11) of the least squares (LS) mean difference was below the noninferiority threshold of 0.2 D. Noninferiority was therefore

Table 1 Patient demographics. Transepithelial photorefractive keratectomy (t-PRK)

N (%)	Conventional PRK	t-PRK (with end-treatment laser polishing)	t-PRK (without end-treatment laser polishing)
Female	22 (62.9)	11 (68.8)	11 (57.9)
Ethnicity			
Asian	33 (94.3)	16 (100)	17 (89.5)
Black	2 (5.7)	0 (0)	2 (10.5)
Age, mean (SD)	29.5 (7.6)	29.6 (8.9)	29.5 (6.5)
Dominant eye: OD	23 (65.7)	10 (62.5)	13 (68.4)

OD oculus dexter; *PRK* photorefractive keratectomy; *SD* standard deviation; *t-PRK* transepithelial photorefractive keratectomy

Table 2 Pre and postoperative manifest refraction

Diopters, mean (SD)	Baseline		1 week		3 months		6 months	
	Conventional PRK	t-PRK	Conventional PRK	t-PRK	Conventional PRK	t-PRK	Conventional PRK	t-PRK
Manifest refraction								
Sphere	− 3.96 (1.47) range − 6.75 to − 1.5	− 3.81 (1.47) range − 6.75 to − 0.75	− 0.19 (0.54)	− 0.06 (0.43)	0.11 (0.37)	0.27 (0.41)	− 0.02 (0.35)	0.10 (0.35)
Cylinder	− 0.93 (0.72) range − 2.75 to − 0.25	− 0.96 (0.72) range − 2.50 to − 0.00	− 0.51 (0.45)	− 0.43 (0.72)	− 0.25 (0.23)	− 0.39 (0.33)	− 0.25 (0.25)	− 0.15 (0.21)
Spherical equivalent	− 4.41 (1.57) range − 7.62 to − 1.62	− 4.29 (1.55) range − 7.62 to − 1.62	− 0.44 (0.59)	− 0.27 (0.43)	− 0.01 (0.35)	0.19 (0.43)	− 0.14 (0.39)	0.03 (0.37)

Transepithelial photorefractive keratectomy (t-PRK). During data analysis, a discrepancy between manifest refraction and cycloplegic manifest refraction was detected and corrected in one patient. After agreement with the site, the incorrect data for normal refraction was changed from + 3.25 D to − 3.25 D

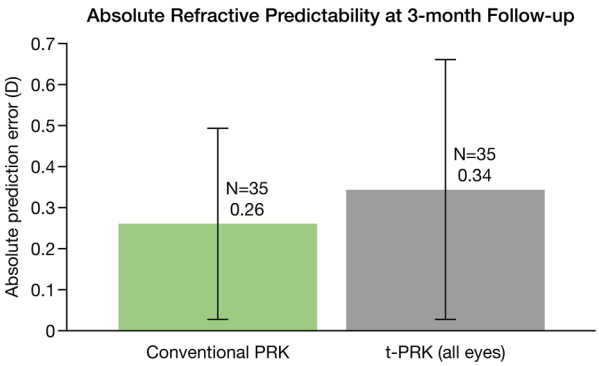


Fig. 2 Absolute refractive predictability at 3 months postoperatively between eyes undergoing conventional PRK and eyes treated with standard t-PRK (all eyes). Transepithelial photorefractive keratectomy (t-PRK)

demonstrated. At 6 months, the mean (SD) absolute prediction error was 0.27 D (0.31) for conventional PRK and 0.26 D (0.26) for t-PRK, $p = 0.820$.

Two AEs were reported in the study, one was an ocular AE (uveitis) reported in the t-PRK group and one was non-ocular (COVID-19 infection) reported in the conventional PRK group. Both AEs recovered without sequelae, and neither was considered related to the study treatment by the investigator. No serious AEs or adverse device effects were reported.

For manifest refraction, there were no statistically significant differences at 6 months between conventional PRK and t-PRK for manifest sphere (– 0.02 D and 0.10 D, respectively, $p = 0.2822$), manifest cylinder (– 0.25 D and – 0.15 D, $p = 0.0762$), or MRSE (– 0.14 and 0.03, $p = 0.2062$). While not clinically significant, the t-PRK-treated eyes had a statistically significant hyperopic outcome compared with conventional PRK-treated eyes: at 1 month postoperatively, manifest sphere was 0.03 D for conventional PRK and 0.31 D for t-PRK ($p = 0.0305$) and at 3 months postoperatively MRSE was – 0.01 D for conventional PRK and 0.19 D for t-PRK ($p = 0.0464$). Within the t-PRK group, eyes receiving end-treatment laser polishing reported a tendency to more hyperopic outcomes compared with those without. This was statistically

significant at a single time point, at 3 months: the 3-month postoperative mean (SD) MRSE was 0.37 D (0.48) for t-PRK with polishing versus 0.04 D (0.33) for t-PRK without polishing ($p = 0.0265$). At 6 months, MRSE was 0.13 D (0.40) and – 0.05 D (0.34), respectively, $p = 0.198$ (Fig. 3).

At 6-month follow-up, monocular photopic UDVA improved from baseline in all eyes, by 15 lines on average (from 20/250 to 20/20). At 6 months, mean (SD) monocular photopic UDVA was – 0.03 (0.10) logMAR for the conventional PRK group and – 0.04 (0.08) logMAR for the t-PRK group. UDVA was ≤ 0.3 logMAR (≥ 20/40) in 100% of the eyes and ≤ 0.0 logMAR (≥ 20/20) in 87.5% of eyes in both treatment groups (Fig. 3). There were no statistically significant differences in photopic UDVA between the treatment groups at any postoperative visits. There were no statistically significant differences between the conventional PRK and t-PRK groups at any postoperative visits for mesopic UDVA. Although there was a statistically significant difference in mean photopic and mean mesopic UDVA at baseline between eyes randomized to end treatment laser polishing compared with those without ($p = 0.0314$) in the t-PRK group, there were no statistically significant differences reported between the subgroups at any postoperative visit for either measure.

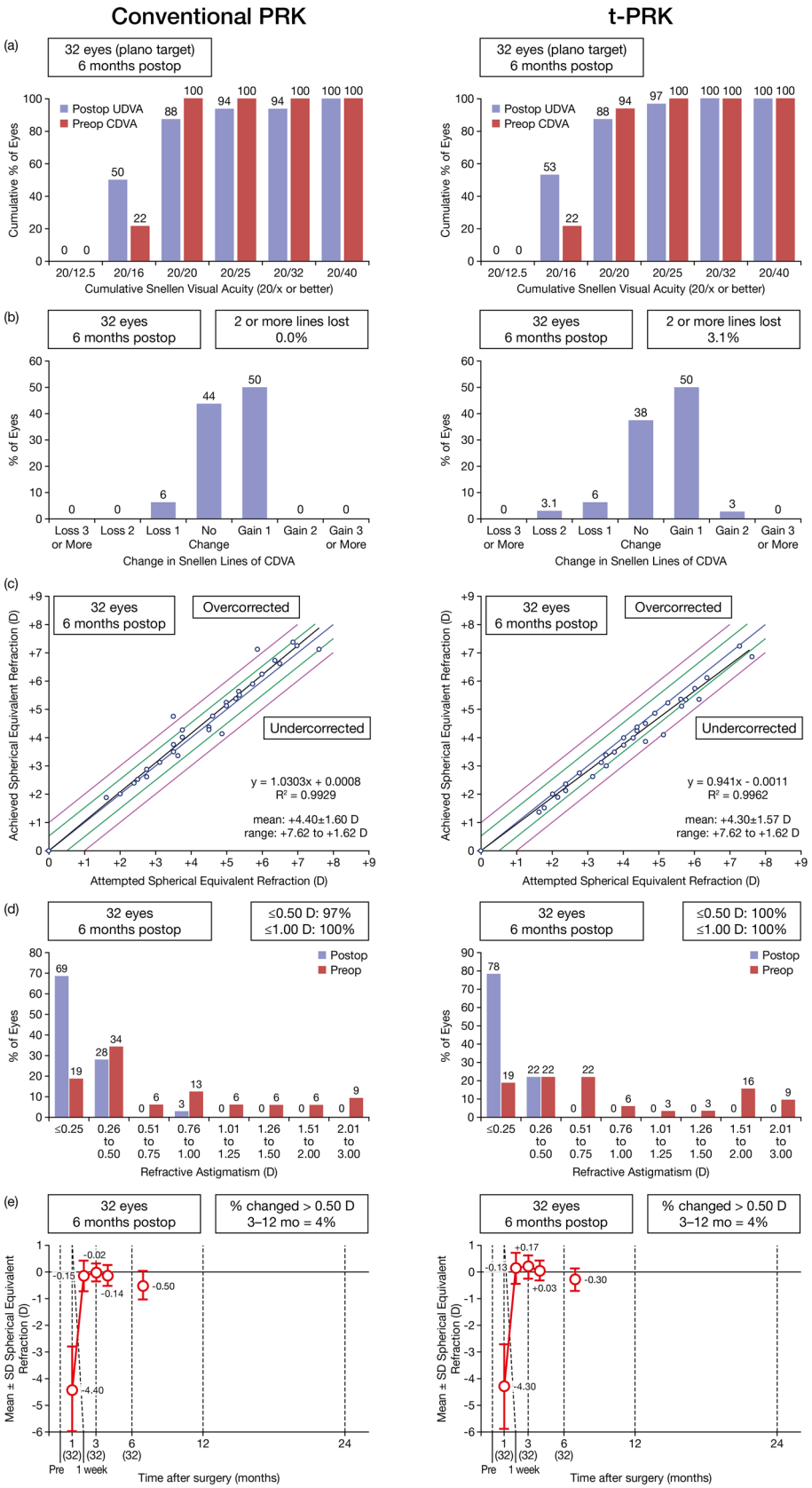
Mean (SD) monocular photopic CDVA was – 0.07 (0.05) logMAR with 100% of the eyes ≤ 0.0 logMAR 20/20 in the conventional PRK group and – 0.06 (0.07) logMAR with 96.9% of the eyes ≤ 0.0 logMAR (≥ 20/20) in the t-PRK group at the 6-month follow-up. At 6 months, two eyes (6.25%) in the conventional PRK group showed a loss of one line of monocular photopic CDVA; in the t-PRK group, two eyes (6.25%, both with end-treatment laser polishing) had a loss of one line and one eye (3.13%, without end-treatment laser polishing) had a loss of two lines. There was no statistically significant difference between the treatment groups for photopic or mesopic CDVA, nor between the t-PRK subgroups.

At 6 months after surgery, diffuse halo ring and starburst were equally reported by the subjects in the two treatment groups. No subject reported distinct halo rings. In the t-PRK with end-treatment sub-group, more patients reported diffuse halo rings (64.3%) than starbursts (35.7%), whereas in the t-PRK without end-treatment more patients reported starburst (61.1%) than diffuse halo rings (38.9%). The differences were not statistically significant. All patients in both groups reported to perceive diffuse glare (type G1) preoperatively and at 6 months after surgery. Following treatment, whether conventional or t-PRK, size and intensity of both halo and glare phenomena were reduced.

Slit-lamp examination demonstrated a change to abnormal grading of corneal clarity for the majority of eyes in both treatment groups after surgery, which returned to normal in all eyes 3 months after surgery. There were no statistically significant differences between the treatment groups or between the t-PRK laser polishing subgroups. Corneal haze, which was 0 for all eyes prior to surgery, was reported at a maximum of grade 2 in 28.6% of eyes in the PRK group and 25.7% of eyes in the t-PRK group 4 days after surgery. Corneal haze was evident in 8.6% of eyes at 1-week post-surgery and was absent at the end of follow-up. There were no statistically significant differences between the treatment groups.

Subjects reported a higher, but not statistically significant, degree and duration of pain in the 7 days following surgery with t-PRK treatment compared with conventional PRK (Fig. 4), with pain degree peaking in the first 3 days after surgery. The degree and duration of pain was also numerically, but not significantly, greater among eyes receiving end-treatment laser polishing compared with those without in the t-PRK group. Subject-reported perceived vision was similar between treatment groups (Fig. 4).

More than 80% of patients reported light sensitivity in their treated eyes from day 1 to day 3 after surgery, which decreased from day 5 to < 9% in both treatment groups 1 week after surgery. There were no statistically significant differences between the conventional PRK- and the t-PRK-treated eyes. Although not statistically significantly different, 15% of patients treated without end-treatment laser polishing reported some light sensitivity after 7 days (versus 0% for eyes receiving end-treatment laser polishing).


Conventional PRK
t-PRK
(a)
32 eyes (plano target)
6 months postop
Postop UDVA
Preop CDVA
Cumulative % of Eyes
Cumulative Snellen Visual Acuity (20/x or better)
20/12.5
20/16
20/20
20/25
20/32
20/40
(b)
32 eyes
6 months postop
2 or more lines lost
0.0%
2 or more lines lost
3.1%
% of Eyes
Loss 3 or More
Loss 2
Loss 1
No Change
Gain 1
Gain 2
Gain 3 or More
Change in Snellen Lines of CDVA
(c)
32 eyes
6 months postop
Overcorrected
Undercorrected
Achieved Spherical Equivalent Refraction (D)
Attempted Spherical Equivalent Refraction (D)
y = 1.0303x + 0.0008
R² = 0.9929
mean: +4.40±1.60 D
range: +7.62 to +1.62 D
y = 0.941x - 0.0011
R² = 0.9962
mean: +4.30±1.57 D
range: +7.62 to +1.62 D
(d)
32 eyes
6 months postop
≤0.50 D: 97%
≤1.00 D: 100%
≤0.50 D: 100%
≤1.00 D: 100%
Postop
Preop
% of Eyes
≤0.25
0.26 to 0.50
0.51 to 0.75
0.76 to 1.00
1.01 to 1.25
1.26 to 1.50
1.51 to 2.00
2.01 to 3.00
Refractive Astigmatism (D)
(e)
32 eyes
6 months postop
% changed > 0.50 D
3–12 mo = 4%
Mean ± SD Spherical Equivalent Refraction (D)
Pre
1 week
Time after surgery (months)

◂**Fig. 3** **a** UDVA, **b** change in CDVA, **c** spherical equivalent attempted vs. achieved, **d** refractive astigmatism, and **e** stability of spherical equivalent refraction. Each presented for conventional PRK and t-PRK. Transepithelial photorefractive keratectomy (t-PRK), monocular uncorrected distance visual acuity (UDVA), binocular corrected distance visual acuity (CDVA)

There were no statistically significant differences on any day to day 7 after surgery between the conventional PRK- and t-PRK-treated eyes for tearing. A statistically significant difference was observed for tearing with end-treatment laser polishing (62.5%) compared with eyes without (21.05%) in the t-PRK group ($p = 0.0181$). No tearing was reported at 1 week post-surgery.

When subjects were asked how satisfied they were with their overall vision, 91.4% of patients at 1 month and 100% of patients at 6 months were satisfied or very satisfied with their overall vision (Table 3). No subjects reported being dissatisfied or very dissatisfied at any timepoint. There were no statistically significant differences between the treatment groups or between the end-treatment laser polishing t-PRK subgroups.

When asked 1 month after surgery which eye had better vision, 17 (48.6%) subjects reported better vision in the conventional PRK-treated eye, nine (25.7%) the t-PRK-treated eye, and nine (25.7%) had no preference. Of the nine subjects reporting better vision in the t-PRK treated eye, six (67%) had been treated without end-treatment laser polishing. When asked which procedure they would recommend, 11 (31.4%) subjects recommended conventional PRK, 11 (31.4%) recommended t-PRK, and 13 (37.1%) had no preference.

DISCUSSION

Despite the development of newer procedures, such as LASIK and small incision lenticule extraction (SMILE), PRK remains a popular and effective option for the correction of myopia and hyperopia. Since its introduction, the methodology of PRK has been refined and the introduction and further improvement of t-PRK offered the potential for similar visual outcomes with shorter surgery and quicker recovery [7]. In this study, we compared the outcomes of conventional PRK with t-PRK on different eyes in the same patients. There were no statistically significant differences between conventional PRK and t-PRK for the primary endpoint of absolute refractive predictability at 3 months, indicating that t-PRK was noninferior to conventional PRK according to the prespecified criteria. This noninferiority finding was reiterated with the manifest refraction assessments at 6 months, visual acuity measurements, halo and starburst, haze, and slit-lamp examinations. In all assessments between conventional PRK and t-PRK, no statistically significant differences were reported in any comparison, indicating that both procedures are equally effective. In addition, subjects had no clear preference for one methodology over the other. These data concur with prior comparisons of conventional PRK with t-PRK. A large ($N = 148$ patients, 277 eyes) retrospective analysis of consecutive procedures at a single center in Poland reported no significant differences in MRSE, higher-order aberrations (HOA), UDVA, pain, and patient satisfaction, with a significantly shorter total surgery time for t-PRK [8]. A retrospective analysis of 120 eyes from 120 consecutive patients receiving either conventional PRK or t-PRK showed no difference in spherical equivalent values, refraction, or visual acuity, although a statistically but not clinically significant difference in HOA was reported [9].

Some studies have reported differences in outcomes between conventional PRK and t-PRK. In a prospective, randomized study of 73 subjects having each procedure conducted on either eye, both spherical equivalence and UDVA were better following conventional PRK compared with t-PRK [14]. Conversely, a larger ($N = 170$ patients, 340 eyes) prospective, non-randomized, controlled study of consecutive patients reported faster healing, faster improvement in uncorrected visual acuity, better safety and efficacy indices, and less postoperative pain with t-PRK versus conventional PRK [13]. A meta-analysis comparing conventional PRK with t-PRK (and LASEK or LASIK) found no significant differences in efficacy, safety, or predictability, but did find that t-PRK was associated with a statistically

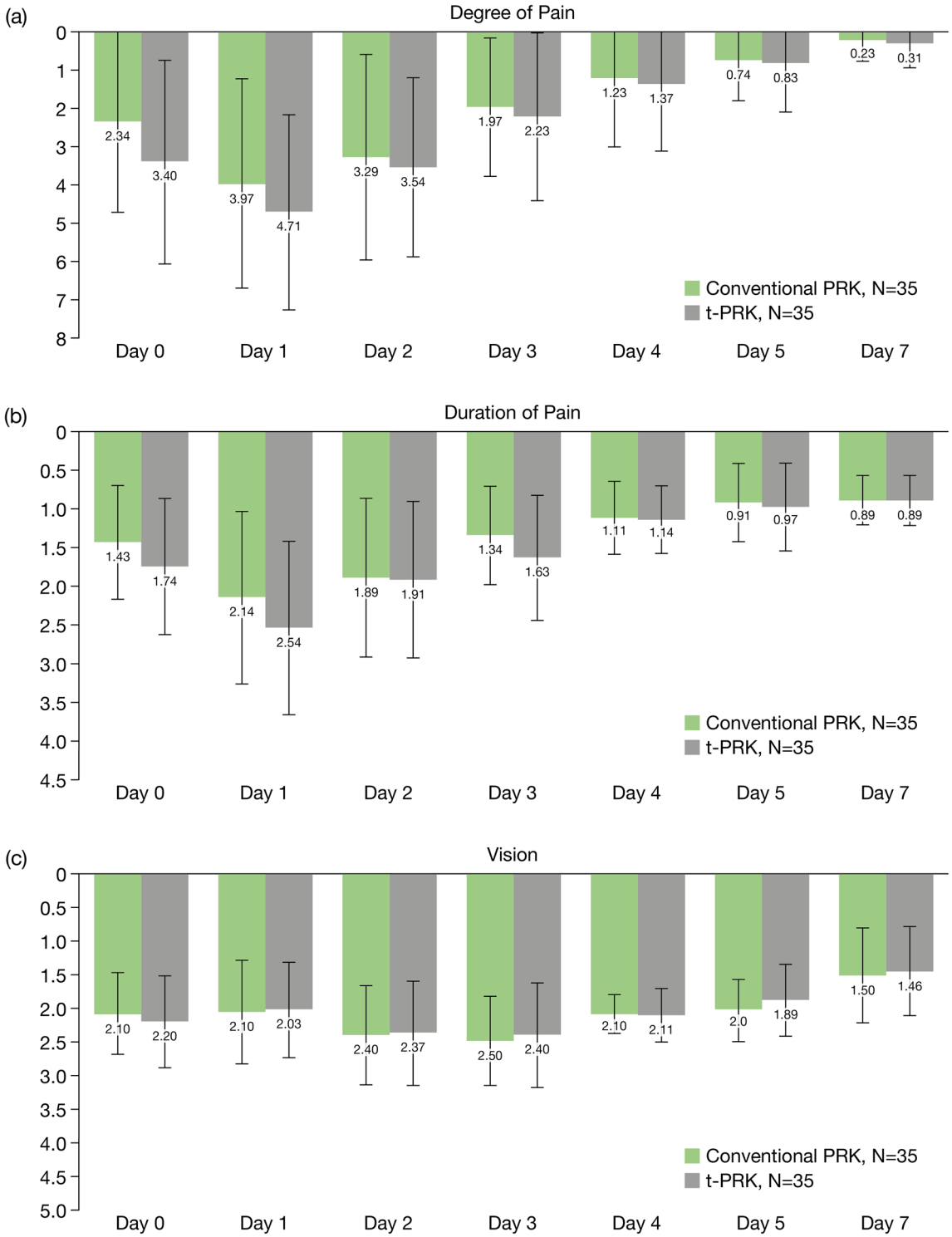


Fig. 4 PROs. **a** Degree of pain [from 0, no pain, to 10, severe pain]; **b** duration of pain [1, 1–2 episodes per day; 2, less than half a day; 3, more than half a day; 4, all day]; **c** perceived vision [1, clear; TV image, faces sharp; 2, blurry, haze, shadows; good enough to watch TV, see faces but not sharp; 3, poor; TV images, faces very blurry; 4, very poor; TV image, faces cannot be recognized] Transepithelial photorefractive keratectomy (t-PRK)

Table 3 Subject-reported satisfaction with overall vision 1 and 6 months after surgery

N (%)	Conventional PRK	t-PRK	
		With end-treatment laser polishing	Without end-treatment laser polishing
1 month			
Very satisfied	20 (57.1)	7 (43.8)	13 (68.4)
Satisfied	12 (24.3)	8 (50.0)	4 (21.05)
Neither satisfied nor dissatisfied	3 (8.57)	1 (6.25)	2 (10.53)
Dissatisfied	0	0	0
Very dissatisfied	0	0	0
6 months			
Very satisfied	31 (96.9)	14 (100)	17 (94.4)
Satisfied	1 (3.1)	0	1 (5.6)
Neither satisfied nor dissatisfied	0	0	0
Dissatisfied	0	0	0
Very dissatisfied	0	0	0

Transepithelial photorefractive keratectomy (t-PRK)

significant lower pain score at day 3 and better epithelial healing for t-PRK versus conventional PRK [15]. Notably, among rankings for all procedures in the meta-analysis, t-PRK was calculated to rank best for lower postoperative haze>0.5, less pain, and faster epithelial healing, whereas conventional PRK did not achieve top rank for any outcome. In the study presented here, there were no statistically significant differences between conventional PRK and t-PRK at 6 months, with the only differences observed being hyperopia with t-PRK at the 1-month (manifest sphere) and 3-month (MRSE) assessments. Neither of these differences remained statistically significant at the next time point and were unlikely to be clinically significant.

This was the first study to evaluate additional end-treatment polishing. This finishing layer was included on the laser for a promising advancement that may accelerate epithelial regrowth fostering hope of faster recovery times. However, the 6-month results did not show significant differences between groups with or without end-treatment, with MRSE following laser polishing slightly hyperopic (by less than 0.2 D and not statistically or clinically significant) and no significant difference between the groups regarding the degree and duration of pain, or their perceived vision and overall satisfaction. More data are needed to draw meaningful conclusions about any potential benefits of end-treatment laser polishing.

Although there was a lack of difference reported between conventional PRK and t-PRK in objective measures of visual acuity, almost twice as many subjects preferred the vision in the eye corrected using conventional PRK than that corrected with t-PRK. Despite this, at the same time point of 1 month after surgery, an equal number of subjects would recommend either procedure, implying that differences between the procedures were not substantial. Combined with the fact that all subjects were happy with their vision 6 months after surgery indicates that both procedures are broadly equivalent and subjects do not hold strong preferences for one over the other. Unusually among studies comparing these procedures, more pain

(albeit not reaching statistical significance) was reported with t-PRK. Typically, recent studies have suggested that healing is considered faster and pain lower for t-PRK than for conventional PRK [16–18], although some older studies have reported the converse [19]. The difference in pain is unlikely to be clinically significant: subjects were pleased with the outcomes of either procedure and willing to recommend them to others.

The strengths of this study include its prospective and contralateral-eye design, with randomization and masking to minimize the influence of subjective responses. Among the comprehensive assessments for efficacy and safety were PROs, which enabled the assessment of clinical and lifestyle outcomes meaningful to the subjects. Variability between subjects was reduced through the use of each subject acting as their own control and receiving both conventional and t-PRK, and a single surgeon conducting all procedures. Limitations of the study include the inherent fallibility of single-masking, in which the subject might deduce which eye received which procedure, the relatively small study population, and the fact that the results from a single site might not be applicable to a wider population. Furthermore, because this was designed as a noninferiority study, no inferences can be made with respect to any superiority of t-PRK compared with conventional PRK for the primary endpoint.

CONCLUSIONS

Both conventional and t-PRK are equally safe and effective, and result in favorable outcomes for subjects with ametropia. The efficiency and speed of the t-PRK procedure versus conventional PRK, combined with the successful outcomes of surgery, should encourage surgeons to consider t-PRK when PRK is indicated in appropriate subjects.

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Data Availability. Data are available from the corresponding author on reasonable request.

Declarations

Conflict of Interest. Robert Edward T Ang is a consultant for Bausch + Lomb.

Ethical Approval. This study was performed in accordance with the ethical principles of the Declaration of Helsinki [10] and Good Clinical Practice (GCP) [11]. The study was approved by the Asian Eye Institute (AEI) and the St. Frances Cabrini Medical Center (SMSC) SCMC-AEI Ethics Review Committee (ERC No. 2019-037). Before the start of investigations, subjects were advised verbally and in writing concerning the nature and consequences of the planned intervention. Their agreement was documented along with consent for anonymized study-related medical data to be used in subsequent publications and communications with authorities.

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